







The following organisations support the recommendations set out in this paper:













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CEO Foreword

Tobacco smoking is the largest cause of preventable illness and death in Ireland, killing almost 6,000¹⁴⁰ people every year. Smoking causes cancer, heart disease, stroke, COPD and a range of other diseases. It can also trigger serious asthma attacks in children and adults. One in two smokers will die of a smoking-related illness¹.

The Irish Cancer Society and Irish Heart Foundation work to prevent this by encouraging young people not to take up the habit and helping current smokers to quit. We have also worked with policy makers to secure the introduction of positive public health measures such as the workplace smoking ban, plain packaging and point of sale restrictions. As a result of these and other actions, the number of Irish smokers has decreased by 80,000 people in last three years alone².

Ireland is making real progress in the battle against smoking but of course it's still not enough. There are thousands of people who want to quit but believe they can't or don't have the support they need to do so. In fact, as many as 4 in 10 smokers have made an attempt to quit in the past 12 months⁴.

More must be done to help people break the habit. To that end, we continue to lobby Government to invest in programmes proven to help people quit smoking.

Our organisations also continuously monitor international research on smoking-related issues to identify new and better ways to reduce smoking rates. As part of this work, we have also carried out an extensive review of emerging research regarding e-cigarettes and considered the views of major international health bodies such as the World Health Organisation and the Centre for Disease Control and Prevention (CDC) in relation to these products. This paper sets out the results of that review.

Having considered the available evidence, we must urge caution in relation to e-cigarettes. Although it is generally accepted e-cigarettes are less harmful than tobacco, there is insufficient research to date on their long-term impact on users. Several studies have also highlighted that they are less effective than other smoking cessation tools at helping people quit for good.⁵

More worryingly, e-cigarettes are being heavily marketed to children, leading to what the US Surgeon General described as an 'epidemic' of youth e-cigarette use. Many e-cigarette brands are owned by cigarette companies. Data from the US shows that America's teens reported a dramatic increase in their use of e-cigarettes in just a single year, with over 37% of 12th graders reporting use in the past 12 months, compared to 28% percent in 2017.

Claims by e-cigarette companies that they don't market their products at children and just want to help existing smokers move to a safer alternative must be treated with scepticism. The high vaping rate amongst teenagers shows otherwise. It would also be extremely naïve to believe the public health claims of an industry that lied for so long about the damage caused by cigarette smoking.

For the reasons set out in this paper, we are calling for tighter regulation of e-cigarettes and heated tobacco products (which are not for sale in Ireland yet). We also reiterate our call for the Government to do more to help smokers quit for good by funding smoking cessation methods that have been proven to work.

Ireland's smoking rate has dropped from 27% in 2008 to 20% in 2018 (17% daily smokers, 3% occasional smokers)⁸, so what we are doing is working – we just need to do more of it. We need to invest in the strategies we know will make a difference and not be distracted by claims that could actually harm people's long term health. We must also protect our young people from predatory marketing designed to get them hooked on nicotine and undermine the great progress that has been made in reducing smoking in Ireland.⁹

Together, we can make Ireland smoke free and ensure people live longer, happier lives as a result.



Tim Collins
Chief Executive
Irish Heart Foundation



Averil Power Chief Executive Irish Cancer Society

Overview

The Irish Cancer Society and Irish Heart Foundation have reviewed international research regarding e-cigarettes and HTP to inform our organisations' position on these products, as well as examining emerging evidence on heated tobacco products (HTP).

A 2017 HIQA health technology assessment has recommended that the most effective intervention in quitting smoking is use of the medicine varenicline, used alone or in combination with nicotine replacement therapy (NRT). The report also showed that behavioural support has been shown to further increase the chances of quitting, while not enough evidence exists to recommend e-cigarettes as a smoking cessation aid¹⁰.

This paper seeks to provide a balanced, objective, evidenced assessment of e-cigarettes and heated tobacco products.

This paper will outline our policy recommendations on these products before presenting evidence to support these recommendations in two parts. Part one relates to e-cigarettes while part two looks at HTP. Both sections will outline the health risks associated with each product, their safety concerns, and current regulations.

With the increasing availability of e-cigarettes and the anticipated release of HTP to the Irish market, our key concerns are as follows:

- E-cigarettes are less harmful than combustible cigarettes, but health risks remain.
- There is not enough evidence e-cigarettes are an effective quit aid for smokers; rather other methods have been proven to be more effective.
- There is a need for greater evidence on the long-term health consequences of e-cigarette use.
- As a result of clever marketing, e-cigarette use is increasing among young people and may act as a gateway to smoking.
- The exclusion of vaping from the indoor smoking ban and other controls is resulting in children and adults being exposed to second hand vapour and may also renormalize smoking.
- Tobacco firms may attempt to undermine public health policy by using e-cigarettes as a Trojan Horse to secure meetings at which tobacco control and public health are discussed. Article 5.3 WHO Framework Convention on Tobacco Control (FCTC) states that public health policies on tobacco control should be protected from the vested interests of the tobacco industry.
- · Claims heated tobacco products carry a reduced health risk are unfounded.
- Investment is needed in smoking cessation strategies we know will make a difference in supporting people to quit smoking

We believe that this paper is important in the context of advancing technologies and a changing market as well as in response to the tobacco industry's efforts to position these products as wellness items.

Policy recommendations: E-cigarettes

We believe e-cigarettes should be regulated in the same way as tobacco products with regards to advertising, use indoors, and sales to minors.

We therefore recommend the following policy measures:

- Reconvening of the Department of Health Tobacco Policy Review Group to review evidence on e-cigarettes.
- Prohibit e-cigarette product advertising through all communications mediums, including outdoor areas (billboards, buses) and at the point of sale.
- Strengthen the ASAI code to address current breaches of the code.
- Prohibit the sale of e-cigarettes to anyone under the age of 18.
- Extend the indoor-smoking ban to e-cigarettes.
- Prohibit e-cigarette use in Public Service Vehicles.

- Prohibit e-cigarette use in vehicles where persons under the age of 18 are present.
- Stricter enforcement of the WHO Framework Convention on Tobacco Control (FCTC).

