



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

# **Report on the results of the public consultation on the draft health technology assessment (HTA) of smoking cessation interventions**

**22nd March 2017**



## **About the Health Information and Quality Authority**

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation** – Registering and inspecting designated centres.
- **Monitoring Children's Services** – Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality** – Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** – Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information** – Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care service.

## Table of Contents

<b>About the Health Information and Quality Authority .....</b>	<b>3</b>
<b>1. Introduction and overview .....</b>	<b>5</b>
<b>2. The consultation process .....</b>	<b>5</b>
<b>3. Analysis and discussion.....</b>	<b>5</b>
3.1 Thematic analysis .....	6
3.1.1 Safety and effectiveness of e-cigarettes .....	7
3.1.2 E-cigarette licensing and regulation .....	11
3.1.3 Implementation issues .....	13
3.1.4 Advice and information on e-cigarettes .....	16
3.1.5 Effectiveness of behavioural interventions .....	19
3.1.6 Safety and effectiveness of varenicline and NRT .....	20
3.1.7 Harm reduction.....	23
3.1.8 Further areas of research.....	25
3.1.9 Other issues.....	27
3.2 Specific comments.....	34
<b>4. Summary of changes to the HTA of smoking cessation interventions</b>	<b>45</b>
<b>5. Comments received.....</b>	<b>47</b>
<b>6. References.....</b>	<b>92</b>
<b>7. Appendices .....</b>	<b>93</b>



## **1. Introduction and overview**

In January 2016, HIQA commenced a health technology assessment (HTA) of smoking cessation interventions following a request from the Department of Health for HIQA to examine the clinical and cost-effectiveness of a range of different treatments to help people quit smoking. The aim of the HTA is to inform health policy decisions about potential improvements to the provision of smoking cessation services within Ireland's public health service. A public consultation was held to provide all interested individuals and organisations with the opportunity to comment on the draft report prior to the report being finalised.

This report summarises the feedback received from the public consultation process, and details HIQA's responses to the issues raised, including any changes that were made to the report as a result.

## **2. The consultation process**

The draft HTA of smoking cessation interventions was published on the HIQA website on 5 January 2017. The public consultation period closed on 3 February 2017. The consultation webpage contained links to the draft report, appendices, and a consultation feedback form that could be downloaded and emailed to the relevant email address. There was also an option to provide comments via an online form.

A press release was issued at the start of the consultation period and the findings of the draft HTA were widely reported in the media. Individuals and organisations with a potential interest in this HTA were also contacted directly to make them aware of the consultation. This included relevant departments within the HSE, Irish and international experts in smoking cessation, patient advocacy groups and manufacturers of smoking cessation interventions.

All comments received were saved on the consultation email account or in an online database, before being transferred to NVIVO software for analysis.<sup>(1)</sup>

## **3. Analysis and discussion**

A total of 48 separate submissions were received, 13 from individual respondents and 35 on behalf of organisations. The template for making a submission was unstructured to allow people to be as focused or wide-ranging in their comments as they wished. All submissions are reproduced in full in Section 5 of this document and in the appendices.

Qualitative research methods were used to identify the main themes raised in the submission feedback. A thematic analysis was conducted using NVIVO software. This

involved reviewing and coding each submission to identify common themes across contributors.<sup>(1)</sup> A random sample of submissions was coded independently by two people to check for consistency in coding. Multi-dimensional coding was employed for themes where there was a high degree of conflicting opinion to reflect whether the sentiment being expressed was positive or negative in relation to a given issue.

The results of this analysis were used to identify major themes, breaking these down into sub-themes where appropriate, and these are responded to as a group in the analysis and discussion provided below. A catch-all coding category was used to capture specific comments requiring a response that did not fit neatly into an identified theme. HIQA's responses to these comments are provided in Section 3.2.

### 3.1 Thematic analysis

Table 1 provides a list of the main themes identified in the responses to the public consultation, ordered by their overall frequency. Feedback relating to e-cigarettes accounted for half of all comments in the thematic analysis. The next most common issue highlighted was how prospective changes in the delivery of smoking cessation services would be implemented. This was followed by comments relating to the effectiveness of behavioural therapies, and the safety and effectiveness of varenicline in combination with nicotine replacement therapy (NRT).

**Table 1 Identified themes and coding frequency**

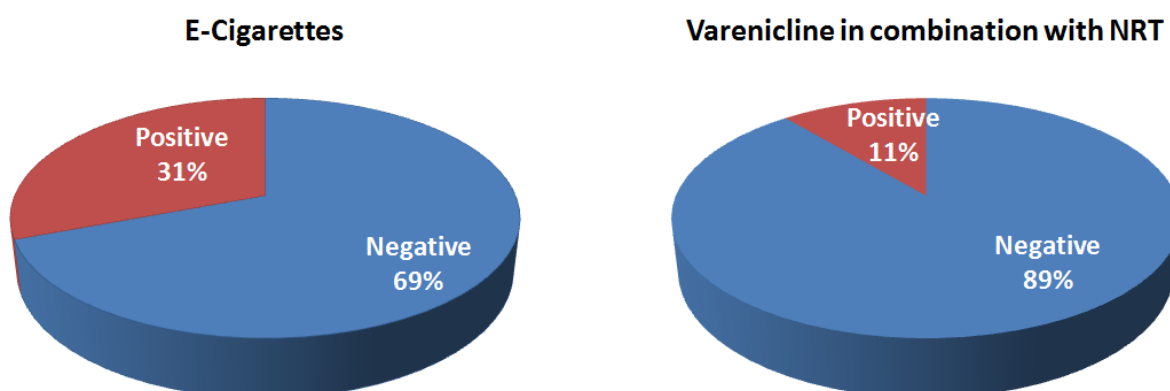
<b>Theme</b>	<b>Coding Frequency</b>
Safety and effectiveness of e-cigarettes*	<b>39</b>
E-cigarette regulation and licensing	<b>22</b>
Implementation issues	<b>18</b>
Advice and information on e-cigarettes	<b>14</b>
Effectiveness of behavioural interventions	<b>9</b>
Safety and effectiveness of varenicline + NRT*	<b>9</b>
Harm reduction	<b>7</b>
Further areas of research	<b>6</b>
Inequalities and smoking cessation	<b>6</b>
Differences in unassisted quitting	<b>4</b>
New technologies	<b>3</b>
Ethical status of smoking	<b>2</b>
Other types of interventions	<b>2</b>
Use of observational data	<b>2</b>
Description of current services	<b>1</b>
Differentiation of NRT products	<b>1</b>

\*multi-dimensional nodes

Comments on the two interventions that were identified in the HTA as the most cost-effective alternatives (e-cigarettes, and varenicline in combination with NRT)

were further classified as being positive or negative in sentiment. This was a subjective interpretation of whether the overall tone of the comments tended to favour each intervention, or not, on the whole. The breakdown of the sentiment associated with comments for these two themes is presented in Figure 1, which shows that feedback on both interventions tended to highlight potential drawbacks associated with their use more strongly than potential advantages.

**Figure 1 Coded sentiment towards effectiveness and safety of smoking cessation interventions**



The following sections provide a summary and discussion of each theme identified in the analysis, and describes any changes made to the HTA report as a result of the issues raised.

### 3.1.1 Safety and effectiveness of e-cigarettes

The feedback in relation to the safety and effectiveness of e-cigarettes centred mainly on three issues: weaknesses in the evidence base to support their use as a smoking cessation method, uncertainty about the long-term effect of vaping, and the lack of any e-cigarette products in Ireland that are licensed as a smoking cessation intervention.

#### *Evidence base*

Concern was expressed about the lack of studies that have evaluated the effect of e-cigarettes compared with placebo or other interventions on long-term abstinence. Some of the feedback received regarding this is detailed below:

*"The evidence to support the use of these products as smoking cessation tools is severely limited given participant population numbers and studies available."*

*"e-cigarettes...have no clinical evidence of safety and efficacy in reducing tobacco use."*

*"We would re-emphasise the lack of data supporting the use of e-cigarettes in smoking cessation, with 6 month absolute quit rates worse than control (7% v 11%)."*

The draft HTA report recognises that there are limitations in regard to the available data on e-cigarettes as a smoking cessation aid, which are described in detail in Section 8.2 of the *HTA of smoking cessation interventions* and mentioned throughout the report. Two randomised controlled trials that met the stated inclusion criteria were identified in the systematic review of the literature, both of which were rated as being at low risk of bias. As such, there is no strong justification for selectively excluding this evidence. To preserve the integrity of the analysis, all studies meeting the pre-defined inclusion criteria were treated in the same way and evaluated using the same analytical framework, which is based on the relative difference in quit rates within the trial rather than comparing absolute quit rates across trials.

In the case of e-cigarettes, this analysis showed that although neither study found a statistically significant treatment effect, the pooled effect was statistically significant. However, the assessment of the strength of the recommendation that can be made based on the available evidence, taking into account other factors such as directness (the extent to which the people, interventions, and outcome measures are similar to those of interest) and imprecision (data is imprecise if the confidence intervals are sufficiently wide that an estimate is consistent with either important harms or important benefits), is low. This means that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. This is strongly reflected in the conclusion of the HTA, which finds that the available evidence is not sufficient to recommend the use of e-cigarettes as a smoking cessation intervention at present.

### *Long-term effects*

Uncertainty about the long-term impact of using e-cigarettes was raised in the feedback. Potential harms mentioned included adverse health effects for people using e-cigarettes and those exposed to exhaled vapour, renormalisation of nicotine consumption in society and the fear that e-cigarettes would act as a gateway to smoking in people who would not otherwise have started. Some of the feedback received included:

*"there are unknown factors in regard to the longer-term consequences of vaping, which may emerge over time and this uncertainty must impact on current advice from health services."*

*"recommends that e-cigarettes are not endorsed as a smoking cessation aid until further evidence on the long-term risks becomes available."*

*"the safety of the inhalation of glycerine and propylene glycol, contained in e-cigarettes, is not well established other than when heated and oxidised propylene glycol can form propylene oxide, which is a known carcinogen."*

*"greater emphasis might be helpful in the HTA on the specific dangers of e-cigarettes among teens. The recent report by the Surgeon-General (2016) also highlights these dangers. Teens are now using e-cigarettes instead of smoking from which they may progress to cigarettes. The main focus for our health service regarding children and teens is to prevent them from using any tobacco product in the first place."*

*"caution in recommending e-cigarettes for smoking cessation as this does not address the challenge of nicotine addiction and may ultimately encourage the smoking of tobacco in the long run, thus compounding the problem of smoking in Ireland."*

*"caution must be exerted, particularly as question marks still exist as to whether e-cigarettes have the potential to appeal to current non-smokers who may become habitual e-cigarette users, developing nicotine dependency as a result. Similarly, risks exist that the perceived comparative safety of e-cigarettes may encourage former smokers to engage in their use. Such habitual e-cigarette use or nicotine dependency may act as a gateway to traditional combustible cigarette use."*

The HTA focused exclusively on e-cigarettes as a smoking cessation intervention. The two randomised controlled trials of e-cigarettes identified in the systematic review evaluated the use of e-cigarettes by smokers for 12 weeks after their quit date, with smoking cessation outcomes evaluated at 6 months in one study and 12 months in the other. Both of these studies reported that about 70% of quitters had also stopped using e-cigarettes by the end of the study.<sup>(2, 3)</sup> In comparison, recent data from the UK indicates that about 90% of those who successfully quit using NRT had stopped taking NRT one year later.<sup>(4)</sup> These findings challenge any assumption that people wishing to use e-cigarettes as an aid to cessation simply substitute e-cigarettes for combustible tobacco. However, they also show that a proportion of successful quitters continue to use nicotine products long after they have stopped smoking. Any potential harms associated with long-term use of nicotine products could have major implications for a decision to promote these kinds of interventions.

As with any new intervention, the absence of definitive data on the long-term safety profile of a treatment when it is first introduced means that judgement is required when estimating the level of risk it poses. Work by both Public Health England and the Royal College of Physicians (UK) has concluded that although the use of e-cigarettes is unlikely to be risk-free, the best available estimate based on expert opinion is that they are likely to be 95% less harmful than smoking.<sup>(5, 6)</sup> The first direct comparison of the metabolite levels of nicotine and important carcinogens and toxins in long-term e-cigarette or NRT users was published after public consultation on the draft HTA had begun. Based on this study, which compared levels of toxins and carcinogens in former smokers who were using e-cigarettes or NRT for at least six months, the study concluded that there was 'no evidence that long-term e-cigarette-only use was associated with greater levels of carcinogens or toxins than NRT-only use'.<sup>(7)</sup>

A complete synthesis of the available evidence in relation to the long-term health effects of e-cigarette use is beyond the scope of this HTA. However, the work of other public health bodies did not indicate that there was sufficient evidence of harms to exclude e-cigarettes as a smoking cessation intervention in this HTA. While this HTA draws attention to concerns in relation to the potential long-term health effects of e-cigarette use in individuals using these products (HTA report section 7.3) or others exposed to e-cigarette vapour (HTA report section 2.1.1.2), it has not attempted to quantify these effects.

A similar approach was taken in relation to the potential impact on society that increased e-cigarette use may have on smoking initiation rates among people who have never smoked before. Although estimating overall population trends in e-cigarette use among people who have never smoked was outside the scope of the HTA, there is a concern that a policy decision for smoking cessation practitioners to advocate the use of e-cigarettes by those attempting to quit may contribute to increased e-cigarette use among people who have never smoked. This type of e-cigarette use may act as a gateway to smoking combustible tobacco. It is difficult to estimate the relative contribution of promoting e-cigarettes as a smoking cessation aid to any growth in the use of e-cigarettes among people who have never smoked, as it is likely to be influenced by a range of other factors, such as marketing of e-cigarette companies and regulations on the sale of these products. Estimating the proportion of people who would later switch from e-cigarettes to smoking (but would never have started smoking were it not for having been e-cigarette users) is even more uncertain. While the available evidence on this issue was not examined in the report, it was appropriate to highlight it as something that would need to be considered by policy-makers when interpreting the results of the analysis of the

effectiveness and cost-effectiveness of different smoking cessation interventions (Section 8.2 of the HTA).

### 3.1.2 E-cigarette licensing and regulation

Some respondents questioned whether it was justifiable to include e-cigarettes in the analysis at all since they are not licensed as a medicine and are not currently endorsed by the HSE smoking cessation services. Some of the feedback in relation to licensing and regulation included:

*"E-cigarettes cannot be presented as smoking cessation aids unless they are classified as medicinal products, subject to Irish pharmaceutical laws and standards, and such products would be required to be the subject of a marketing authorisation before being placed on the market in Ireland."*

*"We acknowledge the incomplete knowledge and long-term effect of e-cigarettes but as it is still an unregulated product, we are wondering about your decision to include it in the cost-effectiveness analysis... Would it have been better to do the cost-effective analysis on the known approved evidence-based pharmacotherapy only? Conventional evidence-based smoking cessation programmes cannot be compromised by e-cigarettes."*

*"as e-cigarettes are not yet proven as effective or safe, are not yet recommended by the HSE, and cannot be legally promoted as such, we propose that they should not be included in the cost effectiveness analysis at this time."*

While an e-cigarette product has been granted a license to be sold as a medicine in Britain, there are currently no products approved by the Health Products Regulatory Authority (HPRA) in Ireland.<sup>(8)</sup> However, the 2015 Healthy Ireland survey shows use of e-cigarettes is widespread among Irish smokers as a means of quitting smoking, with almost 30% of quitters reporting that they used e-cigarettes alone or in combination with another smoking cessation aid.<sup>(9)</sup> Failure to include what has become, in the space of five years, the most popular smoking cessation aid in Ireland would seriously undermine both the internal and external validity of the analysis.

The objective of the cost-effectiveness analysis was to identify how to maximise the quit rate based on the best available evidence on the costs and effectiveness of all the interventions available to smokers in Ireland. Given that e-cigarettes are freely available in this country, and there are studies that meet the inclusion criteria for the HTA that have examined their effectiveness as a smoking cessation intervention, there is little justification for excluding them



from the analysis completely. As outlined earlier, it is recognised that limitations exist in the evidence base for e-cigarettes and, where appropriate, we have reported the results of some analyses with e-cigarettes included and with e-cigarettes omitted in order to examine the impact of future studies failing to confirm the existing treatment effect estimate (for example, Figure 6.25 and Figure 6.26 of the HTA).

Device safety and the provision of product information in the absence of regulatory approval were mentioned in a number of submissions. These submissions approached regulatory approval in a number of different perspectives, including:

*"We would suggest that the Irish government and statutory agencies should consider actively encouraging manufacturers of electronic cigarettes, and other nicotine containing products, to seek medical licensing, so that where the health case is made, such products can be appropriately advertised and promoted to smokers and to health professionals."*

*"We therefore obviously welcome the new regulations governing this industry as we also test competitor brands as a matter of course. The results of some of these tests are truly shocking, some with many thousands of times the maximum limit for formaldehyde, benzopyrene and acetyls and incorrect nicotine levels. Therefore, the sooner these products are removed from sale the better, as consumers assume if they can buy the product it must be safe."*

*"By regulating or communicating with excessive caution, well-intentioned authorities can make the situation worse, cause avoidable harm to consumers and protect the cigarette trade.... These could arise by reducing appeal, making the products harder to use, by hampering innovation, by raising prices, by denying the means to communicate and, above all, by creating regulatory barriers to entry that have the effect of protecting the incumbent cigarette trade against disruptive innovation. Ireland's health community should take great care to avoid compounding these errors."*

*"Regulation is another such condition. If more smokers are to switch to vaping in order to bring about the reduction in smoking rates and cost saving to the state as per the draft HTA, this will not happen if products are made less available, more expensive, less effective, or less attractive to use."*



*"vaping products have never been unregulated. Previous to their inclusion in the revision of the EU Tobacco Products Directive, they were subject to a range of provisions under the general Products Safety Directive, as well as other EU and Irish regulations including those specific to batteries, chemicals and weights and measures. With the introduction of the provisions under the revised directive, composition and aerosol emissions are included in the required pre-market notification scheme."*

*"cases of nicotine poisoning from vials, and some cases of lithium battery explosions and thermal injuries. These suggest a need for product regulation and consumer advice. (For example UK fire services report that fires from electronic cigarette devices generally result from use of the wrong charger.) They do not give grounds for considering electronic cigarettes to be unsafe per se."*

While acknowledging the regulation and licensing of e-cigarettes is important, a comprehensive assessment of issues, such as the risk of individual harms as a result of poor-quality devices and liquids, or the potential to decrease overall quit rates by creating barriers to e-cigarette use through over-regulation, is beyond the scope of the HTA. The fact that e-cigarettes are currently allowed to be sold as a consumer product, subject to the pertaining regulations, was sufficient to include them in the analysis. Section 5.3 of the HTA report details the safety profile of this intervention and Section 7.1.3 describes recent new regulation relating to them. However, some feedback suggests that increased regulation may result in an increase in the cost of e-cigarettes and, as such, may affect the cost-effectiveness results which are sensitive to changes in this parameter. This has been added to the HTA report (Section 6.4).

### 3.1.3 Implementation issues

A number of submissions highlighted perceived inefficiencies in the way services are organised and delivered currently, as well as potential barriers to implementing any of the changes to provision of smoking cessation interventions described in the HTA. This feedback included comments on the need for improved access to smoking cessation by increasing the number of nurse prescribers and eliminating barriers to accessing support:

*"Practitioners would like to advocate for inclusion of NRT on DPS scheme to reduce cost to smokers and increase their chances of quitting."*

*"In the experience of Practitioners, medical staff are sometimes reluctant to prescribe licensed smoking cessation aids (dual NRT therapy, and*

*occasionally monotherapy) to smokers who are looking for help to quit. If recommendation of dual therapy (NRT and Varenicline) is accepted, then training for prescribers will be necessary."*

*"The report acknowledges that efforts to increase the use of combination varenicline and NRT will place additional demands on general practitioner (GP) or nurse prescriber services. Community pharmacists should be able to supply such products to medical card patients without the need to get a prescription from their GP. Indeed, the Health (Miscellaneous Provisions) Bill 2016, which is currently going through the Oireachtas, will facilitate this."*

*"Preference is often due to convenience and availability. If 'Nurse Practitioners' were available in every clinic it seems likely that this would have marked effect or at least I think it would be valid to raise the issue."*

*"If all SCS [smoking cessation service] practitioners were registered prescribers we believe it would transform the service and would result in smokers getting the best available treatment in many more interactions."*

Difficulties providing smoking cessation to subgroups of the population were also mentioned in a number of submissions:

*"There is a clear need to embed smoking cessation support for service users in Mental Health settings, provided routinely by Mental Healthcare Providers."*

*"Practitioners experience difficulty in getting intermittent NRT prescribed for pregnant smokers who have tried to quit using behavioural support alone and failed, but who are keen to get further support if appropriate."*

*"consideration should be given to a recommendation to address barriers to accessing pharmacotherapies [including GP visit costs and drug costs] through a chronic disease care scheme perhaps as part of the new GP contract; in addition, consideration should be given to recommendation of nurse prescribing for cessation pharmacotherapies for all clinical nurse specialists (Cardiac, respiratory, diabetic nurse specialists etc) as well as face to face counsellor services providing access to medications which are currently licensed for over the counter use which would greatly reduce barriers to access."*

*"While the draft HTA addresses the current configuration of services, including behavioural supports, and behavioural supports aligned to*

*pharmacological support, which include referral or self-referral, but it has not assessed the effectiveness of targeted support programmes based at reducing the social gradient, something which is recognised as an important cornerstone of smoking cessation policy in the Tobacco Free Ireland policy document, which notes that "targeted and tailored smoking cessation interventions should be used where necessary, for example, in socially disadvantaged areas."*

Potential implementation issues associated with any decision to advocate or fund e-cigarettes within the publicly funded health system were also raised. Feedback included:

*"Your cost analysis may not have fully acknowledged that most smokers are happy to fund the switch to vaping themselves. The approach that is piloted by some of the Stop-Smoking Services in England at the moment is to supply starter packs (particularly to disadvantaged smokers), with clients selecting and buying their own e-liquid thereafter. The cost of this provision is only about £25 per smoker."*

*"If Irish stop-smoking advisors avoid e-cigarettes, the service throughput and usefulness is likely to diminish."*

The underlying issue that connects all of these comments is the impact these issues will have on the uptake rates of the most effective quitting interventions. For instance, it seems reasonable to assume that improving access to prescription and non-prescription interventions and adapting services to meet the needs of particular subgroups will improve uptake rates, but the HTA does not examine the available evidence for this, or compare the different approaches that could be chosen (this has been highlighted in section 7.2.1.1) as this is beyond the scope of the analysis as defined by the terms of reference. Instead, this analysis identifies prospective changes in the mix of interventions that would maximise overall quit rates in Ireland. Having identified the most cost-effective interventions that would improve quit rates, and taking account of plausible changes in the uptake rates of these, the HTA provides important information to policy-makers about the types of changes that would be most beneficial, but does not identify the best way of bringing about these changes in practice. While a comprehensive analysis of implementation issues is beyond the scope of this HTA, where relevant we have highlighted issues in regard to potential barriers to increased uptake of cost effective interventions, such as the very limited number of nurse prescribers, and the restrictions that apply to the prescribing of NRT products for medical card holders.

### 3.1.4 Advice and information on e-cigarettes

Two distinct issues on the provision of advice and information about e-cigarettes were raised in the public consultation. The first relates to the role of the healthcare practitioner in helping smokers to choose the option that best meets their needs and circumstances, and smokers being fully informed about the relative benefits and harms of each. Feedback in relation to this included:

*"Practitioners are observing a lot of confusion about e-cigarette use, and in the absence of regulation of the products are finding it difficult to offer clear advice on their use. This confusion arises as a result of the following; multiple brands and generations available/is one product "safer" than another one/ should they be used as harm reduction or smoking cessation aids."*

*"The Department of Health's own research, Healthy Ireland Survey 2016, found that of those who successfully quit smoking, 32% use vaping to do so. However, neither the HSE or Department of Health provide consumers with information or support on vaping products which is just crazy when you consider the above facts."*

*"Some smokers will likely never initiate a visit to a smoking cessation provider, or may have previously tried all other ways to stop smoking, and may be thinking about switching to vaping but is put off by misleading media reports. To make it clear to this cohort of smoking that vaping is an acceptable and better thing to do than continue to smoke, this should be addressed as a matter of urgency."*

*"Anecdotal evidence from our members' customers who have previously interacted with a smoking cessation provider, as well as calls to our office requesting information about products from smoking cessation advisors, would indicate that there are wide ranging differences in the quality of information about vaping products supplied to smokers by individual service provider staff."*

These points reinforce the importance of continuous education and training for smoking cessation practitioners on the evolving evidence on the balance of benefits and harms of e-cigarettes to ensure that consistent, high-quality advice is provided to smokers considering using e-cigarettes to help them quit. This is highlighted in the draft HTA report (Section 8.2, and Executive Summary).

A related comment on the role of the healthcare practitioner questioned whether the report should state that it is challenging for medical professionals to provide

information on the risks and benefits of e-cigarettes, as a 'comprehensive safety evaluation cannot be made in the face of incomplete evidence, meaning the public cannot be given full information on which to base their decisions', saying:

*"We consider this an unhelpful formulation. Most medical interventions carry risks, often quantifiable but sometimes not, and interventions frequently have to be recommended in conditions of imperfect information. Medical professionals should be able to explain the potential benefits and risks of interventions, and include statements of uncertainty where they are relevant, as set out by the Royal College of Physicians (RCP) in London in its 2016 report, "Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure." This does not constitute "the provision of inaccurate information", as implied by the draft HTA."*

This submission also questioned the conclusion that 'it is reasonable to await the results of ongoing trials before deciding whether to recommend e-cigarettes in preference to combination NRT for populations where varenicline is contraindicated, not tolerated or not preferred', saying:

*"Again, we consider this an unhelpful formulation. It would be reasonable for medical professionals to give advice on electronic cigarettes..., leaving the final decisions to patients, as required by the principle of autonomy. We note that the RCP in London concluded that: "in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK."*

We agree with the point that where uncertainty exists in relation to a given treatment, the goal of health professionals should be to clearly inform people about what is and is not known, and within this context, the likelihood of potential unknown harms. We also accept that even if subsequent research changes what is currently known, this would not constitute the provision of inaccurate information, and the report has been updated to reflect this (Section 7.1.2.1). The second point, however, is different to the first, insofar as it relates to what specific advice should be given to policy-makers about e-cigarettes as a result of this HTA. The clinical and cost-effectiveness analysis found that although the incremental cost of the benefits gained by using NRT rather than e-cigarettes is relatively high when using point estimate average effect sizes, there is so much uncertainty about the effect of e-

cigarettes that one would need to await the results of ongoing studies before having enough confidence in these results to enact a policy that aims to prioritise one over the other at the present time.

The second issue in relation to providing advice and information about e-cigarettes related to the learning curve for users of these devices, and the need for support and guidance as to how to operate them effectively. These comments included:

*"[vape shop staff] asses, from the customer's patterns of smoking, which will be the best nicotine strength and flavour to start with, and through discussion of their day to day lifestyle, the best device for them. (people who work outdoors for example, may need a sturdier device, etc.). Through conversation and training in how to use the product, they will have discussed and trouble-shot foreseeable barriers the smoker may encounter in making the transition, how to maintain their device, vitally important battery safety information, and tips and tricks to get back on track if they find themselves craving to smoke again."*

*"Vapers can take anything up to around a year to find their personal essential flavours and their right time, before being able to make the switch to vaping exclusively."*

*"We devised a STEP initiative (Switch To Electric Programme) that assisted smokers to make the life change to vaping. We talk with the customer regarding their existing habit and devise a strategy that gives them the best starter kit and the right e-liquid for them. We then monitor their progress over a period of time and help them eliminate tobacco from their lives for good."*

As outlined earlier, this HTA only considered e-cigarettes as a smoking cessation intervention that would be used for a period of 12 weeks, which is consistent with the clinical trials that evaluated it as such. Continued use beyond this is not advocated in the HTA, particularly given the uncertainty around the harms associated with long-term use. However, there is potential for the type of advice on the use of e-cigarettes outlined in the above comments to improve adherence rates for the duration of the 12 week course, and thereby help to maximise the effectiveness of e-cigarettes as a smoking cessation intervention. Therefore, smoking cessation practitioners supporting people making a quit attempt involving e-cigarettes should consider the need to provide practical advice on how to use them, along with information needed to make an informed decision about whether to use them.

### 3.1.5 Effectiveness of behavioural interventions

The positive contribution of behavioural support to smokers attempting to quit was highlighted in numerous submissions. Some submissions suggested that these types of interventions were not given adequate prominence in the HTA report:

*"As respiratory healthcare professionals we wish to make a general comment around the importance of brief interventions and the role that healthcare professionals can play in prompting and supporting patients in the cessation of smoking. We believe that training and practice of brief interventions should be mandatory throughout the health service and a fundamental part of all training curriculums."*

*"...welcomes the recognition (page 281) that the addition of any type of behavioural support to a pharmacological intervention increases the chances of successful quitting, and expresses the hope that further analysis of the effectiveness of targeted community and voluntary supports will be undertaken before the final HTA."*

*"We note that there is currently a form of centralised funding for delivery of very brief advice. Based on the known effectiveness of this intervention we advise on efforts to protect this activity as a method of increasing quit attempts, particularly in primary and secondary care."*

*"The importance and value of Brief Interventions could be highlighted much more in the document. The need for smoking cessation to be raised at all relevant health encounters, through Brief Interventions should be emphasised in the conclusions."*

A considerable amount of evidence examining the effectiveness of behavioural interventions was examined in the Chapter 4 (clinical effectiveness) of the draft HTA and synthesised in the same way as the evidence for pharmacological interventions and e-cigarettes. However, evidence synthesis of behavioural interventions poses additional challenges. This is primarily due to the absence of consistent definitions of each type of behavioural support, in terms of the frequency and duration of the interventions, and the profile of the people delivering it. The varying definitions result in a high degree of heterogeneity that weakens the conclusions that can be drawn from pooled estimates of effect. Furthermore, a decision was taken to include brief intervention arms in the active control group and report effect estimates relative to this rather than do-nothing arms. The analysis found that this active control that includes brief



advice and written material was 50% more likely to lead to quitting compared with no intervention.

The results of our analysis supports another issue raised in submissions, which was the importance of providing behavioural support along with pharmacological interventions, to maximise quit rates (see section 4.2.7), and that there is a risk of losing out on this benefit if the vast majority of quit attempts involving e-cigarettes take place without any involvement of smoking cessation services (section 8.1):

*"the value of very brief advice in the context of smoking cessation is likely to be enhanced if a greater proportion of smokers are able to swiftly access evidence based behavioural support along with one or more quitting aid/s via HSE smoking cessation clinics."*

*"There is concern that most e-cigarette users will never make contact with smoking cessation services and therefore will not get optimal support to quit."*

### 3.1.6 Safety and effectiveness of varenicline and NRT

A number of submissions raised concerns about the HTA finding that varenicline in combination with NRT was the most effective treatment for helping smokers achieve long-term abstinence. Primarily, this feedback related to the evidence supporting such a claim, and the regulatory status of combining these two treatments.