Policy recommendations: Heated Tobacco Products (HTP)

Given claims HTP are safer than traditionally cigarettes are unfounded, failure to subject them to the same restrictions as cigarettes pose a major public health risk. Unless they are taxed the same way as cigarettes, we could end up with a new wave of cheaper tobacco products entering the Irish market.

We therefore recommend the following policy measures:

- · Regulatory alignment of HTP and traditional cigarettes.
- Apply the same rate of excise to HTP as to cigarettes.
- Include text and photographic health warnings on all HTP packaging.
- Prohibit all marketing for HTP products.
- · Extend the indoor smoking ban to include HTP.
- Stricter enforcement of the WHO Framework Convention on Tobacco Control (FCTC) to ensure the tobacco industry, or their representatives, are not involved in any aspect of public policymaking regarding HTP.

SECTION 1: E-CIGARETTES

What are e-cigarettes?

An e-cigarette is a device which vaporises and delivers a chemical mixture known as an "e-liquid" to the lungs in the form of an aerosol.

E-Liquids are typically composed of nicotine, propylene glycol and other chemicals.¹⁴

All e-cigarettes comprise of a lithium battery, a cartridge containing the e-liquid, an atomizer which heats the e-liquid to create the aerosol, and a mouth piece.

The design of e-cigarettes has changed considerably since products were first marketed in Europe in 2006.¹⁵ First-generation devices resemble conventional cigarettes. These comprise low-capacity disposable or rechargeable batteries and combined cartridges and atomizers.

Second-generation devices resemble pens and use larger batteries and fluid-filled reservoirs (tanks), filled from bottles of e-liquid. Third-generation devices bear little resemblance to cigarettes, use larger-capacity batteries, replaceable heating coils and wicks for atomizers and adjustable and programmable power delivery.¹⁶

E-liquids are available on the Irish market with nicotine strengths of 0, 3, 6, 9, 12, 18 and 20 milligrams (mg). The average combustible cigarette contains about 12mg of nicotine.¹⁷ It is also possible for users to create their own e-liquid by mixing 20mg "nicotine shots" with larger bottles of nicotine free e-liquid.

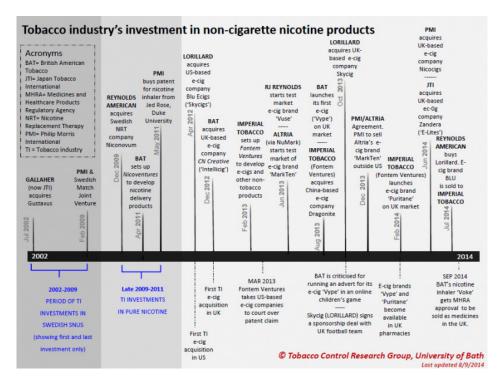
E-cigarettes and the tobacco industry

The tobacco industry controls a considerable share of the e-cigarette market in Ireland and internationally. E-cigarette brands available in Ireland include Vype and VIP, which are owned by British American Tobacco, and Logic, which is owned by Japan Tobacco International.¹⁸ There are also a number of e-cigarette and e-liquid companies that are not affiliated with the tobacco industry.

In 2018, tobacco company Altria acquired a 35% stake in "Juul", an e-cigarette device that has 72% of the e-cigarette market share in the U.S.²⁰ Juul launched in the UK in 2018 and continues to expand across Europe.²¹ The company has launched in Ireland and wrote to many health organisations including the Irish Cancer Society and the Irish Heart Foundation in May 2019 with the intention of meeting to discuss "eliminating combustible cigarettes in Ireland" as well as highlighting their "commitment to protecting young people". Such commitments have not been observed in the United States, where in 2018 the U.S. Surgeon General declared youth Juul use as "an epidemic".²²

The "Foundation for a Smoke Free World" (FSFW) was founded in 2017. FSFW states on its website that its purpose is to "improve global health by ending smoking in this generation". FSFW was established by tobacco company Philip Morris International (PMI) in an attempt to partner with the World Health Organisation (WHO) to promote its "IQOS Mesh" e-cigarettes and its IQOS heated tobacco products (HTP). 24 25

In 2019, tobacco company Imperial Brands made a large financial contribution to a grassroots campaign, "Let's demand smarter vaping regulation!" which sought to petition the European Commission to regulate e-cigarettes differently from tobacco products. ²⁶ It has been noted that the tobacco industry is using e-cigarettes as a "Trojan horse" to undermine tobacco regulations and rehabilitate their image. ²⁷ While the WHO Framework on Tobacco Control prohibits tobacco companies from influencing public policy, tobacco companies may try to use e-cigarettes as a vehicle to meet with policy-makers and influence public health decisions.



Tobacco industry investment in non-cigarette products as of September 2014. Source: tobaccotactics.org

Where the tobacco industry previously disputed evidence that cigarette-use was damaging to health, the industry has recently changed its tactics to acknowledge the health implications of tobacco use. With this, the industry encourages traditional cigarette-smokers to become e-cigarette and HTP users, citing harm reduction.²⁸

Regular conventional cigarettes are still being aggressively marketed to low-income markets worldwide so the industry should not be regarded as having changed its dubious practices, ²⁹ .Sales are shifting from developed markets, like those in Western Europe, where smoking prevalence is declining and where tobacco company operations are more restricted by government policies, to emerging markets, like those in Asia and Africa, where tobacco companies take advantage of lax regulatory environments, growing populations and increasing incomes.³⁰

Given the heavy presence of the tobacco industry in e-cigarettes, we believe that policy makers and clinicians should be vigilant in considering the motivations of those behind e-cigarettes. E-cigarette companies and interest groups with mission statements containing phrases like "eliminating cigarettes" and "a world free from combustible tobacco"³¹ should be regarded with caution as ultimately these industries are motivated to keep people addicted to nicotine. We are concerned that these very addictive nicotine delivery products could lead to a population of nicotine addicted individuals and potential future harm.

Is the use of e-cigarettes safe?

- -While short term evidence has found that e-cigarettes are less harmful than combustible cigarettes, e-cigarettes are not harm free, and more longitudinal evidence is required to assess long-term risk.
- -We cannot categorically say that e-cigarette use increases cancer risk, but e-cigarette use may cause precursor events to cancer, such as lung inflammation and DNA damage in the lungs.
- -While e-cigarettes cause less harm to the cardiovascular system than smoking, research suggests that these products can alter vital signs such as heart rate and blood pressure.