In regard to the evidence for combination therapy with varenicline and NRT the following were among the points raised:

*"Ramon (2014), studying a group of smokers smoking 20 or more cigarettes per day, fails to demonstrate an efficacy advantage for the primary abstinence endpoint - but does indicate difference in subgroup analyses. This distinction is not mentioned. Koegelenberg (2014) did find an efficacy advantage in a different smoker group (those smoking 10 or more cigarettes per day), however even this manufacturer (Pfizer) funded study referred to the need for further studies to assess long-term efficacy and safety."*

*"Varenicline + NRT as a treatment regimen shows promise but has not been evaluated in any known Smoking Cessation Service to date nor has a pricing structure for such a regimen been published or experienced. Mechanistically this combination is counter intuitive so needs careful examination."*



*"It is likely given difference in nicotine pharmacokinetics between formats that a higher risk of adverse events could result from the use of faster release nicotine formats other than patch."*

*"With regard to treatment with Varenicline + NRT this is interesting but as you point out there are only 2 RCT neither of them seems to have reported results at 1 year. Studies referenced below cast doubt on those findings. We are not aware of any SCS that is using this combination. If this were a recognised treatment regimen, which it is not, the 'real world' costs might be quite different from your estimated costs. So again are you confident that it is appropriate to report this as if it is reliable?"*

*"I am surprised but accept the findings re combination of Champix and NRT as my understanding is the safety and efficacy of Champix and other smoking cessation therapies have not been studied."*

The evidence for the efficacy and safety of varenicline in combination with NRT is limited, echoing many of the issues discussed previously in relation to e-cigarettes. This includes the absence of long-term safety data on the combined use of these two interventions, and the fact that only two studies with long-term follow up have compared varenicline with NRT to the use of varenicline alone. While one of these reported a statistically significant improvement in quit rates with the combination therapy, the other did not. However, preservation of the validity of the analysis demands that the same inclusion and exclusion criteria are applied across all interventions, and that the same statistical methods are used to synthesise the data. The results reported in the HTA reflect this, and take into account the uncertainty surrounding the effectiveness estimate based on two randomised controlled trials. This includes the fact that the conclusion of the HTA advises that attempts involving varenicline, either alone or in combination with NRT, were likely to be the most effective, rather than concluding that combination therapy should always be recommended ahead of varenicline monotherapy.

The final HTA has updated Chapter 4 (clinical effectiveness) to emphasise that the NRT product used in both trials was nicotine patches. The cost of the combination therapy in the economic analysis has also been updated to reflect this (Section 4.2.9). Text has also been added in this chapter to address feedback about the mechanism of action of varenicline (a nicotine receptor partial agonist) being at cross purposes with the mechanism of action of nicotine replacement therapy, taken from the literature (Section 4.2.5).<sup>(10)</sup> This does not provide a definitive explanation of why combination therapy works,

but rather shows that one does not necessarily counteract the other when both are used in combination.

A number of submissions refer to the fact that combination use of varenicline and NRT is not supported by the labelling of either of these pharmacotherapies, and that this therefore constitutes off-label use of these products.

*"At this time the use of varenicline and NRT in combination is not supported by the labelling of either varenicline or NRT. The off-label nature of this combination means that there is no recognised posology or safety record on which to make treatment recommendations and therefore they should not be included in the cost effectiveness analysis for use in combination."*

*"We acknowledge varenicline + NRT having the greatest treatment effect relative to control... but would note that varenicline is not authorized to be used in this way and that Pfizer therefore does not market or recommend it as such."*

*"the use of varenicline and NRT in combination is off label use and the legislation prohibits the promotion of this by pharmaceutical companies."*

*"It is also of note that should the conclusion about the use of varenicline and NRT in combination remain as published in the draft report it is likely to lead to confusion and uncertainty in the real world. Manufacturers of licensed medicines are only able to communicate about the use of their products in ways consistent with the product label, and frequently they need to respond to questions about product use from healthcare professionals. If guidance from HIQA states such combination use is effective and cost effective whilst manufacturers have to state that they cannot recommend such use due to product labelling there is the potential for confusion, not to mention questions on liability should there be any negative consequences."*

The opinion of the Health Products Regulatory Authority (HPRA) was sought in an attempt to clarify this matter. The HPRA indicated that provided each product is used in accordance with the approved product information, prescribing two products for the same condition should not necessarily be construed as off-label use. This issue was also raised with HSE smoking cessation practitioners, who reported that although the use of varenicline in combination with NRT was considered rare, it is currently used by a proportion of Irish smokers to help them quit. This is consistent with the results of the

2015 Healthy Ireland survey results.<sup>(9)</sup> However, even if it was the case that combining these products was not consistent with their current licensing, it would still not justify excluding studies that examined the effect of combination treatment, as it is important that the HTA reflects the totality of evidence in this area, recognising that regulations can be updated when new evidence emerges.

As these issues are of potential significance for the development of clinical practice guidelines, they have been highlighted in Chapter 7 of the HTA on the wider implications of changes to the way smoking cessation services are delivered.

### 3.1.7 Harm reduction

The use of e-cigarettes as a harm reduction measure, through fully or partially substituting combustible tobacco with e-cigarettes, was discussed in a number of submissions. This issue is outside the scope of the HTA, which only examined the effectiveness of e-cigarettes as a smoking cessation aid intended to be used for a finite period, in the same manner as NRT, by smokers wishing to quit. However, in the analysis, people abstaining from combustible tobacco after using e-cigarettes were treated as successful quitters regardless of whether or not they continued to use e-cigarettes afterwards. The distinction between the use of e-cigarettes as a cessation intervention or as a harm reduction measure is therefore problematic, as a proportion of successful quitters are likely to continue using them (as outlined in Section 3.1.1 of this report). The feedback received from the public consultation highlights that different interpretations of the nature of e-cigarettes has implications for how they are licensed, marketed and evaluated. Feedback on harm reduction included:

*"Practitioners wondered about the use of e-cigarettes as a harm reduction method for vulnerable clients who may never realise their desire to quit completely."*

*"People who do not wish to quit have been shown to be helped to reduce the number of cigarettes they smoke and to quit smoking in the long term, using NRT (e-cigarettes), despite original intentions not to do so. Preliminary findings show that combining availability of appealing e-vapour products for smoking substitution with professional advice from trained staff, it is possible to achieve high and stable success rates."*

*"The RCP makes the important observation that e-cigarettes are consumer products and that their success in part derives from their appeal to those who would never even try to quit smoking via conventional*

*methods or are unwilling or unable to quit. E-cigarettes are not medical aids to reduce craving and withdrawal during a quit attempt, but an alternative way of taking the recreational drug nicotine. It is important, therefore, not to treat e-cigarettes as medicines, to misapply concepts like 'efficacy' or to rely on randomised controlled trials that are suited to singular interventions, such as administering a drug. The 'efficacy' of e-cigarettes is not a property of the device and liquid, but the outcome of a complex ecology of behavioural influences, including properties of the product, but also peer support, marketing, beliefs about risk and scare stories in newspapers, local availability, the attitude to smoking/vaping in the social and work environment, and the policy framework – packaging, warnings, restrictions, diversity, marketing, taxation etc. Users tend to progress over time, acquire vaping skills and switch products to more complex configurations, lower nicotine liquids and more diverse flavours as they migrate away from tobacco. A period of dual use may be part of a transition that lasts longer than any RCT ever would, but ends in permanent smoking cessation. Because of their poor efficacy, conventional smoking cessation techniques also involve prolonged "dual use", but this occurs serially with successive quit attempts and relapses back to smoking then the next quit attempt and so on until success, or through an indefinite cycle of cessation and relapse."*

*"However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK (Recommendations, original emphasis). Taking all the available evidence into account, the organisation that first reported on Smoking and Health in 1962, endorses a tobacco harm reduction approach including the promotion of e-cigarettes. Ireland's ambitious goal to be tobacco-free by 2025 has been translated into achieving a smoking prevalence rate of less than 5%. This goal is very ambitious. It will be exceedingly challenging if the only strategies to be deliberately deployed are complete cessation and reduced initiation. Current rates of decline in smoking are unlikely to come close to meeting this target. However, a third strategy is available, that is to encourage smokers to switch to smoke-free products – primarily e-cigarettes but also other nicotine products that does not involve combustion and smoke. Many smokers will find it easier to switch from smoking to vaping than to stop both smoking and nicotine use altogether. The switching strategy only involves giving up part of what is involved in smoking. Switching from smoking to vaping allows the user to continue*

*using nicotine and to maintain several behavioural and sensory aspects of smoking, though with radically reduced risk and a contribution to the attainment of the 2025 smoking prevalence target."*

*"Observations in my clinic are consistent with discussion at the FCTC COP meeting on ENDS/ENNDS in November, 2016. The physical, psychological and conditioned behavioural components of tobacco smoking are maintained with the use of non-medical ENDS. Persons who use these devices are not quitting or treating their tobacco use, they are opting for a reduced harm product - an alternative to smoking tobacco "that produces a satisfactory experience to the user in terms of the speedy delivery of sufficient nicotine to mimic the sensory feel of smoking". (WHO, 2016)."*

*"If current smokers cannot or do not wish to stop smoking by any other means, they should be actively encouraged and supported to make the switch to vaping."*

*"We acknowledge the parameters of the terms of reference of the HTA in regards to the point above. However, it is the IVVA's view that if vaping is only recommended to smokers in the context of an explicit quit attempt, it will fail to reach the cohort of smokers who are resistant to the idea of quitting and who may see it as an unattractive proposal for them. By the acknowledgement of the harm reduction potential of vaping, alongside the message that using their vaping product exclusively will have better outcomes, it may well turn out to be the case where this cohort of smokers who might not otherwise have made an explicit quit attempt, achieves smoking cessation."*

While considerations about harm reduction, including the potential role of e-cigarettes among the subgroup of smokers who do not want to make a quit attempt, are beyond the scope of this HTA, the feedback received on this issue provides a valuable resource for smoking cessation policy-makers to consider as part of the wider approach to tobacco control in Ireland. See Appendices for full submissions.

### 3.1.8 Further areas of research

A number of submissions commented on the need for more research on e-cigarettes:

*"We are, however, very eager to see more (and more in depth) research on the long-term health effects of e-cigarettes in particular. A focus on*

*composition, ingredients etc will shed more light on these products and will help better inform their suitability as a cessation tool."*

*"There is more than one trial looking at the efficacy of vaping in pregnancy currently ongoing in the UK, and there are now guidelines available for smokers who are pregnant on vaping. It is therefore the IVVA's view that it would be prudent for the research knowledge gap identified above to be filled, if it is the case that these populations may benefit from direct advice about switching to vaping when all other options have been exhausted."*

*"It should also be used to identify areas of tobacco control research where there is paucity of data from an Irish perspective. Funding should be made available to further research these areas."*

*"The Draft Report acknowledges that continued research is required going forward to monitor the impact of vaping products on consumers and the population as a whole. In this respect, we would urge the HIQA to provide more clarity on what it considers is required in terms of further research and, from this, we recommend that the Department of Health commission such research and continue this on an annual basis."*

*"We suggest that the Department of Health, should undertake these studies to assess the role played by vaping products in achieving Ireland's 2025 tobacco control goals and the more overarching longitudinal studies on vaping products as a category in Ireland on an ongoing basis."*

*"Another way in which the Department of Health can enhance the knowledge regarding how vaping products are being used in Ireland is by expanding the sample size and questions in the Healthy Ireland survey. Widening the sample size and scope of questions will allow the Department of Health to more effectively gauge the potential that vaping products can play in providing an alternative to smoking in Ireland."*

*"To ensure that the final HTA is used to full effect it is important that the HTA offers constructive ideas on what public health bodies in Ireland can do to ensure Irish smokers and vaping product users are being supplied with legitimate and up-to-date information."*

There are ongoing studies that examine the effectiveness of e-cigarettes as a smoking cessation tool, including one being carried out within the smoking cessation service in the UK that is due to report in 2018.<sup>(11)</sup> An additional section has been added to Chapter 4 on clinical effectiveness to highlight the



ongoing work in this area, and when results of these studies are due to become available.

### 3.1.9 Other issues

A number of other themes emerged less frequently in the feedback received from the public consultation. These are discussed in this section.

#### Inequalities and smoking cessation

*"the Irish Cancer Society posits that the social gradient associated to smoking means that any policy designed to reduce prevalence should ensure that those in the most deprived areas gain the most from such policies, and should be the focus of targeted supports enabling them to quit."*

*"All available evidence suggests that actions should aim to reduce the steepness of the social gradient through the delivery of a universal service on a scale and intensity to the level of disadvantage (Marmot M, Strategic review of health Inequalities in England post-2010). There is emerging evidence pointing to the importance of working in partnership with the community and voluntary services (CVS) in order to deliver smoking cessation support to people living in socially and economically disadvantaged areas."*

*"in achieving the desired outcome of not only reducing smoking prevalence, but enabling people, especially those in deprived and low income communities, to cease smoking, additional consideration in the final HTA should be given to the effectiveness of targeted community level intervention in areas of deprivation."*

*"a proposal by the EU Commission to amend the directive on manufactured tobacco products (Directive 2011/64/EU), and include a harmonised rate of excise duty on vaping products... would have more of a negative effect on smokers with low incomes, and may drive those who would likely switch to the informal economy, in order to save money."*

*"Where is the proposed method to combat cessation inequalities to incorporate an equity element into performance measurement? p 78 ( I have been seeking this for 5 years)."*

This HTA recognises that the impact of smoking is not distributed evenly across society and that targeted measures are required to focus efforts on those most affected; however, these are issues are not within the scope of the HTA.

### Differences in unassisted quitting

*"In the experience of Practitioners, unassisted quitters are very different from smokers who are actively looking for help to quit as these people may have experienced many failed quit attempts/may have co-morbidities/ may be under pressure from Healthcare Practitioners and family members to quit for health reasons."*

*"The main findings of the report indicate that we increase the number of smokers accessing evidence based medications such as combination varenicline and NRT however there is limited discussion on how to get more smokers engaged with any kind of health professional where they can be delivered a Brief Intervention and ideally be directed to the treatment which is likely to have the most positive outcome. If the majority of smokers choose to quit unaided our ability to impact on the percentage who access any kind of support and ultimately improve success rates is limited. While recognising the scope of the health technology assessment, final recommendations from this report should include a strong focus on the importance of a full and comprehensive tobacco control framework including more detailed discussion and recommendation around making every contact count (MECC), the role of brief intervention and referral to more intensive behavioural and pharmacological support."*

*"A recommendation from the HTA should be to target these people who wish to quit but decide not to use cessation aids available in Ireland. This relates to section 3.4.4 Smoking cessation in Ireland (Page 72). It is stated that "The most common approach, used by half (50%) of respondents, was to have no help."*

*"More research into why such group would choose "willpower" alone may better inform us of the best smoking cessation aids to use for these people."*

An analysis of smoking cessation treatments differs from other healthcare interventions in a number of ways, with perhaps the most important being that despite strong evidence of the effectiveness of some available therapies, approximately half of quit attempts in Ireland are unassisted.<sup>(9)</sup> However,



people who quit smoking differ considerably across a wide range of characteristics, including how heavily addicted they are and how motivated they are to quit. The proportion of smokers who choose unassisted quitting are likely to differ in important ways from the people who choose to use behavioural or pharmacological support to help them quit. Therefore, it cannot be assumed that everyone who is currently choosing to quit unassisted will derive the same benefit from using an intervention as those who enrol in trials on the basis that they would be randomised to either a placebo or intervention group. As such, the conclusion of the HTA states that, 'smoking cessation services should seek to increase the uptake of the use of varenicline (alone or in combination with NRT) among smokers wishing to use some type of pharmacological support in their attempt to quit.'

### New technologies

*"We would also point out that electronic cigarettes are not going to be the last potentially harm reducing product offered to smokers. On 30th November 2016, Philip Morris International launched IQOS, a potentially 'reduced risk' tobacco product in the UK. The device uses compressed tobacco in a 'mini-cigarette' form in a vapouriser. Unlike electronic cigarettes which vapourise nicotine suspended in a liquid, the IQOS heats and vapourises tobacco. PMI has submitted extensive evidence to the US Food and Drug Administration seeking approval for iQOS in the US market, and has already launched the product in several other countries including Japan... The Irish government, statutory agencies and health professionals will need to consider a general approach to harm reduction that will enable a rational regulatory and policy response to all harm reduction products aimed at smokers, not simply electronic cigarettes."*

*"E-cigarettes are not the only product to offer promise as an alternative to smoking for those adult smokers who intend to continue smoking. As recognized by more than 50 of the world's leading tobacco and nicotine policy experts: There are now rapid developments in nicotine-based products that can effectively substitute for cigarettes but with very low risks. These include for example, e-cigarettes and other vapour products, low nitrosamine smokeless tobacco such as snus, and other low-risk non-combustible nicotine or tobacco products that may become viable alternatives to smoking in the future."*

*"As HIQA and the Irish government continue to assess this pressing topic, it is important to be mindful of the rapid pace of innovation in the area of*

*potentially less risky alternatives to cigarettes and ensure that regulation and policies leave room for new developments and do not have the unintended consequence of discouraging adult smokers from switching to scientifically substantiated less risky alternatives to cigarettes.”*

As none of these new technologies are currently on sale in Ireland or backed up by good evidence of effectiveness as a smoking cessation aid, they were not included in the HTA. However, this feedback does highlight the rapidly evolving market in alternatives to conventional tobacco cigarettes, and the likelihood of additional interventions emerging in the coming years.

### Ethical status of smoking

*"5. We consider the section of the draft HTA on ethical, societal and legal implications to be particularly important. Page 272 discusses the principle of respect for autonomy – which may be defined in this context as the right of patients to make their own decisions on their healthcare and lifestyle, supported by medical professionals providing them with the best available information and advice. We believe that this principle includes an obligation on medical professionals not to stress the benefits of particular interventions or actions without also informing patients of potential risks, and that it also includes an obligation not to place undue emphasis on risks where the evidence shows a particular intervention or action is much more likely to confer benefits. It is well established that human beings are typically poor judges of risks relative to benefits, and this requires medical professionals to be particularly careful not to describe actual or potential risks in a way that discourages patients from utilising beneficial interventions.*

*6. On page 272, it is suggested that smoking cessation interventions could "take the form of either a harm reduction strategy or a more absolutist approach" and that "a harm reduction strategy aims to eliminate the damaging effects of a particular behaviour, without eliminating the behaviour itself. A more absolutist approach would seek to eliminate the behaviour entirely. For example drug addiction and prostitution are perceived to be inherently wrong ..."*

*7. This prompts two comments. First, what is the relevant "behaviour" in the context of this report? Is it the consumption of tobacco, mainly by smoking? Or is it the consumption of nicotine? It is of course the nicotine which creates addiction in smokers, but the smoke that does the overwhelming preponderance of harm. Secondly, we would suggest that*

*not all drug addiction is in fact considered "inherently wrong". Public beliefs on what is "wrong" in this context are heavily influenced by the legal status of the substance and the harm caused by its use. For example, the UK (and no doubt Ireland) has many people who are dependent on caffeine and could be described as "addicted". This is not considered "inherently wrong". The report gives no evidence to support the conclusion that dependence on nicotine should be considered – "inherently wrong". This is a critical question when considering which health interventions to recommend to smokers, and what to say about them."*

*"Extract 'Although smoking is harmful to the smoker and to third parties who inhale tobacco smoke, it is not generally considered to be morally wrong and is therefore a matter of individual choice'.*

*In reference to the above, it is correctly stated that smoking is harmful to both the smoker and third parties. As it is now firmly established (W.H.O.) that smoking is harmful to third parties, the issue of whether it is morally correct to smoke at a time and place where others can be harmed must surely be questioned. This would also apply to outdoor areas, such as, sports stadia, crowded streets and rail platforms.*

*The issue of smoking in the workplace has been dealt with by way of legislation and third parties are now protected when indoors. However, the workplace smoking legislation does not protect non-smokers from environmental tobacco smoke in outdoor areas where smokers are allowed to smoke.*

*The issue of non smoking staff working in outdoor bar areas, which are often polluted with tobacco smoke, highlights a group of workers who are not protected by the workplace legislation. The morality of having bar staff, mostly young people, working in polluted carcinogenic environments should indeed be questioned as should the morality and legality of smokers using outdoor areas - and as a consequence - non-smokers ingesting carcinogens."*

These issues were discussed with the member of the Expert Advisory Group who carried out the ethical analysis, and following this additional text was added to clarify that although the point stands in relation to the moral status of an individual's decision to smoke, this does not extend to exposing others to harm as a result of one's decision to smoke (Section 7.1.2.1 of the HTA report). Text has also been added to clarify that although the provision of inaccurate

information on comparative risk is fundamentally unethical, in circumstances where the long-term health risks of an intervention, such as e-cigarettes, are not possible to quantify precisely, medical professionals should explain the known risks and benefits to patients, including a statement of uncertainty about unknown risks where relevant (Section 7.1.2.1 of the HTA report).

### Other types of interventions

*"Mass media is especially important since we need to both grow the number of those with intention to quit, but as highlighted in HI Survey, we need to grow the proportion who are translating these intentions into successful quits by using effective services and interventions. The numbers currently using the more effective interventions are currently very small and that represents a significant challenge. Again, acknowledging the scope of the health technology assessment, in that context it would be helpful if one of the final recommendations considered the need to at least maintain the current campaign spend and ideally an increase in same."*

*"Screening, documentation and identification of tobacco use status as a means to improving access to smoking cessation interventions was omitted from the document- these are seen as crucial to improving smoking cessation interventions by all health professionals in any healthcare setting."*

Interventions to increase the proportion of smokers who want to quit, and make a quit attempt, play a very important role in lowering overall smoking prevalence. However, these are outside the scope of this HTA, which focussed on intervention help smokers attempt to quit to do so successfully. Similarly, interventions designed to increase the uptake of certain types of smoking cessation treatments also fall outside the scope of this analysis.

### Use of observational data

*"Some Practitioners felt that observational studies and their recommendations should have been included in literature review."*

*"The focus on trials for efficacy may need to shift to looking at a combination of relative risk communication and after-market population level studies instead. It is likely that this approach, with careful methodology and survey questions, will give a clearer picture of the efficacy of vaping products."*

A large number of randomised controlled trials have been carried out to examine the effect of various pharmacological and behavioural smoking cessation interventions. As these trials represent the highest quality evidence with which to estimate the effect of interventions, it was important that they would be the primary source of data for the analysis. However, there are some circumstances where observational data might be considered preferable to randomised controlled trials; for example, in situations where there are substantial doubts about the applicability of the trial data. This might arise for a variety of reasons, such as the level of similarity between Irish smokers and the population involved in the trial, advances in a particular intervention that have occurred since the trial was carried out (for example, availability of second generation devices, new approaches being developed within a particular type of behavioural therapy and so on) or where wider changes in society and smoking behaviours may affect the intervention being studied.

However, these decisions require very careful consideration because any decision to favour observational evidence puts the analysis at far higher risk of bias due to the inherent limitations of these study designs. Per the protocol for the review of clinical effectiveness data that was endorsed by the Expert Advisory Group at the outset of the HTA, the characteristics of the randomised controlled trials identified in the systematic review of the evidence were critically appraised to ensure they were generally applicable to the population of interest in this HTA.

### Description of current services

*"I was disappointed that the Document did not report on the local intensive Smoking Cessation Services that are available in Ireland and also to report in more detail the lack of services provided in General and Maternity Hospitals."*

Descriptions of the current configuration of smoking cessations services for the general population of smokers in Ireland, smokers receiving secondary mental health services and pregnant women are provided in sections 7.2.1.1, 7.2.2.1 and 7.2.3.1, respectively.

### Differentiation of NRT products

*"it makes no reference to the different types of technologies and benefits of certain technologies on the market within the NRT category. The diversity of technologies available within the NRT category is pertinent"*

*when considering available treatments for patients and consumers attempting to quit.”*

The analysis of the effectiveness of NRT combined data on all types of this intervention (gum, patch, lozenge, and so on) to generate an overall effect estimate for this treatment (Section 4.2.9 of the HTA). A single overall estimate of the effectiveness of NRT was used as no statistically significant difference has been demonstrated between the two most studied NRT interventions (patch and gum), despite the numerous studies that have been carried out, and there are comparatively few studies available for the other NRT treatments. With so few studies carried out on some of the newer types of NRT, using different estimates of the effect of these types of interventions would run the risk of type I errors (finding an effect where none exists).

### **3.2 Specific comments**

In addition to the themes that emerged from the qualitative analysis, there were a number of specific comments or questions relating to various parts of the report. These are addressed in this section.

*“I’m wondering if it is possible for the exact brand(s) of e-cig that were studied to be mentioned in the appendix? This might give us an idea as to whether this is a brand that can be purchased in Ireland?”*

The New Zealand trial used the Elusion e-cigarette, and the Italian trial used the Categoria model 401 e-cigarette.<sup>(2, 3)</sup> However, it is unknown if these particular brands are available in Ireland, or whether advances in e-cigarette technology mean that they would be considered appropriate for those wishing to use e-cigarettes in their quit attempt. Rather, the results of these trials were considered the only high-quality source of data with which to estimate the effect of using any type of e-cigarette.

*“Section regarding motivational interviewing and brief interventions. I believe the carbon monoxide breath test monitor (Smokerlyzer) tool should be used in conjunction with brief interventions and motivational interviewing by more health care professionals in their practice. e.g General practitioners, consultants, practice nurses, physiotherapists, community nurses, public health nurses, occupational therapists, wellness coaches and many more. I believe it is a highly useful aid/tool in smoking education and behavioural health. It is a visual aid which may encourage clients to quit and helps to measure their progress.”*

The potential impact of carbon monoxide testing on the effectiveness of behavioural interventions was not estimated, so it is outside the scope of this HTA to provide advice on their use in this manner.

*"Report makes comparisons between delivery of smoking cessation services in UK and Ireland, but the reality is that services are delivered very differently in both countries. We have large gaps in availability of one to one services in Ireland and Practitioners here are unable to prescribe smoking cessation aids to clients. This increases barriers to compliance with treatments for clients."*

The analysis does not assume that services in Ireland are or will be comparable to those in the UK in terms of the model of care, the extent of face-to-face support, or the funding and prescription of treatments. Rather, UK data is used to inform estimates of the extent to which e-cigarette use may rise in the coming years. This is based on the assumption that the increasing uptake of e-cigarettes over the last five years in England may be replicated in Ireland. While the UK data informs the estimate of peak e-cigarette use reaching 45% in Ireland, the use of other behavioural or pharmacological interventions has not been changed to match the level of use currently in England.

*"The Healthy Ireland survey questions were felt by some Practitioners to be incomplete in terms of local services being referenced and also that use of generic versus trade names for treatments may cause confusion. It was noted by others that this issue may be clarified by those administering the survey."*

This comment has been forwarded to the Department of Health, who commissioned the Healthy Ireland survey, for consideration.

*"Reference Individual Counselling and Intensive Advice on page 123, do you have a definition of these supports for the report?"*

As per Section 4.2.3 of the HTA, these interventions are described as follows:

Intensive advice: combining interventions of motivational interviewing (a brief psychotherapeutic intervention intended to increase the likelihood that a person will make an attempt to change their harmful behaviour) and clinician support (more intensive than brief advice but less intensive than individual counselling in terms of frequency and duration of interaction).

Individual behaviour counselling: a face-to-face encounter between a smoking patient and a counsellor trained in assisting smoking cessation.



*"Maternity feedback and observations Practitioners would like to advocate for routing carbon monoxide testing to be done at first antenatal visit for all pregnant women in an effort to identify pregnant smokers and offer support to quit, bearing in mind that many pregnant women are reluctant to disclose the fact that they smoke."*

The potential impact of carbon monoxide testing on the effectiveness of smoking cessation among pregnant women was not estimated by this HTA and it is outside the scope of this HTA to provide advice on its use in this manner. However, this issue is raised in Section 7.3.2 of the HTA.

*"Pg 71 reference to "exemption" - suggest a slight correction to a paragraph which is not technically accurate in its current form. Suggested revision of text to: In the Irish context the Workplace legislation banning smoking in indoor workplaces came into effect in 2010. Irish stand-alone psychiatric hospitals (i.e. hospitals which were not attached to an acute site) had an exemption in the legislation at that time, however the HSE Tobacco Free Campus Policy endorsed by senior management in 2012 sets out a policy for the organisation which goes above and beyond the minimum requirements set out within this legislation. The organisational policy requires all HSE sites and services whether owned leased or funded by the HSE to implement a Tobacco Free Campus Policy prohibiting smoking in all indoor areas and outdoor campus grounds thereby providing a supportive environment for cessation. Aside from providing a supportive environment, one of the key purposes of the policy is to treat tobacco addiction as a healthcare issue. Enacting the Tobacco Free Campus policy in a phased way across all sites and services was a key action of the Tobacco Control Framework 2010."*

The relevant text has been updated to correct this inaccuracy (section 7.2.2.3).

*"As outlined in this document a common side effect of Bupropion is dry mouth. Advice needs to be given by those providing smoking cessation services regarding the management of dry mouth, due to the impact it has on oral health:*

- a. Providing information on oral lubricants (saliva substitutes)*
- b. Providing information on diet for e.g. although sucking sweets may give temporary relief, it will cause severe dental caries in the absence of saliva. Frequent consumption of drinks sweetened with sugar (e.g., soft drinks, tea) should also be avoided. Even sugar-free sweets and drinks can be problematic due to their acid content which is erosive to the teeth, especially in the absence of saliva.*



*c. Preventing disease through the use of fluoride mouthrinses and mouthrinses to control plaque."*

The section describing the side effects of bupropion (section 5.5.1) is only intended to outline the potential side effects associated with each intervention. Providing information on the management of these side effects is beyond the scope of this report.

*"Have we any evidence that healthcare workers are availing of opportunities to encourage cessation as part of consultations ?P 22"*

This issue was not examined as part of the HTA and the report does not state to what extent this advice is being given to smokers when opportunities arise. Instead, Healthy Ireland survey data was used to estimate the proportion of people receiving different types of support in their quit attempt. However, the HSE policy of providing brief intervention training and advocating that this should be used during any interaction with smokers is described in Section 7.2.1.1.

*"Smoking cessation and its management is cyclical, with patients attempting several times to quit smoking; this strategy should be factored into any recommendations."*

This HTA examined smoking cessation from a population perspective in order to guide national policy-making aimed at decreasing smoking prevalence in Ireland. As such it concentrates on the potential for improving the overall uptake of the more effective interventions across the entire cohort of smokers, the likely effects of this on the number of people quitting successfully, and the long-term effects this will have on the prevalence of smoking related illness. The results of the trials that were carried out in similar populations can be used to inform this analysis, as participants in these trials were all drawn from a general population of smokers, each of whom had their own quitting history that may have involved many failed attempts using a variety of interventions in the past. Therefore, it is reasonable to apply the same average effect to a similar population in Ireland. However, estimating the likelihood of success for an individual smoker, taking account of their smoking history, quitting history, and the range of other factors that influence quitting and motivation to quit, is a far more difficult task and one that we did not attempt to complete. While this submission highlights a very salient point in relation to the experiences of individual smokers, this analysis adopted a wider perspective and used the corresponding data to compare overall average changes in the number of smokers in the different comparators used in the model.

*"I am not sure why HIQA are reviewing this when all the evidence is well established in relation to the efficacy of smoking cessation medications and interventions? Monies would be better spent investing in smoking cessation services which are lacking in a number of counties."*

While many studies have examined the effect of individual smoking cessation interventions, this HTA is the first study to examine the clinical and cost-effectiveness of changing the mix of interventions provided at national level compared to the existing standard of care. As such, it provides valuable new information to policy-makers in Ireland seeking to lower the prevalence of smoking. The HTA is also the first to examine the cost-effectiveness of e-cigarettes. Given the number of people that smoke in Ireland, and the high costs of treating smoking-related illness, even small improvements in the provision of services are likely to have a significant beneficial impact. In addition, it is also important to ascertain whether the programmes that currently receive funding are providing value for money compared to other potential services that could be offered should resources be reallocated. The HTA shows that smoking cessation interventions are highly cost-effective, while also providing additional information on the specific interventions that should be prioritised on the basis of their clinical and cost-effectiveness.

*"The concern is with the detail of the questions for the tobacco section and the response set in show cards and the survey as a cross-sectional design was one at a single point in time i.e. Q12 - Possibility of bias is considerably high as some elements of QUIT were listed- however the 1:1 support of clinic and groups were omitted from the list. Dual or combination treatments of licensed medications alone or in combination of behavioural support were omitted, regardless of intensity or location of intervention."*

The HTA recognises the limitations of the Healthy Ireland survey in relation to smoking and quitting behaviours, which is just one aspect of the survey, and therefore cannot go into as much detail on this specific topic as one might like for the purposes of this HTA. This comment has been forwarded to the Department of Health for consideration.

*"Terms of reference cite the general population; though no analysis of smoking cessation interventions in secondary acute hospital service was completed. Over half of the full time smoking cessation practitioners are Clinical Nurse Specialists employed within these settings. This would be of great value, especially as evidence document is to inform a clinical guideline for smoking cessation interventions in the general population, secondary*

*mental health and pregnant women- all are represented and referred to my nurse-led acute hospital smoking cessation service."*

Due to the scope of this HTA, as well as the time and resource constraints, certain intervention and subgroups of the overall population were prioritised. The settings and subgroups selected were informed by input from the Expert Advisory Group (which comprised a broad range of stakeholders) and in the context of the decision that the HTA is intended to inform. The scope of the clinical guidelines will not necessarily be the same as that of the HTA, and could include general secondary care services if deemed appropriate.