E-cigarettes are still relatively new, so we do not know the long-term impact that they have on health. At this moment in time, e-cigarette use cannot be deemed to be completely safe, but the research conducted to date on the short-term safety of e-cigarettes concludes that they are considerably less harmful than conventional cigarettes.

As the vapour from e-cigarettes does not contain tobacco combustion products such as tar, which have been proven to be responsible for most of the adverse health effects of smoking, the HSE, which implements the tobacco control policy developed by the Department of Health, holds that e-cigarettes are not risk-free but are a potentially safer alternative for individuals who may find it difficult to stop using tobacco³³.

In its evidence review of e-cigarettes, the Health Information and Quality Authority of Ireland (HIQA) stated that due to the reduced levels of toxicants produced by the typical use of e-cigarettes, it was concluded that is it likely that e-cigarettes are less toxic than cigarette smoke³⁴.

Public Health England (PHE), the executive agency that provides the National Health Service (NHS) and the British government with evidence-based support, conducted an evidence review of e-cigarettes and found that e-cigarette use is safer than smoking³⁵. It based these findings on the evidence that the most dangerous and harmful constituents of cigarette smoke are significantly lower in e-cigarettes vapour than in tobacco smoke.

However, the Lancet has criticised this report on e-cigarettes by PHE, stating that the reliance by PHE on work that the authors themselves accept is methodologically weak, along with the declared conflicts of interests surrounding its funding, raises questions about the conclusions of the PHE report and the quality of the agency's peer review process³⁵.

In 2019, Juul labs Ireland, in which tobacco company Altria has a 35% stake, wrote to the Irish Cancer Society and Irish Heart Foundation to provide research which focused on risk reduction in 90 adult smokers who switched to a juul device for 5 days. The research found that participants benefited from nearly a 100% reduction in carcinogens and toxicants which contribute to tobacco-related cancers, heart and lung disease.

A cautious approach must be taken to industry-funded research. In the case of the study provided by juul for example, the research measures 8 biomarkers of tobacco exposure which are present in cigarettes. By stopping smoking therefore, participants had a dramatic reduction in exposure to these biomarkers, simply because they were not smoking³⁷.

The research conducted on e-cigarette safety to date is mixed. A recent study published from the US³⁸ found that over a quarter of e-cigarette products sold there contained traces of the micro-bacterial toxin endotoxin that has been associated with myriad health problems in humans, including asthma, reduced lung function, and inflammation.

Between 2012 and 2015, 343 incidents of e-liquid poisoning were reported to national poison centres across 10 EU member states, while Ireland had the second highest number of incidents of the ten member states (90). Of the incidents analysed, 42.7% were among children.³⁹

Evidence on the safety of e-cigarettes is constantly emerging and although most of the short-term evidence has found that e-cigarette use is safer than smoking cigarettes, there are still risks present, and as we do not know what the long-term health implications are, more longitudinal evidence is required to assess long-term risk.

E-cigarettes and cancer: what we know

Evidence continues to emerge on the link between e-cigarettes and cancer. At present, we cannot categorically say that e-cigarette use increases cancer risk, however there are a number of areas of initial concern, which are described in this section.

When cancer develops in the lungs, the cells change and grow in an abnormal way. Many lung cancers begin in the wall of the bronchi. As the cancer grows it forms a collection of cells (tumour). Lung cancer can occur in men and in women. In Ireland it is the fifth most common cancer.⁴⁰

About 2,500 Irish people are diagnosed with lung cancer every year. More Irish men and women die from lung cancer than any other type of cancer.⁴¹

Patients usually live with lung cancer for many years before it becomes apparent. Early lung cancer will generally not produce symptoms. It takes around 8 years for a squamous cell carcinoma, for example, to reach a size of 30 mm when it is most commonly diagnosed.⁴² For this reason, long-term studies must be awaited to fully determine the cancer risk associated with e-cigarette use.

Aerosols emitted from e-cigarette use can boost the effects of carcinogen-bio activating enzymes, and after long term inhalation, can cause DNA damage to occur, both of which are precursor events to cancer.⁴³

Furthermore, the high temperature reached by e-liquids in the vaporisation process can generate numerous toxic substances which get inhaled directly into the lungs. These substances cause lung inflammation, another precursor to cancer. 44 45 It has been estimated that 27% of e-liquids and disposable cartridges contain traces of endotoxin, a microbial agent, while 81% contain traces of glucan, both of which are associated with lung inflammation. 46

According to a 2017 study, at a normal voltage setting (4.0V), the daily exposure to formaldehyde from consuming 3g of liquid via an e-cigarette would only be 32% lower than smoking 20 conventional cigarettes.⁴⁷

Previous studies have pointed to higher levels of formaldehyde emissions, where e-cigarette users are exposed to 'dry puffs'.

Dry puffs occur when the voltage setting on an e-cigarette is too high, or there is insufficient liquid in the refillable tank, causing the user to experience a burning taste upon inhalation. When users are exposed to dry puffs, high levels of formaldehyde are inhaled.⁴⁸

In 2011, the National Toxicology Program, an interagency program of the US Department of Health and Human Services, named formaldehyde as a known human carcinogen in its 12th Report on Carcinogens.⁴⁹

E-cigarettes and cardiovascular disease: what we know

The research to date on the impact of e-cigarettes on the cardiovascular system is limited and confined to short-term health impacts. At this moment in time, e-cigarette use cannot be deemed to be completely harmless to the cardiovascular system as studies⁵⁰ have suggested that e-cigarettes may cause, similar to conventional cigarettes, harm to the cardiovascular system, although this risk is likely to be lower than the risk associated with smoking⁵¹.

A 2017 paper from the Trends in Cardiovascular Medicine⁵² journal reviewed the available data on the cardiovascular toxicity of nicotine and its implications for e-cigarette use. It found that the cardiovascular risks of nicotine from e-cigarette use in people without underlying cardiovascular disease was quite low but expressed concerns that nicotine from e-cigarettes could pose some risks for users with cardiovascular disease.