*"Levels of Smoking Cessation Interventions within the Intensive or dedicated Smoking Cessation Service were omitted from the analysis- as we do not use one intervention alone- multi-component treatments are provided. In my own service I provide eight levels of treatment which includes tailored to quit plans, prescription and withdrawal therapy. In a cost effective analysis of such service provision- only dedicated hours used in delivering cessation services should be used- with many of our current practitioners this may equate to 20 - 80% of their current WTE and such full salary should not be considered the cost for cessation interventions nationally."*

When estimating the cost of behavioural support, only the time spent on providing smoking cessation services to individuals motivated to make a quit attempt was included in the economic evaluation. It was recognised that smoking cessation practitioners provide a range of other clinically and economically valuable services, including promoting quit attempts and reducing initiation rates. As such, if total salary costs were included, rather than the cost of the time spent delivering smoking cessation interventions, this would overestimate the economic cost of this aspect of the service.

*"Following consultation of the HTA on smoking cessation interventions, there were some corrections noted by Primary Care Reimbursement Service (PCRS) as follows;*

*d. Page 33: Section 2.1.1.1: 'While all NRT products available in Ireland are now available without a prescription, to be reimbursed through the PCRS they must be prescribed by a doctor or nurse prescriber who is registered with the PCRS'. Doctors and nurse prescribers are not registered with the PCRS. They hold a contractor agreement with the HSE in order to prescribe for medical card holders on GMS prescription forms. NRT were always available without a prescription (over the counter products)*

*through the pharmacy, the only recent change was the deregulation of certain NRT items from Pharmacy only medications to General Sales List."*

As a result of this feedback, this inaccuracy has been addressed in the HTA report (Section 2.1.1.1).

*e. "Beyond Ireland, only the UK fully fund NRT in Europe'. Ireland partially funds NRT for those patients with medical card eligibility under the GMS scheme. NRT is not fully funded."*

As a result of this feedback, this inaccuracy has been addressed in the HTA report (Section 2.1.1.1).

*f. "Page 238: Section 6.2.9: This section implies that a patient can obtain up to three months' supply of medication which is not the case. 'For those with a Medical Card, up to three months' supply of medication may be prescribed at a time (and dispensed in monthly aliquots)' NRT cannot be written on a duplicate (3 monthly) GMS prescription form. For those with a Medical Card, NRT must be prescribed on a single monthly GMS form. One month supply is obtained each time. Patients are not limited to a maximum duration of therapy."*

As result of this feedback, this inaccuracy has been addressed in the HTA report (Section 6.2.9). Limitations on the prescribing of NRT also have implications for the economic analysis, as we had assumed that a quit attempt involving NRT would necessitate one GP visit by medical card holders for it to be reimbursed through the Primary Care Reimbursement Service (PCRS). Combining the prescribing rules outlined in the above comment with PCRS data on the mean duration of quit attempts involving NRT (51 days), means that the average smoker with a medical card will require two GP visits, rather than one. The cost of quit attempts involving NRT was adjusted to reflect this in the economic analysis, and discussion of the effect of these differences in funding for NRT compared with other smoking cessation interventions has been added to the section on organisational issues (Section 7.2.1.1).

*g. "Note: 2012 PCRS annual report figures used in this section (6.2.9). 2015 PCRS annual report figures are available from [www.pcrs.ie](http://www.pcrs.ie)> PCRS Publications> PCRS, Financial and Statistical Analysis."*

The 2012 data was used to estimate the average cost of a GP visit as part of a calculation that was carried out for a previous analysis by HIQA. This calculation has been updated using the most recent data available, which is described in detail in an appendix that has been added to the report (Appendix 12). The economic analysis

results have also been updated to reflect the change in this parameter. The more recent PCRS data was also used where required to calculate the other parameters in the analysis.

*"I note that there was no Mental Health Divisional representation on the EAG?"*

While it is not possible to invite representatives from all individual groups, HIQA does endeavour to enlist the expertise of at least one member from each of the areas that are potentially relevant to a given HTA project. Given that smoking cessation is but one aspect of the overall provision of mental health services, a nominee from Faculty of Addiction Psychiatry, College of Psychiatrists of Ireland was requested. The public consultation afforded HIQA the opportunity to directly contact other relevant groups, such as the Health Service Executive (HSE) Mental Health Division, to request involvement and input into the assessment process.

*"Section 3.4.5 (p75) states that 29% of quit attempts are supported through e-cigarette usage. Elsewhere it is reported that e-cigarette use is 26% (p280). It is unclear where this statistic comes from and whether it refers to the % of the population who have ever tried e-cigarettes or whether this refers to regular usage."*

The 26% refers to those for whom e-cigarettes are the only intervention used to support their quit attempt, while the 29% includes those who used e-cigarettes in combination with any other pharmacological or behavioural support. This data was taken from the 2015 Healthy Ireland survey. This point has been clarified in the Executive Summary, Section 3.6 and Section 8.1.

*"The section on the effects of second-hand smoking on children is much smaller than in many similar documents. "For children, exposure to second-hand smoke increases the risk of sudden infant death syndrome, acute respiratory infections, ear problems and more severe asthma. Furthermore, exposure to second-hand smoke slows lung growth" (page 54 of the draft HTA document). There are large sections on pregnancy and mental health and similar emphasis on children would have been welcome. Second-hand smoking is a major cause of morbidity in children and the effect of this can be a useful stimulus for tobacco cessation in parents."*

The scope of the HTA was limited to evaluating the clinical and cost-effectiveness of smoking cessation services targeted at adult smokers. As such, the cost-effectiveness analysis only modelled changes in the prevalence of four smoking-related illnesses in adult smokers (stroke, chronic obstructive pulmonary disease

[COPD], ischaemic heart disease [IHD] and lung cancer). The analysis therefore presents a conservative estimate of the overall utility gain at a societal level from increasing smoking quit rates.

*"As far as I can see there are no Irish data used in this? Our own paper below and the annual reports from HSE lead me to believe that your assumptions are unreliable in general for Ireland. However when we come to Ecigs we suggest the results from 2 fairly inconclusive RCT should not be used to make national recommendations. It may be said that the report does not make recommendations but your misleading press release and the failure to correct it in subsequent interviews suggest that you are offering the report as a way forward including a role for Ecigs and this does not seem appropriate at present."*

In the absence of any Irish randomised controlled trials evaluating the effectiveness of e-cigarettes as a smoking cessation intervention, the HTA used international data, synthesising it using the same approach and statistical methods that are used for all the other smoking cessation interventions included in the analysis. In recognition of the fact that at the time of completion of this report only two published RCTs are available, and that there are important limitations associated with them, it was concluded that there is insufficient evidence at present to recommend the use of e-cigarettes as a smoking cessation method. This HTA made every effort to report these findings in a neutral, unbiased and adequately nuanced manner that clearly presents the results of the empirical analysis in the report itself, and in any engagement with the media as part of the public consultation.

*"Your costings seem to suggest that Ecigs will be used for 3 months as might occur in an RCT. There is no evidence that when Ecigs are used ad libitum that they will only be used for only 3 months. So I cannot understand how a decision to assume 3 months usage was made or agreed. As far as I know even in UK the duration of usage in their 'real world' estimates no such assumption is made? Your costs are therefore unreliable and may be misleading."*

The decision to use a three-month usage of e-cigarettes was considered at length when designing the analysis. A distinction was imposed on the use of e-cigarettes as a smoking cessation method and the use of e-cigarettes as a harm reduction measure by the complete substitution of combustible tobacco with e-cigarettes (see Section 3.1.7 of this report). As for all other smoking cessation interventions included in the HTA, the duration of the treatment course was informed by the randomised controlled trials identified in the systematic review of the literature. Two



randomised controlled trials in relation to e-cigarettes were identified for inclusion, both of which provided a 12-week treatment course of e-cigarettes as a smoking cessation intervention. Those who successfully quit smoking, but continued to use e-cigarettes afterwards were considered to have chosen to become e-cigarette users rather than being considered as smokers engaged in a long-term quit attempt. In this regard, the HTA treated e-cigarettes the same way as NRT, as a proportion of smokers who use NRT will also continue to use in the long term, however; only the cost of a standard course of treatment was included in the analysis.

*"You neither know the effectiveness nor the cost of Ecigs in an Irish Smoking Cessation setting, casting doubt on your results which needs to be made clear in summaries and press releases. Did you not consider that maybe the reason that there were no similar analysis of Ecigs cost-effectiveness to yours was that there are inadequate data available on which to base such an analysis? You risk causing severe damage to the smoking cessation service if action were to be taken on the basis of this estimate."*

The sharp rise in the popularity of e-cigarettes as a smoking cessation aid among Irish smokers highlights the need for a rigorous, objective analysis of the scientific evidence for the clinical and cost-effectiveness of this intervention. While there is no guarantee that one will arrive at unambiguous conclusions, it at least provides a clear picture of what the best available evidence shows, and where the most important gaps in knowledge lie. The effectiveness estimates in this instance were based on two randomised controlled trials identified in the systematic review of the literature and which met the pre-defined criteria. The costs were informed by e-cigarette products currently on sale in Ireland. Taking into account the overall results of the analysis, the HTA adopted a conservative approach to e-cigarettes, advising that decision-makers await the results of ongoing trials before recommending the use of this intervention.

The estimate of the opportunity cost of a GP consultation for smokers with a medical card was discussed in one submission, which raised a number of concerns about the data used to calculate this parameter. This related primarily to the estimate of the average number of GP visits that medical card holders require annually, and also the total expenditure by the public health system to provide these services;

*'This costing is in part based on estimates of general practice visits per patient provided in the Living in Ireland Survey, a survey series which concluded in 2001. The survey relied on retrospective reporting by survey respondents, who were asked to recall how many visits to general practice they had undertaken during the past 12 months. This method of*



*estimation has been criticised due to its potential for memory error, which cannot easily be mitigated or controlled for (Short et al., 2009; Wolinsky et al., 2007). The most recent Living in Ireland Survey estimated that General Medical Services (GMS) scheme patients visit their general practitioner 5.3 times annually, on average. However, a more recent examination of visitation rates in Irish general practice, based on actual practice records rather than patients recall over the past twelve months, concluded that GMS patients visit their general practitioner approximately 7.7 times annually, on average (Behan et al., 2013).'*

*'The figure of €483.14m in Primary Care Reimbursement Service (PCRS) payments made to general practitioners in 2012 encompasses payments across a spectrum of practice areas. This total payment to general practitioners includes out-of-hours payments, payments for special items of service, practice supports for various staff, contributions to indemnity insurance, and other miscellaneous payments, in addition to ordinary capitation payments for the care of GMS patients'*

In addition, it was highlighted that provision of smoking cessation services is not explicitly included in the current GMS contract;

*'...while consultations in general practice may discuss patients' lifestyle habits and their contribution to patients' health, there currently exists no agreement for general practitioners to provide targeted smoking cessation interventions or services under the GMS contract.'*

The part of the report detailing the current configuration of services has been updated to state that the provision of smoking cessation services is not currently included in the GMS contract (Section 7.2.1.1 of the HTA report).

The issue of the calculation of the average cost of a GP consultation for those with a medical card was considered in detail, and this estimate was recalculated using the most recent data available. This analysis has been described in detail in an additional appendix (Appendix 12). The economic analysis has been updated to reflect the changes to this parameter which resulted in no substantive change to the outcomes of the analysis.

#### **4. Summary of changes to the HTA of smoking cessation interventions**

The following is a list of changes made to the final report following the public consultation:

- Results of the first study examining the safety of long-term e-cigarettes use, which was published during the consultation period, has been added to the chapter on safety (Section 5.3.6).
- The results of an existing Irish study on e-cigarette use in children have been added to Section 5.3.13.
- Discussion of the potential for increased regulation to lead to a rise in the cost of e-cigarettes has been added to the economic analysis chapter (Section 6.4).
- Discussion of the potential beneficial effect of increased nurse prescribing has been added to the chapter on organisational implications (Section 7.2.1.1).
- The description of the smoking ban has been amended in Section 7.2.2.3.
- The clinical effectiveness chapter has been updated to specify that all studies of varenicline in combination with NRT involved NRT patches (Section 4.2.9).
- The possible mechanism of action for the combination of NRT and varenicline proposed in the literature has been described in Section 4.2.5.
- The regulatory status of combination therapy with NRT and varenicline has been clarified in Section 7.2.1.2.
- Statements in relation to the moral status of smoking and ethical issues about the provision of information on the long-term effects of vaping have been qualified in Section 7.1.2.1.
- Inaccuracies in the description of how NRT is funded in the public health system have been addressed in Section 2.1.1.1. This led to an increase in the average cost of quit attempts involving NRT, which required the cost-effectiveness analysis to be re-run (Section 6.3). Additional information has been added to the organisational implications (Section 7.2.1.1) to discuss the impact these differences in funding have on the cost-effectiveness of NRT.
- The cost of a GP consultation has been recalculated using the most recent data available and the economic analysis has been updated to reflect the changes to this parameter. Appendix 12 has been added to the report, which describes the methods used to calculate this cost.
- After consultation with the Expert Advisory Group, the sensitivity analysis in Section 6.2.2 was changed to only examine the cost-effectiveness of interventions for the cohort of people for whom varenicline is not a viable option, both when e-cigarettes are included and excluded. Additional scenario analysis has been added to the budget impact analysis (Section 6.4) at the request of the Expert Advisory Group.

- A brief summary of ongoing trials involving e-cigarettes has been added in Section 4.2.9. A summary of ongoing trials for smokers receiving care from secondary mental health services has been added in Section 4.3.5.
- The conclusion of the report has been amended to remove references to combination varenicline and bupropion being among the treatments that the health system should seek to maximise, given that it is strictly dominated by varenicline and NRT (Section 8.3 and where necessary throughout the report).
- The advice to the Minister for Health arising from the HTA has been added as a separate section at the beginning of the report.
- A plain language summary has been added after the executive summary.

## 5. Comments received

#	Name	Capacity	Comments
1	Person #1	Personal	In relation to electronic cigs, it appears that there were 2 studies included and both referred to first generation e-cigs. For the most part patients will have no concept of what the term `first generation' means. I'm wondering if it is possible for the exact brand(s) of e-cig that were studied to be mentioned in the appendix? This might give us an idea as to whether this is a brand that can be purchased in Ireland?
2	Person #2	Personal	Smokers should not be led to believe that e-cigarettes are any less dangerous than standard cigarettes. E-cigarettes are also as dangerous to those around them as it is for the smoker. The vapour is no less harmful which contains nicotine than it would be with a standard cigarette. They are designed to give people their nicotine fix and it is as simple as that. They are extremely fashionable for young people who want to take up the habit and even come with all kinds of flavours and aromas to make them very popular. To many young teenagers they are cool and hip and can be easily smoked in places where they are banned with a good chance of getting away it. This is already the case and one can see breaches of smoking legislation with e-cigarettes. The e-cigarette are a dream come through for the tobacco industry who have a device that is very convenient for smokers. The tobacco industry can also save itself a fortune in packaging, who now only have to deliver their controversial product in the shape of small phials of liquid. Far from stopping or reducing people's smoking habit or making it safer, e-cigarettes will be more popular than ever. They could also be abused or adapted by people wishing to replace nicotine phials of liquid with banned substances and inhale their vapour. The can act like a very small pot pipes. Much larger glass versions appear in some head shops. E-cigarettes are not a step forward, there is just not so much smoke with them — the benefits end there. All nicotine products carry serious health risks, whether they be gums, sprays, patches. E-cigarettes are a no lesser evil when it comes to a cancer causing products.
3	Person #3	Personal	The HTA Assessment of Smoking Cessation Interventions is a valuable resource but I was disappointed that the Document did not report on the local intensive Smoking Cessation Services that are available in Ireland and also to report in more detail the lack of services provided in General and Maternity Hospitals. Most of the patients referred to our Service have chronic diseases with co-morbidities and require intensive one to one support to help them quit smoking. We have a Database with our patients records and their on going follow up support recorded daily so this work can be measured. A lot of time has been spent by Smoking Cessation Officers rolling out the Smoke Free Campus Initiative over the past number of years and delivering Brief Interventions Training in tandem with supporting patients, staff and colleagues to quit smoking. There has been no extra Staff appointed to help with this increased workload, we have the same number of Smoking Cessation Officers in place now as we had delivering the Service in 2002. If we hope to achieve less than 5% Smoking prevalence by 2025 we need to start by addressing the shortage of Smoking Cessation Officers delivering the Service in the Community and Hospital Settings. The Maternity, Mental Health and University Hospitals require on site full time Smoking Cessation Officers. We are only offering a token service for a few hours a week at present with no support available in some General and Maternity Hospitals.

	<p>I would also have liked an assessment made to compare the Service provided by the National Quitline www. QUIT.ie and the local Smoking Cessation Service where provided and the profile of the patients that are supported to quit by each of these quit services and the outcomes and cost effectiveness. All Hospital Managers, GPs, Consultants and NCHD's require Training and support regarding the Smoke Free Campus Initiative and Pharmacotherapy to support their patients to reduce and quit smoking. This training and support is fundamental and the first basic step needed if we hope to reach our targets by 2025. Some Medical Staff are unaware of changes and targets in relation to Smoke Free Campus and Smoking Cessation guidelines which makes the work of the local Smoking Cessation Officer unduly difficult and challenging.</p> <p>I have never seen a patient in the past 16 years prescribed both NRT and Varenicline by any Medical Doctor. I find it challenging at times to get combination NRT prescribed to help chronic smokers to quit. Despite the evidence I don't think patients need both NRT and Varenicline to help them quit smoking. I feel that taking one form of Pharmacotherapy correctly as prescribed at the appropriate time is challenging for many patients therefore asking them to take two will not be cost saving. Patients will also find it difficult to differentiate which treatment is the cause of their side effects if and when they should arise. There is very little evidence to support both NRT and Varenicline compared to giving a patient behavioral support and Combination NRT.</p> <p>There was no reference made to the age, medical profile and quitting history of those who use E cigarettes to quit smoking. From my experience older patients and those with co-morbidities need more intensive one to one support to make a quit attempt with Pharmacotherapy. While some patients may quit with e cigarettes they may also be using some NRT either at the same time or have used it during a previous quit attempt. They may also be getting behavioural support as well as using the ecig to quit. Patients also tend to use ecigs even though they may have a Medical Card because ecigs are more easily accessed without the need to visit a GP, get a prescription and go to a Pharmacy. Further questioning and clarification on this topic needs to be explored to get more up to date and accurate data.</p>
<p>4 Action on Smoking and Health (UK)</p>	<p>Organisation See Appendix 1.</p>
<p>5 Philip Morris Ltd</p>	<p>Organisation Please find attached Philip Morris Ltd's response to the consultation on HTA Smoking Cessation Interventions.</p> <p>I thought I would also take the opportunity to share a link to our new website which sets out our company's goal to design a smoke free future. I also enclose an interview on this issue with our Chief Executive Officer, André Calantzopoulos, which was published in The Sunday Times last October which I trust is of interest.</p> <p>I hope that our submission is of helpful to the work that HIQA is doing in the area of harm reduction. Philip Morris Ltd would be delighted to meet with HIQA to discuss any aspects of our submission in more detail.</p>

			See Appendix 2.
6	Person #4	Personal	Section regarding motivational interviewing and brief interventions. I believe the carbon monoxide breath test monitor [Smokerlyzer] tool should be used in conjunction with brief interventions and motivational interviewing by more health care professionals in their practice. e.g General practitioners, consultants, practice nurses, physiotherapists, community nurses, public health nurses, occupational therapists, wellness coaches and many more. I believe it is a highly useful aid/tool in smoking education and behavioural health. It is a visual aid which may encourage clients to quit and helps to measure their progress.
7	Irish Medical Organisation	Organisation	See Appendix 3.
8	Perrigo PLC	Organisation	<p>We support the comments provided by IPHA on behalf of the healthcare industry.</p> <p>In addition we would like to make the following comments:</p> <p>The document makes reference to Nicotine Replacement Therapies in section 2.1.1.1. This section is intended to provide an overview of the available technologies on the market. However, it makes no reference to the different types of technologies and benefits of certain technologies on the market within the NRT category. The diversity of technologies available within the NRT category is pertinent when considering available treatments for patients and consumers attempting to quit.</p> <p>Chefaro Ireland DAC, a division of Perrigo, holds a licence for an NRT patch with patented superior technology to the rest of the market - NiQuitin patch. The specially formulated smart control technology facilitates deliver of nicotine at first dose faster than other patches. NiQuitin patches have a distinct pharmacokinetic profile due to Smart Control Technology, in which the adhesive contains a rapidly-delivered loading dose of nicotine and a separate reservoir delivers an ongoing, steady stream of nicotine. This is inherently important when accounting for the fact that compliance with NRT products can be a problem for people when they first try to quit smoking. in such an instance quitters need to receive the nicotine fast in order to relieve cravings. Data is held on file in support of this.</p>
9	Irish Vape Vendors Association	Organisation	See Appendix 4.

10	HSE Smoking Cessation Practitioners Forum	Organisation	<p>General feedback and observations Some Practitioners felt that observational studies and their recommendations should have been included in literature review.</p> <p>Report makes comparisons between delivery of smoking cessation services in UK and Ireland, but the reality is that services are delivered very differently in both countries. We have large gaps in availability of one to one services in Ireland and Practitioners here are unable to prescribe smoking cessation aids to clients. This increases barriers to compliance with treatments for clients.</p> <p>The Healthy Ireland survey questions were felt by some Practitioners to be incomplete in terms of local services being referenced and also that use of generic versus trade names for treatments may cause confusion. It was noted by others that this issue may be clarified by those administering the survey.</p> <p>In the experience of Practitioners, unassisted quitters are very different from smokers who are actively looking for help to quit as these people may have experienced many failed quit attempts/may have co-morbidities/ may be under pressure from Healthcare Practitioners and family members to quit for health reasons.</p> <p>Practitioners would like to advocate for inclusion of NRT on DPS scheme to reduce cost to smokers and increase their chances of quitting.</p> <p>In the experience of Practitioners, medical staff are sometimes reluctant to prescribe licensed smoking cessation aids (dual NRT therapy, and occasionally monotherapy) to smokers who are looking for help to quit. If recommendation of dual therapy (NRT and Varenicline) is accepted, then training for prescribers will be necessary.</p> <p>There is some concern about prescribing dual therapy, as Practitioners find that many clients experience difficulty in complying with one treatment.</p> <p>Reference Individual Counselling and Intensive Advice on page 123, do you have a definition of these supports for the report?</p> <p>Mental Health feedback and observations There is a clear need to embed smoking cessation support for service users in Mental Health settings, provided routinely by Mental Healthcare Providers. This should include group support and provision and monitoring of smoking cessation treatments.</p> <p>Practitioners wondered about the use of e-cigarettes as a harm reduction method for vulnerable clients who may never realise their desire to quit completely.</p>
----	---	--------------	---



	<p>Maternity feedback and observations Practitioners would like to advocate for routing carbon monoxide testing to be done at first antenatal visit for all pregnant women in an effort to identify pregnant smokers and offer support to quit, bearing in mind that many pregnant women are reluctant to disclose the fact that they smoke.</p> <p>There is a clear need to embed smoking cessation support in routine antenatal care provided in acute and primary care services.</p> <p>Practitioners experience difficulty in getting intermittent NRT prescribed for pregnant smokers who have tried to quit using behavioural support alone and failed, but who are keen to get further support if appropriate.</p> <p>E-cigarette feedback and observations Practitioners are observing a lot of confusion about e-cigarette use, and in the absence of regulation of the products are finding it difficult to offer clear advice on their use. This confusion arises as a result of the following; multiple brands and generations available/is one product "safer" than another one/ should they be used as harm reduction or smoking cessation aids.</p> <p>Concerns raised about possibility of gateway effect with e- cigarette use.</p> <p>They are used by some smokers as a cost effective means of trying to quit compared to other smoking cessation aids.</p> <p>There are increasing numbers of e-cigarette users attending one to one services looking for support to quit their use.</p> <p>There is currently no mechanism to capture adverse events reported by users as they are not licensed as a medicine.</p> <p>There is concern that most e-cigarette users will never make contact with smoking cessation services and therefore will not get optimal support to quit.</p>
<p>11 Health Promotion Dept, HSE Organisation</p>	<p>General Feedback Within the Health and Wellbeing Division of the HSE, the Clinical Programmes Team, is developing a Health Behaviour Change Framework and Implementation Plan for Health Professionals in the Irish Health Service, this document is called Making Every Contact Count. The framework sets out how interventions to support lifestyle behaviour change need to be integrated into our health service. Health care professionals are being asked to make each routine contact that they have with patients count in terms of chronic disease prevention.</p> <p>The aim of Making Every Contact Count is chronic disease prevention. It is about enabling health care professionals to recognise the role and opportunities that they have through their daily interactions with patients in supporting them to make health behaviour changes.</p>

The health behaviours which are the focus of attention at the outset are the four main lifestyle risk factors for chronic disease; tobacco use; physical inactivity; harmful alcohol consumption and unhealthy eating. It will require that all clinicians, frontline staff and leadership teams respond to their responsibility in implementing Making Every Contact Count for improved health outcomes for all.

Within the framework there is a model for Making Every Contact Count. This is presented as a pyramid with different levels. Each level represents an intervention of increasing intensity with the low intensity interventions at the bottom of the pyramid and the specialised services at the top. Implementing the Making Every Contact Count approach seeks to begin the process at the basic level of brief advice and brief intervention. In practice this will mean that all health professionals and healthcare assistants will be trained to a level that enables them to conduct a brief intervention with their patients when appropriate. It is hoped to launch and distribute this framework document in the coming weeks.

A key part of this framework is on the training of all health professionals in the area of brief interventions, so we welcome the support which the HIQA HTA on Smoking Cessation Interventions makes to behavioural interventions such as brief advice and brief interventions. We would have liked if this support was more robust in the report. The framework document also sets out a clear and agreed definition for behavioural change interventions, the inconsistency in defining these terms is something that is referred to a number of times in the report.

12	Irish Pharmaceutical Healthcare Association (IPHA)	Organisation	See Appendix 5.
13	Policy Group on Tobacco of the Royal College of Physicians of Ireland	Organisation	See Appendix 6.

14	HSE Tobacco Free Ireland Programme	Organisation	<p><b>General Comments</b></p> <p>Overall, the HSE Tobacco Free Ireland Programme welcomes this draft report on HIQA's health technology assessment of smoking cessation intervention. Smoking is a leading cause of preventable morbidity and mortality in Ireland, and a significant cause of costs facing the HSE. Tackling tobacco use is a priority for the HSE, and this is reflected in its corporate plan, annual service plan and the programme plan for the HSE Tobacco Free Ireland Programme. We recognise the need to strengthen and scale up smoking cessation services in Ireland if the policy goal of Tobacco Free Ireland is to be achieved. The HSE will play its role, and looks forward to translating the advice in this report into clinical practice guidelines under the auspices of the National Clinical Effectiveness Committee.</p> <p>However, for effective smoking cessation services to reach their potential in positively impacting health, the HSE offers some comments for consideration by HIQA as it develops final recommendations for the Minister in relation to how the numbers of quitters accessing supports can be grown and how barriers might be addressed.</p> <p><b>Specific Comments</b></p> <p>1 - Recognition of the need to grow number of quitters accessing support</p> <p>On page 69 there is reference to the methods used for cessation. During the drafting of the document there was a discussion re the types of aids used by smokers. A pie chart graph, based on Healthy Ireland Survey data, was presented indicating that the majority of smokers try to quit unaided, about a quarter tried e cigarettes and a very low percentage used quitlines, a qualified counsellor, Varenicline, Bupropion or NRT. These data indicate that the increasing the impact of smoking cessation supports requires growth in the proportion of quitters who access support as well as use of effective supports. This is important context and we would suggest that a paragraph and chart representing same be included in the final report. The main findings of the report indicate that we increase the number of smokers accessing evidence based medications such as combination varenicline and NRT however there is limited discussion on how to get more smokers engaged with any kind of health professional where they can be delivered a Brief Intervention and ideally be directed to the treatment which is likely to have the most positive outcome. If the majority of smokers choose to quit unaided our ability to impact on the percentage who access any kind of support and ultimately improve success rates is limited. While recognising the scope of the health technology assessment, final recommendations from this report should include a strong focus on the importance of a full and comprehensive tobacco control framework including more detailed discussion and recommendation around making every contact count (MECC), the role of brief intervention and referral to more intensive behavioural and pharmacological support.</p> <p>Mass media is especially important since we need to both grow the number of those with intention to quit, but as highlighted in HI Survey, we need to grow the proportion who are translating these intentions into successful quits by using effective services and interventions. The numbers currently using the more effective interventions are currently very small and that represents a significant challenge. Again, acknowledging the scope of the health technology</p>
----	------------------------------------	--------------	--

assessment, in that context it would be helpful if one of the final recommendations considered the need to at least maintain the current campaign spend and ideally an increase in same. This point was raised at our last EAG by Dr. Paul Kavanagh.

In summary, it is welcome that the report identifies effective and cost effective smoking cessation supports in the Irish context. Recommendations should consider how the population impact of effective smoking cessation supports can be maximized through growing the numbers of quitters who access support as well as ensuring that the supports offered are effective.

2 - Organisational issues to address barriers to accessing effective smoking cessation supports.

Both the chapters on economic evaluation and organisational implications discuss briefly the incentives/barriers to accessing effective pharmacological interventions. There is a discussion on access i.e. access to a smoking cessation counsellor is free, medical card holders can avail of free GP visits and pharmacological support, which is important in addressing inequalities however the analysis has taken a quasi-societal perspective so it does not distinguish between costs to the HSE and out of pocket expenses for those without medical cards. As the report recommends maximum uptake of Varenicline and NRT - which for many smokers will mean out of pocket expense - it would be useful if some additional commentary and analysis on the cost effectiveness and budget impact were provided which may helpfully inform policy initiatives such as providing free access to pharmacological supports for all smokers (the majority of whom we know are in lower SEGs however may not have access to a medical card).

For example, consideration should be given to a recommendation to address barriers to accessing pharmacotherapies [including GP visit costs and drug costs] through a chronic disease care scheme perhaps as part of the new GP contract; in addition, consideration should be given to recommendation of nurse prescribing for cessation pharmacotherapies for all clinical nurse specialists (Cardiac, respiratory, diabetic nurse specialists etc) as well as face to face counsellor services providing access to medications which are currently licensed for over the counter use which would greatly reduce barriers to access.

In summary, in concluding its report and making recommendations to the Minister for Health, HIQA should consider how the evidence of its HTA can inform policy regarding organisational issues which may better address barriers to accessing effective smoking cessation supports. The basis for this feedback is as per the point above, i.e. a need to consider how the population impact of effective smoking cessation supports can be maximized through growing the numbers of quitters who access support as well as ensuring that the supports offered are effective.

3 - Some minor points here in relation to text changes

Pg 71 reference to "exemption" - suggest a slight correction to a paragraph which is not technically accurate in its current form.