E-cigarettes also emit other potentially harmful constituents like carbonyls; this includes aldehydes such as formaldehyde which could present a major health concern. Due to the limited nature of the clinical studies evaluating the effects of e-cigarette aldehydes on the human cardiovascular system, we rely on and extrapolate evidence from non-e-cigarette use, including animal evidence which revealed that formaldehyde exposure altered heart rate, blood pressure and cardiac contractility⁵³.

A 2017 contemporary review on the Impact of electronic cigarettes on the cardiovascular system by the American Heart Association and the American Stroke Association⁵⁴ examined several studies that suggested that e-cigarette use acutely and negatively (increased) vital signs, such as heart rate and blood pressure.

Further long-term research on the impact of e-cigarettes on cardiovascular disease is required, but we cannot deem these devices to be harm-free to the cardiovascular system.

Viability as a quit tool

63% of smokers are thinking about quitting.⁵⁵ At present, long-term evidence on the efficacy of e-cigarettes as a quit tool is limited.

The most compelling study in favour of e-cigarettes as a smoking cessation tool compared the efficacy of e-cigarettes versus Nicotine Replacement Therapy (NRT) for smoking cessation in 886 participants. The study found that after one year, 18% of e-cigarette users were abstinent from smoking versus 9.9% of NRT users.⁵⁶

The same study found that among those abstinent after one year, 80% of those in the e-cigarette group were still using an e-cigarette versus 9% of NRT users still using NRT, which shows that 4 out 5 people who used an e-cigarette to quit smoking were still reliant on e-cigarettes after one year.

Other studies however have shown only modest improvements in tobacco cessation rates with e-cigarette use. 57 58

A greater body of research on the long-term efficacy of e-cigarettes as a quit-tool is needed. While early studies suggest that e-cigarettes may be effective in helping smokers to stop using tobacco, there is not enough evidence at

present to suggest that e-cigarettes are more effective than NRT, for example, to end nicotine addiction⁵⁹. A 2017 HIQA Health Technology Assessment of smoking cessation interventions found that the most effective smoking cessation intervention is the use of a combination of the prescription drug varenicline and NRT together.⁶⁰ Professional smoking cessation services, along with the use of NRT increase the chances of success in quitting up to four times.⁶¹

We believe that quitting smoking using evidence-based methods of quitting remains the safest and most reliable way of giving up smoking. Given that e-cigarettes have been shown to be potentially harmful to health, and are not as efficacious as a smoking cessation tool as recommended evidence-based methods such as NRT and Varenicline, the Irish Heart Foundation and Irish Cancer Society cannot recommend the use of e-cigarettes as a quit tool at this time.

Profile of e-cigarette users

It is difficult to determine an exact profile of a typical e-cigarette user in Ireland given the lack of research and surveys conducted. The 2018 Healthy Ireland survey states that 4% of the current population use e-cigarettes and that a further 12% of the population have tried them at some point⁶². These figures suggest that an estimated 160,000 people in Ireland currently use e-cigarettes. The report further revealed that 9% of current smokers and 10% of ex-smokers use e-cigarettes.

In the UK, more adult males than females have both tried e-cigarettes (21.9% to 17.1%) and are current e-cigarette users (6.5% to 4.8%)⁶³. This is similar to the data from the EU where men (17%) are slightly more likely than women (12%) to say they have tried e-cigarettes⁶⁴. In Ireland, men are more likely to smoke conventional cigarettes than women (22% to 17%)⁶⁵ which may indicate that slightly more men in Ireland are e-cigarette users than women.

Motivation for why an individual uses an e-cigarette gives us a greater understanding of their profile. In Ireland, 17% of those who have tried to quit smoking in the past year, and 30% of those who have successfully quit smoking, currently use e-cigarettes which could suggest that users may be using these devices as a smoking cessation tool⁶⁶.

This trend can be seen again at an EU wide level⁶⁷ which found that 61% of those surveyed used e-cigarettes to stop or reduce tobacco consumption. This was significantly higher than for other factors behind their decision to start using e-cigarettes, such as the belief that it was less harmful than using tobacco (31%), it was cheaper than tobacco (25%) and that users could use the devices in places where smoking is not allowed (15%). Such evidence indicates that the typical e-cigarette user is a smoker or ex-smoker who is using e-cigarettes to stop or cut down smoking cigarettes.

Use among youth - evidence on gateway to tobacco use

E-cigarette companies claim that their products are intended for adult use only and that they are designed as a smoking cessation tool for smokers attempting to quit⁶⁸. These claims cannot be trusted given the heavy presence of the tobacco industry behind these companies.

E-cigarette companies have been investigated⁶⁹ for using marketing techniques on social media that intentionally advertise their products in a way that appeals to young people.

The research on e-cigarette use among youths in Ireland is limited. The latest Irish research indicates that the prevalence of e-cigarettes among young people aged 15-17 is relatively high as almost a quarter (24.7%) of respondents have tried e-cigarettes at least once.⁷⁰ These figures are similar to those found in the UK where 23%⁷¹ of youths have tried e-cigarettes but considerably lower than in the US where 37% have reported having experimented with these devices in the past year⁷².

However, the number of young people in Ireland who reported using e-cigarettes on a regular basis is on the rise. In 2015, 11.0% stated that they used an e-cigarette in the last 30 days and 6.8% reported daily use⁷³, which was an increase on the previous year when only 3.2% of youths reported current e-cigarette use (once a month or more) ⁷⁴. The most common reason for using e-cigarettes was "out of curiosity" (61.2%) and worryingly the number of e-cigarette users among never smokers almost doubled from 4.2% in 2014 to 8.3% in 2015.

At present, there is no law preventing the sale of e-cigarettes to those under the age of 18 in Ireland. While retailers may implement age restrictions as a matter of policy, the absence of law preventing sales of e-cigarettes to children is contributing to the growth in use of these products among young people.

Although the daily usage rate among youths in Ireland remains relatively low, we are concerned that without proper

regulation, there is a risk that we may follow the pattern seen in the US where daily e-cigarette use among teenagers has risen a startling 78% from 11.7% in 2017 to 20.8% in 2018⁷⁵.

Evidence on whether e-cigarette use among youths can lead to eventual use of tobacco is mixed. A recent report from the UK suggests that e-cigarette use does not normalise smoking for young people^{76 77}. The research examined the renormalisation of smoking among young people during the period 1998-2015 when there was limited e-cigarette regulation and rapid growth in their use. It found that the number of teens who had ever tried smoking fell rapidly from 60% to 19% over that time, while regular smoking dropped from 19% to 5%. In particular, there was a marginal slowing in the decline of regular smoking during the years from 2010 to 2015, when e-cigarettes were emerging rapidly but were yet relatively unregulated, showing that during the study period, the emergence of e-cigarettes did not reverse the decline in teen tobacco use.

However, the EU Tobacco Products Directive⁷⁸ states that "electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking". Other studies have suggested that youth e-cigarette use has migrated to conventional cigarette use. A 2015 US longitudinal assessment of 2,530 14 year olds who had never used tobacco products, found that students who had ever used an e-cigarette were far more likely to subsequently ever use tobacco during a 6 month follow-up period than those who had never used an e-cigarette (30.7% vs 8.1%)⁷⁹. A further study of 2,309 school aged children found that non-smokers who had used e-cigarettes showed more willingness to smoke cigarettes compared with those who had never used tobacco products. The authors highlight that willingness to smoke is a predictor of future cigarette smoking.⁸⁰

Evidence on whether e-cigarette use among youth can act as a gateway to traditional tobacco use is mixed and still relatively short-term. Nonetheless, we are concerned that e-cigarette use among youths can act as a potential gateway to smoking.

Case study - Juul

Juul is an American electronic cigarette brand that first launched in San Francisco in June 2015. The Juul product heats up a small cartridge containing e-liquid to create vapour, which dissolves into the air.⁸¹ The Juul device is charged through USB ports and uses flavoured nicotine cartridges. The nicotine in Juul cartridges is provided by nicotine salts, which is derived from tobacco leaves.

Usage of the product has increased significantly in the US in recent years, and its sales account for over 72% of the e-cigarette market⁸². Tobacco company, Altria, the company behind Marlboro cigarettes invested \$12.8 billion into Juul to take a 35% percent stake in the company in 2018⁸³.

The rapid increase in use of the product, particularly among teenagers, has led to scrutiny of its sales and marketing methods. E-cigarette use among school-aged students in the U.S. has undergone a starling rise, with 20.8% using e-cigarettes daily and 27.7% using e-cigarettes on 20 days or more in the past 30-day period in 2018⁸⁴.

The U.S. Centres for Disease Control and Prevention has accused companies like Juul of single-handedly driving a spike in youth e-cigarette use⁸⁵. Health professionals in the US criticised the company for clearly marketing their product on social media in a way that appeals to young people. Research has shown that over time more teenagers in the US are seeing e-cigarette ads. In 2016, an estimated 4 in 5 children aged 11-18 were exposed to e-cigarette advertising from at least one source, which is a significant increase over 2014 and 2015. Nearly seven in 10 youths (17.7 million) were exposed to e-cigarette advertising in retail stores in 2016, while approximately two in five were exposed on the Internet or on television⁸⁶.

A recent report⁸⁷ examining the advertising techniques over the first three years that the Juul device was on the market in the US (June 2015 – November 2018) concluded that its advertising imagery in the first 6 months were patently youth-oriented and that for the following 2 ½ years it was more muted, but the company's advertising was widely distributed on social media channels frequented by youths.

This surge in use has led the US Surgeon General Jerome Adams to declare youth e-cigarette use as an epidemic⁸⁷. Juul is now expanding globally and entering new markets, such as the UK, where it launched its product in October of 2018⁸⁸. The company has launched in Ireland this year.

We are concerned that without proper regulation a similar epidemic to U.S. youth e-cigarette use may occur in Ireland.

Current Regulations

"In 2016, Ireland passed legislation which transposed the European Commission's Tobacco Products Directive (TPD)⁹⁰ into national law.

Article 20 of the TPD requires Ireland and EU member states to observe the following provisions on e-cigarette products:

- Restriction of nicotine-containing e-liquid containers to 10 ml
- · E-liquids' nicotine content must not exceed 20mg
- Except for nicotine, only ingredients that do not pose a risk to human health are used in e-liquid.
- · Products must be child proof and tamper proof
- · Products carry pre-determined health warnings regarding nicotine

E-cigarette product manufacturers must submit a notification to the HSE prior to placing the product on the market.

The notification should contain a full list of ingredients and its quantities, toxicological data, a description of product components and a declaration that the manufacturer bears full responsibility for the product's safety and quality.

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Article 20 also prohibits the advertising of e-cigarette products to the public in certain printed publications (newspapers, magazines, periodicals and similar publications as well as brochures and fliers), information society services (e.g. internet advertising and commercial e-mail), radio, television and through event promotion.^{93 94}

Where e-cigarette products make medicinal claims (such as smoking cessation), they must be regulated with the Health Products Regulator Authority (HPRA) as a medicinal product in the same way that Nicotine Replacement Therapies (NRT) are regulated and require marketing authorisation from the HPRA before being placed on the market in Ireland. 95 96

The ASAI has a set of standards for e-cigarette advertising within the ASAI code. Section 17.8 states that marketing communications should not encourage non-smokers or non-nicotine users to use e-cigarettes, while section 17.9 states that communications should not be likely to appeal to people under 18, especially through association with youth culture and the use of fictitious characters. However, e-cigarette products are known for their colourful, cartoonish packaging, which may appeal to children, including through the use of characters. Hese products are widely available on the Irish market.

Advertising of e-cigarette products is still permitted at the point of sale (POS) in retail outlets where e-cigarette products are sold, and in outdoor areas such as billboards, posters, and bus shelters.¹⁰⁰

The effects of POS tobacco advertising on youth and adult smoking uptake have been well documented both in Ireland and internationally, with children and adolescents who are more frequently exposed to tobacco POS advertising being 1.6 times more likely to have tried smoking and 1.3 times more likely to be susceptible to future smoking. 101 102

Exposure to e-cigarette POS displays among smokers is associated with lower chances of cigarette smoking cessation. ¹⁰³ In Scotland, 36% of retailers which sell tobacco products display e-cigarette products immediately adjacent to products of interest for children (e.g. confectionary, collectable cards, chewing gum, toys and stationary). ¹⁰⁴ It has also been shown that adolescents who recall e-cigarette POS advertising are more susceptible to e-cigarette use. ¹⁰⁵

Ireland is party to the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC). Article 5.3 of the FCTC provides that public health policies on tobacco control should be protected from the vested interests of the tobacco industry.¹⁰⁶

The workplace tobacco smoking ban, which was introduced in Ireland in 2004, does not extend to e-cigarettes. As a matter of policy, private premises may prohibit e-cigarette use at their discretion. E-cigarette use is prohibited in all HSE buildings and HSE smoke-free campuses, for example. Dublin Bus has also prohibited the use of e-cigarettes on its buses as a matter of policy.