Suggested revision of text to:

In the Irish context the Workplace legislation banning smoking in indoor workplaces came into effect in 2010. Irish stand-alone psychiatric hospitals (i.e. hospitals which were not attached to an acute site) had an exemption in the legislation at that time, however the HSE Tobacco Free Campus Policy endorsed by senior management in 2012 sets

			<p>out a policy for the organisation which goes above and beyond the minimum requirements set out within this legislation. The organisational policy requires all HSE sites and services whether owned leased or funded by the HSE to implement a Tobacco Free Campus Policy prohibiting smoking in all indoor areas and outdoor campus grounds thereby providing a supportive environment for cessation. Aside from providing a supportive environment, one of the key purposes of the policy is to treat tobacco addiction as a healthcare issue. Enacting the Tobacco Free Campus policy in a phased way across all sites and services was a key action of the Tobacco Control Framework 2010.</p>
15	Irish Thoracic Society	Organisation	<p>The Irish Thoracic Society wishes to strongly commend HIQA and the Expert Advisory Group for their work in the health technology assessment on smoking cessation interventions. It is a very comprehensive, robust and valuable piece of work. We support the report's recommendations and hope that the resources required to implement these in a manner that provides equitable access to all who need these services are put in place. We also hope that the considerable work that has been undertaken in this report can be sustained and built upon through continued surveillance of this area.</p> <p>As respiratory healthcare professionals we wish to make a general comment around the importance of brief interventions and the role that healthcare professionals can play in prompting and supporting patients in the cessation of smoking. We believe that training and practice of brief interventions should be mandatory throughout the health service and a fundamental part of all training curriculums.</p>
16	Cork University Hospital Smoke Free Campus Implementation Group	Organisation	<p>On behalf of the CUH Smoke Free Campus Implementation Group, we welcome this most comprehensive HTA of Smoking Cessation Interventions. We strongly feel that it will provide an evidence based approach for practitioners and healthcare professionals on the effectiveness of smoking cessation interventions for the future. If certain medications are proposed, by this HTA, as preferred combined therapy options for smokers who wish to quit, then such products should be funded by the GMS and the Drugs Refund Scheme. In relation to electronic cigarettes, it is very helpful that this HTA has provided some clarity around their use, but we look forward to your further clarification on same in the future.</p> <p>We find in CUH that the Smoking Cessation Service is a positive one, which is working very well. It is important that this service is valued, as it does achieve measurable results. In expanding Smoking Cessation Services nationally, we could pro-actively address smoking practices in a far greater and effective manner, given that the average length of stay for smokers in CUH is approximately one day longer than for non-smokers.</p>

17	Person #5	Personal	<p>I would like to thank you for producing a document that isn't full of fallacies to begin with. I've marked that my reply is both personal and as part of an organization, I'm a member of a few vaping forums and feel I can comment for all the other members as our stories are all the same. We are all ex-smokers that have managed to quit solely with the aid of vaping and we are all concerned about the amount of misinformation constantly in the media about vaping. I personally smoked 5*12.5 gram packets of tobacco a week and stopped completely after only two weeks of vaping and I have never had so much as a craving to go back, this was in May last year. I got a family member, who is 70 and a lifelong smoker, a starter kit and she is now smoke free for five weeks, also suffering no cravings. I've experienced absolutely no adverse effects from vaping at all and I feel healthy and I'm never out of breath anymore. We all tried patches, gum and other nicotine replacement therapies, as well as going cold turkey and none of them worked. There are millions of people who can attest to the fact that vaping simple works where those other methods do not. Of some reports that suggest vaping can lead to smoking in later life and that it glamorizes smoking, I would ask the authors to take a minute and check youtube reviewers of vape gear or any vape forum and see for themselves just how anti-smoking our community is. This has been a lifeline to all of us and by ignoring it and by spreading misinformation, governments are putting tax intakes ahead of public health. Reports such as that of the Royal College of Physicians, which concluded that vaping is 95% safer than smoking never get the same coverage as the headline grabbing shock factor stories that do get reported, and which are littered with untruths. I apologise for being so late with this as there is so much more I'd like to add. The laws around vaping are about to change in May and they will have a serious negative effect for all of us that have relied of vaping to stay smoke free and healthier, as the cost will spiral as a result of the changes. I've written to 8 sitting TD's about this issue, including the Minister for Health, and I haven't received a single reply. This may be one of the last chances for something to be done about these regressive and draconian laws. Please feel free to call or email me about this. I've already spoken to someone in your main office, who kindly pointed me to this form. I sincerely hope someone has the time to contact me. Thank you for taking the time to read this.</p>
18	Mouth Head & Neck Cancer Awareness Ireland	Organisation	<p>We are making this submission on behalf of Mouth Head and Neck Cancer Awareness Ireland: (MHNCAI) is a voluntary, unfunded, community focused group which was founded in 2009. Its members are: MHN Cancer Survivors, Dublin Dental University Hospital, Cork University Dental School and Hospital, Irish Cancer Society, Dental Health Foundation, Irish Dental Association, Members of Regional HNC Multidisciplinary Teams.</p> <p>Mouth Head and Neck (MHN) cancer rates have been rising both in Ireland and in most EU Countries and are projected to continue to do so. In contrast with other forms of cancer, MHN cancer survival rates have shown limited improvement over the last 20 years. A high proportion of patients continue to present with advanced stage disease. As a result, only about 50% of patients diagnosed with this cancer can expect to be alive after 5 years and many will die within the first 18 months.</p> <p>Recognised risk factors include tobacco, alcohol and human papilloma virus and the risk indicator of deprivation.</p>

Other Effects of Smoking on Oral Health include the following:

Periodontal Disease

It is well established that smokers have more severe periodontitis and a poorer response to treatment.

Dental Implants

Placement of dental implants is less successful in smokers.

Dry Mouth\*

Cigarette smoking can exacerbate the symptoms of dry mouth

\* Dry mouth is an oral condition which impacts on both oral health and well-being.

The feeling of a dry mouth is a particularly uncomfortable one and often gives rise to difficulty in speaking and eating and can have a major negative impact on a person's quality of life.

Reduced saliva flow can also give rise to an increased incidence of dental decay, gum disease and oral infection (e.g., candida albicans). People with dry mouth lose the protective effect of saliva in preventing dental caries and trauma to the oral mucosa.

Comments on proposed smoking cessation interventions:

Bupropion

As outlined in this document a common side effect of Bupropion is dry mouth. Advice needs to be given by those providing smoking cessation services regarding the management of dry mouth, due to the impact it has on oral health:

- Providing information on oral lubricants (saliva substitutes)
- Providing information on diet for e.g. although sucking sweets may give temporary relief, it will cause severe dental caries in the absence of saliva. Frequent consumption of drinks sweetened with sugar (e.g., soft drinks, tea) should also be avoided. Even sugar-free sweets and drinks can be problematic due to their acid content which is erosive to the teeth, especially in the absence of saliva.
- Preventing disease through the use of fluoride mouthrinses and mouthrinses to control plaque.

E-cigarettes

There is conflicting evidence regarding the use of e-cigarettes. The Australian Medical Association (AMA) 'has significant concerns about e-cigarettes'.



Public Health England (PHE) published a report in 2015 and stated that 'in a nutshell, best estimates show e-cigarettes are 95% less harmful to your health than normal cigarettes, and when supported by a smoking cessation service, help most smokers to quit tobacco altogether'.

Health experts from the London School of Hygiene and Tropical Medicine and the University of Liverpool strongly disagree with this and claim evidence used in the report was flawed, based on inconclusive evidence which was tainted by vested interests. They are also concerned that experimentation with e-cigarettes among young people in England is 'Worryingly high' and 'this remains a major concern for health professionals and parents' (The Telegraph 2015)

The Lancet also criticises the PHE Report 'Tobacco is the largest single cause of preventable deaths in England --e-cigarettes may have a part to play to curb tobacco use. But the reliance by PHE on work that the authors themselves accept is methodologically weak, and which is made all the more perilous by the declared conflicts of interest surrounding its funding, raises serious questions not only about the conclusions of the PHE report, but also about the quality of the agency's peer review process.

PHE claims that it protects and improves the nation's health and wellbeing. To do so, it needs to rely on the highest quality evidence. On this occasion, it has fallen short of its mission'.

In May 2016, the U.S. Food and Drug Administration (FDA) finalized a rule extending its authority to all tobacco products, including e-cigarettes, cigars, hookah tobacco and pipe tobacco, among others. "We have more to do to help protect Americans from the dangers of tobacco and nicotine, especially our youth. As cigarette smoking among those under 18 has fallen, the use of other nicotine products, including e-cigarettes, has taken a drastic leap. All of this is creating a new generation of Americans who are at risk of addiction," said United States Secretary of Health and Human Services. "Today's announcement is an important step in the fight for a tobacco-free generation - it will help us catch up with changes in the marketplace, put into place rules that protect our kids and give adults information they need to make informed decisions."(FDA 2016)

The Australian Government National Health and Medical Research Council (NHMRC) CEO Statement states the following:

'Electronic cigarettes (e-cigarettes, also known as electronic nicotine delivery systems, electronic non-nicotine delivery systems, or 'ENDS') have recently gained prominence in Australia and around the world, and are marketed online as

a method to assist smokers to quit, or a 'safe alternative' to conventional tobacco cigarettes. However, there is currently insufficient evidence to support these claims and further research is needed to enable the safety, quality and efficacy of e-cigarettes to be assessed'.

and

'There is currently insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting, or about the extent of their potential harms. It is recommended that health authorities act to minimise harm until evidence of safety, quality and efficacy can be produced. NHMRC is currently funding research into the safety and efficacy of e-cigarettes for smoking cessation'.

Key health concerns of the Cancer Council Australia and the National Heart Foundation Australia regarding e-cigarettes include the following:

'The limited evidence available points to a risk that widespread electronic cigarette use could undo the decades of public policy work in Australia that has reduced the appeal of cigarette use in children. Already there are anecdotal reports of electronic cigarettes being confiscated in Australian schools.

The short and long term health effects of electronic cigarette use remain unknown.'

'Major tobacco companies are investing heavily in electronic cigarettes as a product line and are deploying sophisticated marketing strategies mirroring those previously used to glamorise and promote smoking to young people. This marketing trend could normalise the use of an unproven product and, given electronic cigarettes are designed to simulate the act of smoking, risks re-normalising and re-glamorising the act of smoking more broadly'

They highlight that there are three areas that have regulatory gaps:

1. Non-nicotine electronic cigarettes
2. Use in smoke-free environments
3. Advertising

In Ireland, the Irish Cancer Society published a position paper on electronic cigarettes:

- Research into the long-term effects of their using e-cigarettes is not yet available.
- The Irish Cancer Society cannot recommend the use of e-cigarettes without guarantees on their long-term safety.
- In the absence of proven safety and efficacy, the Society wants the Department of Health to regulate e-cigarettes as medicinal product.
- The Irish Cancer Society is committed to a reduction in the rate of smoking in Ireland and has been a tireless

advocate of the Government's goal of a Tobacco Free Ireland by 2025. We recommend that smokers seeking to quit do so by giving up immediately and permanently.

- The Irish Cancer Society wants to ensure marketing of e-cigarettes 'denormalises' smoking rather than renormalise it.
- The Irish Cancer Society believes the workplace smoking ban should not be undermined and therefore supports employers who keep their workplaces free of e-cigarette use.

Most recently in the 2016 Report of the Surgeon General (US) it is stated that 'Tobacco use among youth and young adults in any form, including e-cigarettes, is not safe. In recent years, e-cigarette use by youth and young adults has increased at an alarming rate. E-cigarettes are now the most commonly used tobacco product among youth in the United States'.

'E-cigarettes are tobacco products that deliver nicotine. Nicotine is a highly addictive substance, and many of today's youth who are using e-cigarettes could become tomorrow's cigarette smokers'.

'Comprehensive tobacco control and prevention strategies for youth and young adults should address all tobacco products, including e-cigarettes'.

In view of all of this recent evidence Mouth Head and Neck Cancer Awareness Ireland has concerns regarding e-cigarettes and it is important that evidence concerning the potential harms (or of any benefits) is continually monitored.

We support the implementation of the recommendations of Tobacco Free Ireland Action Plan to achieve the target of Ireland to be tobacco free (5% prevalence rate by 2025).

It is essential to educate and empower teenagers about smoking.

All health care professionals must be encouraged to provide targeted smoking cessation approaches to MHN cancer high-risk groups. (Recommendation 9.8 Tobacco Free Ireland Action Plan). As General Dental Practitioners have the potential to exert significant change in this regard, we are happy to see that they have been identified in this document as a primary care support which promotes smoking cessation services.

#### References

Australian Government, National Health and Medical Research Council (2015) NHMRC CEO Statement: Electronic

			<p>cigarettes (e-cigarettes)</p> <p>Australian Medical Association (2015) Position Statement, Tobacco Smoking and E-cigarettes</p> <p>Cancer Council Australia and National Heart Foundation Australia Position statement - Electronic cigarettes</p> <p>Irish Cancer Society (2014) Position paper on electronic cigarettes</p> <p>Lancet, The (2015) E-cigarettes: Public Health England's evidence-based confusion</p> <p>NHS Choices, Dry Mouth <a href="http://www.nhs.uk/conditions/dry-mouth/Pages/Introduction.aspx">http://www.nhs.uk/conditions/dry-mouth/Pages/Introduction.aspx</a> , cited 18th January 2017</p> <p>Public Health England (2015) E-cigarettes: an evidence update. A report commissioned by Public Health England.</p> <p>Telegraph, The, (2015) `Scientists and health officials at war over safety of e-cigarettes', 15th September 2015</p> <p>United States Food and Drink Administration (2016) FDA News Release `FDA takes significant steps to protect Americans from dangers of tobacco through new regulation'</p> <p>U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.</p> <p>Van Dyke TE, Dave S. Risk Factors for Periodontitis. J Int Acad Periodontol 2005; 7(1):3 -7. Available at: <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1351013/pdf/nihms4855.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1351013/pdf/nihms4855.pdf</a></p>
19	Johnson & Johnson	Organisation	See Appendix 7.
20	Vape Business Ireland	Organisation	See Appendix 8.

21	Person #6	Personal	<p>This is a general comment. A young person doing a health care course with SOLAS (training to be a carer) informed me that out of 20 students 16 were smokers and that was just in his group. There were also a high number of smokers in the other groups Hairdressing etc. I contacted a manager in SOLAS to see if there would be a possibility of having a time slot for someone to speak to the students just to inform them of the services that were available to them, should they wish to stop smoking. They said that could be facilitated and saw a need for same.</p> <p>With that information I contacted our local smoking cessation office to be told they could not facility this. I'm sure they had good reason for not taking up the offer but considering the high numbers of smokers in this group of young people, I felt it was a missed opportunity.</p>
----	-----------	----------	---

22	Liquid Solutions Worldwide Ltd	Organisation	<p>Thank you for the opportunity to offer our opinions.</p> <p>We manufacture premium e-juice in our facility at Six Cross Roads, Waterford.</p> <p>We have all our e-juice independently tested prior to bottling and have done for several years. We therefore obviously welcome the new regulations governing this industry as we also test competitor brands as a matter of course. The results of some of these tests are truly shocking, some with many thousands of times the maximum limit for formaldehyde, benzopyrene and acetyls and incorrect nicotine levels. Therefore, the sooner these products are removed from sale the better, as consumers assume if they can buy the product it must be safe.</p> <p>Our concerns are twofold:</p> <ol style="list-style-type: none"><li>1) The apparent lack of understanding that all e-juices are not the same.</li><li>2) The speed at which these products will be banned from sale and the sellers/importers/producers prevented from so doing again.</li></ol> <p>Based on our perception of the policing of the CLP legislation to date our fear would be that if a similar level was applied to TPD there would be widespread non-compliance.</p> <p>We are aware of a number of these individuals/companies that are already factoring in that they will be able to continue selling for at 2/3 years before the authorities actually pin them down bar minor slaps on the wrist/fines. Given the serious nature of the effects of these toxins to the health of the user and the secondary damage to the industry as a popular, safe and cost effective cessation aid for addicted smokers, we sincerely hope the resources are being made available so effective action around the policing of the legislation is swift and permanent.</p> <p>As a manufacturer, we have made our notifications through the EU-CEG Portal. Submitter ID; 00485 and will be listed on the MHRA website in the coming days.</p> <p>Should you require any further information, please see contact details below.</p> <p>Some helpful websites:</p> <p><a href="https://ec.europa.eu/health/euceg/introduction_en">https://ec.europa.eu/health/euceg/introduction_en</a></p> <p><a href="http://ec.europa.eu/health/tobacco/products/revision_en">http://ec.europa.eu/health/tobacco/products/revision_en</a></p> <p><a href="http://www.hse.ie/eng/about/Who/TobaccoControl/Tobaccoproductdirective/">http://www.hse.ie/eng/about/Who/TobaccoControl/Tobaccoproductdirective/</a></p> <p><a href="https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products#submitted-products">https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products#submitted-products</a></p>
----	--------------------------------	--------------	--

23	ASH Ireland	Organisation	<p>ASH Ireland welcomes the latest research. We are, however, very eager to see more (and more indepth) research on the long-term health effects of e-cigarettes in particular. A focus on composition, ingredients etc will shed more light on these products and will help better inform their suitability as a cessation tool.</p> <p>ASH IRELAND SUBMISSION TO HIQA - UPDATED 30 1 17 (This to be inserted in special doc on the web - when approved by PD)</p> <p>1 February 2017</p> <p>SECTION 2.1: NRT: ASH Ireland is supportive of the use of NRT as a cessation tool. This method is proven to be effective and safe and is also regulated for use.</p> <p>Electronic Cigarettes: E-Cigarettes are now widely regarded as being less harmful than tobacco products and potentially have a long-term role in smoking cessation. However, the overall thrust of the marketing of e-cigarettes is in the context of longer-term use by individual users. Vaping is being presenting as a clearly defined activity, as opposed to being part of a process which could lead to a break from nicotine addiction. The increasing ownership of the e-cig sector by the tobacco industry will ensure that the focus will be on sales and profit and not on cessation.</p> <p>The lack of in-depth research in regard to the impact of longer-term use of e-cigarettes is a major concern, which understandably cannot be addressed in the short-term.</p> <p>The motivation of the nicotine user is critical in regard to why they decide to use e-cigarettes. If the product is marketed and viewed over time by the wider public as a social activity it will prove more difficult for the individual smoker to use the device in the context of cessation.</p> <p>5.3: E-Cigs: The adverse effects related to the use of e-cigarettes are well documented in the Report under review. The ongoing irritation being experienced by e-cig users, which does not decrease over time, is a cause for concern and simply cannot be ignored. It is clear that further analysis is required of the potential long-term development of this irritation into a more serious disease. Early analysis seems to suggest that e-cigarettes are safer than tobacco. However, there are unknown factors in regard to the longer-term consequences of vaping, which may emerge over time and this uncertainty must impact on current advice from health services. The support of vaping on the basis of current knowledge can only be done on the basis of harm reduction and not on the basis of the product being safe.</p>
----	-------------	--------------	--



There is some interesting and informative research/information emerging from the OTRU, Ontario and the University of Victoria's Centre for Addictions Research on the most recent knowledge regarding e- cigarettes, which should be considered in the context of this paper:

1. The Ontario Tobacco Research Unit (OTRU) in partnership with the Centre for Addiction and Mental Health (CAMH) have undertaken a multi-component research study to investigate patterns of e-cigarette use, their effectiveness as a cessation aid and health effects.