The WHO has recommended that parties of the FCTC, including Ireland, prohibit by law the use of e-cigarettes in indoor spaces or at least where smoking is prohibited due to the health risks that e-cigarette aerosol may pose to bystanders.¹⁰⁸

Taxation

E-cigarettes are currently subject to the standard VAT rate of 23%.¹⁰⁹ As e-cigarettes do not contain tobacco, and there is no combustion involved, e-cigarette products do not fall under the harmonised regime for the taxation of tobacco products contained in the Tobacco Products Tax Directive (TPTD), and are therefore subject to rates and structures of duty arrived at by individual EU member states.¹¹⁰

Unlike conventional cigarettes therefore, there is no excise duty placed on e-cigarettes in Ireland. A number of member states (such as Hungary, Italy, Latvia, Portugal, Romania and Slovenia) have introduced excises on e-cigarette products.¹¹¹

The Department of Finance has highlighted concerns with introducing e-cigarette taxation that is not harmonized at the EU-level¹¹²:

- Consumers would be able to purchase e-cigarette products from other member states with no import formalities.
- Based on current usage levels and with challenges of enforcement, excise revenues are likely to be modest.
- Revision of the TPTD may address taxation of e-cigarettes, so it may be prudent to await further developments at the EU level.

The issue of e-cigarette taxation is best addressed within the context of the TPTD and we will continue to work with European partners to monitor any changes in this respect.

Positions of other health organisations

The HSE is responsible for implementing government policy on tobacco control in Ireland which is developed by the Department of Health. The HSE's position on e-cigarettes therefore reflects policy developed by the Department of Health. Ireland's current tobacco control policy, the Tobacco Free Ireland programme (TFI) has set a goal of a smoking rate of less than 5% by 2025. 114

One of the recommendations outlined in the Tobacco Free Ireland policy was to assess the effectiveness of smoking cessation tools. A HTA was subsequently conducted by HIQA which now guides the Department of Health's position on e-cigarettes. The HSE therefore cites lack of evidence on the safety of e-cigarettes and lack of evidence on their efficacy in helping people to quit smoking. Accordingly, the HSE recommends that those looking to quit smoking should use NRT and, where applicable, prescription treatments, such as varenicline, to quit smoking.

In reference to Electronic Nicotine Delivery Systems, (ENDS), which include e-cigarettes, the WHO has stated that:

"The scientific evidence regarding the effectiveness of ENDS as a smoking cessation aid is scant and of low certainty, making it difficult to draw credible inferences".¹¹⁷

The European Public Health Association (EUPHA) have stated that "the health risks associated with e-cigarettes remain uncertain but they cannot be considered safe. What is certain is that statements that they are some percentage safer than conventional cigarettes are so far unjustified". The EUPHA refers to a widely used figure that e-cigarettes are 95% safer than combustible cigarettes, which is incorrect. This figure emerged from a discussion among individuals, who conceded the lack of evidence on which to base their conclusion. 119

The widely cited 95% figure is not based on a detailed review of evidence, supplemented by modelling. In fact, it comes from a single meeting of 12 people convened to develop a multicriteria decision analysis (MCDA) model to synthesise their opinions on the harms associated with different nicotine containing products. The initial paper which contains this 95% figure concedes that "A limitation of this study is the lack of hard evidence for the harms of most products on most of the criteria." ¹²⁰

Public Health England (PHE) conducted an evidenced based review of e-cigarettes in 2015 and found that e-cigarette use is safer than smoking¹²¹. However, these findings have been criticised by health experts from the London School of Hygiene and Tropical Medicine and the University of Liverpool who strongly disagree with this. They claim that the evidence used in the PHE report was flawed and based on inconclusive evidence which was tainted by vested interests¹²².

The PHE's findings on e-cigarettes was also criticized by the Lancet, stating that the reliance by PHE on work that the authors themselves accept is methodologically weak and the declared conflicts of interest surrounding its funding, raised serious questions about the conclusions of the PHE report¹²³.

In Australia, the CEO of the Government's National Health and Medical Research Council (NHMRC) stated that there is currently insufficient evidence to support the claims by e-cigarette companies that they are a safe alternative to conventional tobacco cigarettes. Adding that further research is needed to enable the safety, quality and efficacy of e-cigarettes to be assessed¹²⁴.

SECTION 2: HEATED TOBACCO PRODUCTS

What are heated tobacco products (HTP)?

Heated Tobacco Products or HTP have been around for some time and are not a new technology. First developed by tobacco companies in the 1980s, the production was intended to address the growing concerns about the dangers of second-hand smoke exposure¹²⁵. The very first HTP product was launched on the market in 1988 by the American tobacco firm RJ Reynolds when it released its Premier product in several US cities¹²⁶. Today, HTP are available across most European countries but are not currently available on the Irish market.

HTP differ from e-cigarettes in that they contain tobacco, among other ingredients, including nicotine which makes them highly addictive to users. ¹²⁷ In addition, they often contain non-tobacco additives and ingredients for flavouring.

HTP produce nicotine-infused vapour by heating the tobacco up to 350°C by using a battery-powered heating-system. The heating-system found in the HTP device can be either an external heat source to aerosolise the nicotine from specially designed cigarettes or else a heated sealed chamber to aerosolise nicotine directly from the tobacco leaf. HTP products found on the market are usually one or the other. The heating device requires charging and the user draws on the mouthpiece at intervals to inhale volumes of the aerosol into the mouth, and then into the lungs¹²⁸.

The majority of tobacco companies have introduced their own version of HTPs onto the market. The marketing of the latest generation of devices not only target a specific sub-segment of tobacco users, but also utilise non-traditional techniques and product distribution strategies.