2. January 22, 2017 Under: E-Cigarette Studies |

In a report entitled "Clearing the Air", researchers from the University of Victoria's Centre for Addictions Research write that electronic cigarettes are a replacement for tobacco, not a gateway to it, and that vapor emitted from these devices is less toxic than tobacco smoke. Looking to find answers to the most burning questions regarding vaping, researchers browsed 15 databases and 1622 journal articles on the topic of electronic cigarettes, of which 170 were deemed relevant to their systematic review.

7.1: Ethical, Societal and Legal....

Extract `Although smoking is harmful to the smoker and to third parties who inhale tobacco smoke, it is not generally considered to be morally wrong and is therefore a matter of individual choice'.

In reference to the above, it is correctly stated that smoking is harmful to both the smoker and third parties. As it is now firmly established (W.H.O.) that smoking is harmful to third parties, the issue of whether it is morally correct to smoke at a time and place where others can be harmed must surely be questioned. This would also apply to outdoor areas, such as, sports stadia, crowded streets and rail platforms.

The issue of smoking in the workplace has been dealt with by way of legislation and third parties are now protected when indoors. However, the workplace smoking legislation does not protect non-smokers from environmental tobacco smoke in outdoor areas where smokers are allowed to smoke.

The issue of non smoking staff working in outdoor bar areas, which are often polluted with tobacco smoke, highlights a group of workers who are not protected by the workplace legislation. The morality of having bar staff, mostly young people, working in polluted carcinogenic environments should indeed be questioned as should the morality and legality of smokers using outdoor areas - and as a consequence - non-smokers ingesting carcinogens.

//ends

24	Person #7	Personal	<p>Overall the document was very easy to read ,was a good Literature review of smoking cessation services and is a good resource to have for references.</p> <p>As a cardiovascular appointed Health Promotion Officer working in tobacco control in Ireland I am grateful that you acknowledge that you cannot reflect the debt and breath of this (my) service.</p> <p>I am grateful that you acknowledge:</p> <p>it is clear that there are inequalities in smoking cessation P 15</p> <p>Harm reduction interventions designed to reduce the number of cigarettes smoked per day and interventions to reduce the risk for those who successfully quit smoking are outside the scope of this assessment .P 28</p> <p>Of 11 countries analysed ,the largest increase in inequalities between 2002 and 2012 was observed in Ireland P 77</p> <p>Have we any evidence that healthcare workers are availing of opportunities to encourage cessation as part of consultations ?P 22</p> <p>Where is the proposed method to combat cessation inequalities to incorporate an equity element into performance measurement ? p 78 ( I have been seeking this for 5 years)</p> <p>I am surprised but accept the findings re combination of Champix and NRT. p25</p> <p>as my understanding is the safety and efficacy of Champix and other smoking cessation therapies have not been studied.</p> <p>I congratulate you on this work and look forward to final document .</p>
25	Tobacco Free Ireland	Organisation	See Appendix 9.
26	PurpleBox Vapours	Organisation	See Appendix 10.

27	National Cancer Control Programme	Organisation	<p>This is a very comprehensive, well-researched and valuable report. It clearly outlines the clinical effectiveness and the cost-effectiveness of various pharmacological and non-pharmacological interventions for smoking cessation. The Terms of Reference and Methodology are clearly and simply described. The Results are detailed, precise and comprehensively presented. The chapter on epidemiology is excellent.</p> <p>Our specific comments focus on the implications of this report for health services and for health improvement. In this regard some of the data in the report need to be highlighted:</p> <ul style="list-style-type: none"><li>- the cost of smoking per year in Ireland to the health service is €460m. It costs €1bn in lost productivity and €9bn in loss of welfare - whereas the expenditure on all smoking cessation services in the HSE is €40m.</li><li>- Making Every Contact Count' is HSE policy. So every smoker, on every encounter with the health service will be offered smoking cessation services including pharmacotherapy.</li><li>-This HTA highlights that there is a lot of scope to further improve evidence-based smoking cessation services and opportunities for patients - specifically:<ul style="list-style-type: none"><li>- Varenicline is the best mono-therapy and Varenicline + NRT are the best dual therapy but your HTA page 74 shows that over 50% of patients who try to quit receive no therapy and their next most common cessation aid are e-cigarettes.</li><li>-PCRS data show that prescribing for smoking cessation pharmacotherapy has declined in recent years and that the median duration of bupropion therapy is just 37 days (the recommended duration is 12 weeks). This probably indicates a) that patients are not being offered pharmacotherapy and b) they do not complete their treatment - likely because of relapse and inadequate supports. These data show that we need to do more work to encourage prescribing and to support patients with their therapy.</li></ul></li></ul> <p>We acknowledge the incomplete knowledge and long-term effect of e-cigarettes but as it is still an unregulated product, we are wondering about your decision to include it in the cost-effectiveness analysis. This decision may in some way be seen to legitimise e-cigarettes. Specifically the finding that e-cigarettes were most cost-effective quitting aid will be used as a promotional tool by vendors of the product. This may not be what the health service wants to see especially as there are no long term data on e-cigarettes and the results of the two existing clinical trials did not reach statistical significance. Would it have been better to do the cost-effective analysis on the known approved evidence-based pharmacotherapy only? Conventional evidence-based smoking cessation programmes cannot be compromised by e-cigarettes.</p> <p>We feel that greater emphasis might be helpful in the HTA on the specific dangers of e-cigarettes among teens. The recent report by the Surgeon-General (2016) also highlights these dangers. Teens are now using e-cigarettes instead of smoking from which they may progress to cigarettes. The main focus for our health service regarding children and teens is to prevent them from using any tobacco product in the first place.</p>
----	-----------------------------------	--------------	---

Many thanks for the opportunity to comment.

28	Person #8	Personal	Having some experience recently that i wish i had not had, ie been forced to spend time in a hotel at a wedding, where several people were smoking E Cigarettes, even while food was been served, I Feel very strongly that all smoking should be banned from all indoor use, Work, Pubs, Restaurants, Hotels, Etc. Who wants to be inhaling somebody else's exhalations, regardless of what level of harm they may or may not do, it is simply totally unacceptable in this day and age to allow that to happen anymore, Unfair on everybody, including the staff, workers, etc involved in various industries. Simply Put, Puff Away, anyway you bloody well like, But do it outside at all times, Regardless.
----	-----------	----------	--

29	Person #9	Personal	<p>I am delighted with this initiative. Thanks to all of you for your huge effort to make Ireland smoking free. I have read as much of the report and attachments as I could understand but will admit that much of the statistical data presented is beyond my comprehension.</p> <p>My following comments are general and hopefully will be seen by all of you as constructive:</p> <ol style="list-style-type: none"><li>1. To establish my credentials, let me simply say that I smoked for 40 years. I successfully quit hundreds of times, (once for as long as three years), only to slip back into smoking again. That was, until finally, one day, I learned in just 6 hours how to quit permanently and - as incredible as it may seem - with no withdrawal symptoms. This 'well-kept secret' was Allen Carrs Easyway to stop smoking.</li><li>2. While I was over the moon with this success, I was curious as to why it worked so easily. Here's what I figured out through what Allen teaches:<ol style="list-style-type: none"><li>a. Ask anyone who ever smoked what age they were when they started? Invariably they will answer that they were teenagers. Ever wondered why? The answer is simply that we were convinced by part one of a two-part advertising campaign. Put bluntly, as we learned our sexuality as teenagers, we were also most gullible to influences by our heroes. Typically rock 'n' roll stars had a cigarette and surrounded by beautiful women/men. We wanted that for ourselves. That's an oversimplification of how we got hooked in the first place.</li><li>b. The second part of the advertising is far more subtle and to this day has fooled even the most learned of the medical industry. I can remember being told as a child by my parents, long before I was a teenager, if I smoked, I would be addicted for life. Worse still, while conquering this addiction, we would suffer huge withdrawal symptoms, be nasty to everyone around us and to get fat. This belief is reinforced my most publications offering Help to Quit. This advertising has become such an urban legend that to date, only those who have been lucky enough to read or listen to Allen Carr know the truth. The truth is that there are only withdrawal symptoms if we believe (through advertising) that we will have withdrawal symptoms.</li></ol></li></ol> <p>Allen spends the first three quarters of his book establishing his credentials. He has to in order to demonstrate to the smoker that he is credible. Only then he introduces us to the truth. The simple truth is that smoking itself has virtually no withdrawal symptoms. The advertising has made us believe it has and in turn, makes quitting so difficult. Stopping smoking without any withdrawal symptoms automatically follows for in excess of 90% of listeners who follow through on Allen's Easy instructions.</p> <ol style="list-style-type: none"><li>c. The downside is that many smokers start reading his book in one of those moments when they're determined to quit. They read several chapters initially, and like all books, put it down with the intention of continuing it later. The urge to quit often fades before they have finished the book.</li><li>d. Here is the great news. An audio version of the book is available for less than the price of a packet of cigarettes. It just takes 6 hours to play.</li></ol> <p>Here's what I have told many smokers and it has worked for each and every one of them:</p> <ol style="list-style-type: none"><li>i. Download Allen Carr Easyway to Stop smoking and quit e-cigarettes audio book onto your smart phone right now. Then, Don't listen to it!</li></ol>
----	-----------	----------	--

- ii. Most laugh asking if they don't listen to it, how can it possibly work? I reply "Don't listen to it until the NEXT time you get the urge to quit. Then listen to it in a single 6-hour session." (Allen Carrs face-to-face seminars do exactly that in single 6 hour session – and they give a 100% money back guarantee). Smokers understand these moments – moments that occur several times each year with all smokers over the age of 20 or so. However, many reply saying to me "Six hours?!!! I don't even have six minutes of spare time!"
  - iii. My reply is "If your mother or your child was seriously ill, you would sit by their bedside nursing them for more than six hours....."
  - e. Okay you may think – 'So Alan Carr's method worked for you, Jim. Good for you but what's the point you're making your relation to our consultation document?'  
My point is that while Alan Carr's Easyway is mentioned in your consultation document, I respectfully believe the opportunity of using it has not been explored sufficiently by you. As a minimum, I recommend that you give away free audiobook downloadsof "Allen Carrs Easyway to Stop smoking and quit E-cigarettes" to, say, the first 100 applicants.(at a total purchase cost of just €700 to you from Amazon.co.uk or elsewhere) AND with my suggestion not to listen until the next time THEY decide to quit and then to do so in a single session. To get their download free, they have to provide their email address to you. You send a follow up email say, six months later asking how many of the 100 were successful?
3. It is my true and honest conviction that the results will far exceed all other methods tried by you so far. I have no financial interest in Allen Carr or in Amazon. I simply want everyone who smokes to be able to quit easily and permanently.
4. I am very willing to meet a group of you to discuss my hard-earned first-hand knowledge.



30	Person #10	Personal	<p>Congratulations on this detailed and excellent document. My comment concerns e-cigarettes (EC).</p> <p>Your review is cautious, but it does acknowledge not just the potential pitfalls and caveats but also the promise of EC use for public health. Your cost analysis may not have fully acknowledged that most smokers are happy to fund the switch to vaping themselves. The approach that is piloted by some of the Stop-Smoking Services in England at the moment is to supply starter packs (particularly to disadvantaged smokers), with clients selecting and buying their own e-liquid thereafter. The cost of this provision is only about £25 per smoker.</p> <p>Stop-smoking services should offer EC. As your review shows, it is by far the most popular stop-smoking method and its efficacy is likely to increase if it is accompanied by behavioural support. If Irish stop-smoking advisors avoid EC, the service throughput and usefulness is likely to diminish.</p> <p>Well done again on a great document,</p>
31	Person #11	Personal	<p>I work as a regulatory compliance consultant to various pharmaceutical and medical device companies operating here in Ireland, and also in the US. Part of my work involves determining whether an apparatus is a medical device, and if it is, which class it should fall into. I specialise in determining whether or not automated systems particularly those which contain software or which can be connected to a power supply or have their own in built power supply are medical devices, or accessories to, or components of medical devices.</p> <p>I believe that certain manufacturers of "E-Cigarettes" are placing on the market an apparatus which atomises a solution containing nicotine and propylene glycol.</p> <p>I have been exposed to numerous marketing messages which promote the supply of these devices and I believe these devices to meet the criteria of an automated drug delivery system and are therefore medical devices.</p> <p>I have had difficulty explaining to medical device manufacturers why their devices need to have regulatory approval, whereas other drug delivery systems do not.</p> <p>As nicotine is defined as an addictive chemical, I would suggest that the marketing of Electronic Nicotine Delivery Systems (ENDS) can create a risk to consumers in Ireland if the aforementioned system has not been manufactured in compliance with regulatory requirements.</p> <p>To be clear: to claim that ENDS are tobacco substitutes and may be useful in smoking cessation is to claim that the ENDS would meet the definition of a Medical Device as it would in theory modify the physiological process of a smoker as per Statutory Instrument 252/1994 which you as the competent authority are responsible for policing in this</p>

country. Therefore, I would like to formally complain in writing by way of this email that I have not seen any evidence of compliance with Medical Device Regulations for any of these automated drug delivery systems which are now being widely marketed here in Cork.

If, on the other hand you can document as to why these products are not medical devices, then I would be very happy. I am aware that it is up to the entity placing the product on the market to determine the classification of their products, but if they are not registered but are being placed on the market then I would assume that normal market surveillance would result in them being seized, or alternatively being subjected to regulatory scrutiny for efficacy and safety,.

If the ENDS are not an aid to smoking cessation, then I would appreciate it if you could police claims being made by various manufacturers to this effect.

Can you clarify your position on the regulation of automated drug delivery systems and whether they are in fact a medical device, or does it depend on the drug which is being delivered?

I know that this is a complex issue and has attracted a lot of comment in consumer press, tv, and online. I also note that in the US, the FDA has defined ENDS and is policing them as part of it's remit to control tobacco products. However, there would appear to be a grey area here in Ireland.

I note that other manufacturers of apparatuses which atomise a drug are subject to stringent regulation and in the interest of clarity