A common marketing tactic employed to engage with consumers' health concerns is to claimthat HTPs are significantly reduced risk products – a claim that is scientifically unsubstantiated. Other marketing methods include designing HTPs in a way to boost the users social image, opening dedicated retail stores for their devices and engaging in 'bait and hook' pricing strategies which sees a base device sold at a discounted price 130.

The Tobacco Industry has a large presence in the HTP market. We advise caution to consumers, policy makers and clinicians when faced with the unfounded claims that they are reduced risk products.

Heated Tobacco Products and cancer: what we know

While the evidence on the long-term health outcomes for e-cigarette use is scarce, even less evidence is available on the relative safety of HTP. Unlike e-cigarettes, however, HTP do contain tobacco, and therefore, even without combustion, will deliver the user with the thousands of chemicals (tar, carbon monoxide, nicotine, arsenic, to name just a few¹³¹) that are present in tobacco material.¹³²

Cigarettes contain over 4,000 chemicals, 60 of which are known to cause cancer. 133

Some chemicals present in combustible cigarettes are partially or completely decomposed during the combustion process, meaning that without combustion, HTP may actually present the user with a greater chemical profile than combustible cigarettes.¹³⁴ Furthermore, the ultrafine particles that comprise the aerosol that delivers nicotine may increase the risk of lung and heart diseases.¹³⁵

HTP are marketed as being less harmful than traditional combustible cigarettes, based on claims that they expose users to lower levels of toxicants. A review of the chemical components of Philip Morris' IQOS product found that in terms of the clinical biomarkers of disease, IQOS was not significantly different from cigarettes. 137

Contrary to claims by the tobacco industry, it has not been demonstrated that switching to HTP from conventional cigarettes reduces the risk of developing tobacco-related diseases. 138

Smoking is the single biggest cause of cancer, causing one third of all cancers. 9 out of 10 lung cancers are caused by smoking, while half of all smokers will die from a tobacco-related disease. 139

Almost 6,000 people die each year from tobacco related diseases. 140

Heated tobacco products and cardiovascular disease: what we know

There are limited data and research on the impact that HTP has on cardiovascular health. Nonetheless, given that these devices contain tobacco products and produce aerosols containing nicotine and other chemicals, they cannot be deemed to be harmless to the cardiovascular system. This is of concern as heart disease remains the most common cause of death in Ireland¹⁴¹.

Claims by the tobacco industry that there are significant reductions in harmful and potentially harmful substances and toxicity with HTPs¹⁴² cannot be trusted. A 2018 systematic literature review of the evidence on HTPs¹⁴³ found that most studies were affiliated with the tobacco industry and were biased. It concluded that studies on HTP second-hand emissions and human use were heterogeneous and largely affiliated with the manufacturers.

While long-term evidence on the health impact that HTP has on the human cardiovascular system is required, a 2017 study on the effects of mainstream aerosol emitted from one well-known brand device on rats showed that exposure substantially impaired endothelial function (an important inner lining of blood vessels) comparably to cigarette smoke despite the absence of combustion¹⁴⁴.

Recent evidence from 2018 has also found that acute exposure to the aerosol of one HTP brand impaired the arterial flow-mediated dilation (FMD) in rats and concluded that the use of these devices does not avoid the adverse cardiovascular effects of smoking cigarettes¹⁴⁵. Further research is required but there is already some evidence that shows that the use of HTP is harmful to one's cardiovascular health.

Are heated tobacco products safe?

The WHO currently states that there is no evidence to demonstrate that HTPs are indeed less harmful than traditional cigarettes¹⁴⁶, despite claims of tobacco companies behind the production of these HTPs claiming that these devices are safer than smoking conventional tobacco. At this moment in time, HTPs cannot be deemed safe to use.

Limited independent research has shown that HTPs are just as harmful to the lungs and immune system as traditional cigarettes. Cigarette smokers who have switched to HTP did not experience improvement in pulmonary inflammation or pulmonary function.¹⁴⁷

HTP contain high concentrations of substances which are harmful to human health, such as particulate matter, tar, acetaldehyde (a carcinogen), acrylamide (a potential carcinogen) and formaldehyde (a potential carcinogen)¹⁴⁸

In terms of second-hand exposure to emissions produced by HTPs, there is currently insufficient evidence. Independent studies are needed to assess the risks posed by HTP emissions to bystanders.

HTPs cannot currently be deemed safe due to a lack of independent research and long-term follow-up.

Profile of HTP users

An average user of the HTP would likely be a former or current smoker attempting to quit completely or cut down their habit of smoking conventional cigarettes.

The tobacco companies behind the production of these HTP devices employ advertising tactics that acknowledge the health risks attached to traditional cigarettes and attempt to market their HTP as a cleaner, less harmful alternative to cigarettes for consumers who seek a healthier way to smoke tobacco¹⁴⁹ ¹⁵⁰. These claims cannot be trusted however as HTPs have not been shown to be safe.

Research from the US indicates that both awareness and use of HTP in the US is increasing. Men and adults under the age of 45 years had a higher rate of awareness than women and those over 45 years of age. Furthermore, the evidence showed that cigarette smokers and both current and former users of electronic nicotine delivery systems were more likely to be using HTP¹⁵¹.

Case study - iQOS

The global HTP market is dominated by three leading tobacco companies – Philip Morris International (PMI), Japan Tobacco International (JTI) and British American Tobacco (BAT). The HTP device iQOS from PMI is one of the most commonly found models on the global market.

First launched in Japan at the end of 2014, the iQOS has been introduced in over 40 other countries worldwide. The battery-operated device is inserted into a heat stick containing a tobacco plug. By heating the tobacco up to 350°C, a flavoured nicotine-containing aerosol is generated and released 152.

PMI, the company behind both iQOS and the conventional cigarette Marlboro, claim that their studies on the HTP device show that it significantly reduced the level of harmful chemicals compared to cigarette smoke, but independent research has countered these claims¹⁵³.

The market for HTP is growing significantly, with total sales for these products reaching US\$ 2.1 billion in 2016 and analysts expect it to reach US\$ 17.9 billion by 2021. For PMI, profit margins for the iQOS device are around 30-50% higher than for its conventional cigarette products¹⁵⁴ leading to the company itself forecasting that its flagship HTP device will account for roughly 40% of total revenues by 2025, up from just under 14%, or US\$ 4.1 billion, in 2018¹⁵⁵.

This expected growth highlights how the tobacco companies are shifting their focus from conventional cigarettes to Electronic Nicotine Delivery systems such as iQOS and other HTP, particularly in developed countries where there is greater awareness of the significant health harm that smoking cigarettes can cause.

As stated previously, any messaging from tobacco companies claiming that they are working towards "eliminating cigarettes" and achieving "a world free from combustible tobacco" should be regarded with caution as ultimately these industries are motivated by keeping people addicted to nicotine. Regular conventional cigarettes are still being aggressively marketed to low-income markets worldwide and so the industry should not be regarded as having changed its dubious practices. ¹⁵⁸

These new HTP have not been shown to be risk-free. We believe that these devices should be subject to similar policy and regulatory measures applied to all other tobacco products.

Current regulations

The European Commission has stated the following regarding the regulation of HTP: "With regard to the sale, presentation and manufacturing of these products within the European Union, the relevant provisions of the Tobacco Products Directive apply and should be enforced. This includes the ban on misleading elements foreseen by Article 13 and notably any suggestions that a particular tobacco product is less harmful than others. The Commission oversees whether Member States fully and correctly apply the provisions of the directive." ¹⁵⁹

Tobacco products in Ireland are subject to advertising restrictions whereby all advertising of tobacco products is prohibited with a few limited exceptions, including the permission of POS advertising at retailers that only sell tobacco products. In 2018, plain packaging became a legal requirement in Ireland for all tobacco products along with the existing text and photographic health warnings.

Among other provisions, Article 10 of the TPD provides that health warnings must cover 65% of the front and back of cigarette and roll-your-own tobacco products as well as the banning of misleading promotional information on tobacco and e-cigarette products. Article 11 however provides that member states may exempt tobacco products other than cigarettes, roll-your-own and pipe tobacco from carrying these warnings. This gives member states the authority to allow HTP to carry a general text warning with no health graphic.

We believe that Government should require HTP manufacturers to abide by the same health warning principles which apply to cigarettes.

In the absence of independent short and long-term health research on HTP, the Commission has advised a cautious approach to regulation of HTP. ¹⁶³

The WHO Framework Convention on Tobacco Control (FCTC) was established in response to a global tobacco epidemic. The FCTC requires parties to establish essential infrastructure for tobacco control, including tax and non-monetary measures. ¹⁶⁴ Article 5.3 of the FCTC provides that public health policies on tobacco control should be protected from the vested interests of the tobacco industry.

Under the Irish workplace smoking ban, tobacco use is prohibited in indoor workplaces, public places, and on public transportation.

At the time of writing, HTP are not widely available on the Irish market. It is imperative that when introduced, HTP are widely understood as being a tobacco product and not an e-cigarette product. HTP should be subject to the same current regulations that govern existing tobacco products such as cigarettes, especially in relation to packaging, advertising and indoor tobacco use.

Taxation

Tobacco Products in Ireland are taxed at the standard 23% VAT rate.¹⁶⁵ Further excise duties are reviewed annually by category in the national budget to dictate consumer prices:

Tobacco Products Tax effective Oct 2018 (per Revenue.ie)¹⁶⁶

Product	Rate of Duty (€
Cigarettes	(a) except where paragraph (b) applies, €327.10 per thousand together with an amount equal to 9.04% of the price at which the cigarettes are sold by retail,
	or
	(b) €376.82 per thousand in respect of cigarettes sold by retail where the rate of tax would be less than that rate had the rate been calculated in accordance with paragraph (a)
Fine-cut tobacco for the rolling of cigarettes	€360.827 per kilogram
Other smoking tobacco	€260.199 per kilogram

Regular, sharp increases in the cost of tobacco are the most effective way to get people to quit smoking. Ireland has the second highest priced cigarettes in the EU and the highest total tax take per pack of cigarettes.

Currently there is no standard EU definition on taxation of HTP.

The Minister for Finance has stated that if HTP are launched on the Irish market, they will be taxed as "other smoking tobacco", and subject to a reduced rate of €260.199 per kilogram.¹⁶⁷

Given that limited evidence on the safety of HTP has shown that switching from cigarettes to HTP does not reduce the risk of developing tobacco-related illness, as well as the harmful chemical components of HTP, which are very similar to cigarettes, these products should be subject to the same rate of taxation as cigarettes.

HTP should not be viewed as a cheaper alternative to cigarettes or as a loophole for the tobacco industry to market tobacco products at a cheaper rate.

We believe that retail prices for HTP sticks should not be below those of cigarettes per unit.

Positions of other health organisations

We support the position of the International Union against Tuberculosis and Lung Disease (The Union), which is as follows: "The potential benefits and risks from HTP to the public health remain undetermined but early independent research indicates that the tobacco companies are understating the risks. The Union recommends that governments apply the precautionary principle to the regulation of HTP. Countries should wait for independent assessment of the health effects of HTP and not simply take industry assertions at face value before allowing the sale of these products. ¹⁶⁸

The harmful nature of HTP is widely acknowledged, with both the WHO and the European Respiratory Society (ERS) pointing to the fact that all forms of tobacco, including HTP, are harmful. Tobacco is inherently toxic, containing carcinogens even in its natural form. It is suggested therefore that HTP are not recommended for use, and should be subject to regulatory measures applied to all other tobacco products in line with the WHO Framework Convention on Tobacco Control (FCTC). ¹⁶⁹ 170

Conclusion

Policy-makers should take a cautious approach to regulation and policies relating to e-cigarettes and heated tobacco products. Of particular importance is the continued implementation of public health measures known to prevent uptake of all tobacco products, as well as e-cigarettes. Where evidence on health outcomes for users of e-cigarettes and heated tobacco products is limited, we recommend that policy-makers apply the precautionary principle to regulation. We would encourage those who are seeking to quit smoking to familiarise themselves with the advantages and disadvantages of all the various recommended evidence-based smoking cessation tools.

The Irish Heart Foundation and Irish Cancer Society reiterate their position that quitting smoking using evidence-based methods of quitting remains the safest and most reliable way of giving up smoking. Anyone who wishes to quit smoking is encouraged to seek support. Talk to your GP for support, or call the HSE Quit Team on Freephone 1800 201 203.

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The following organisations support the recommendations set out in this paper:











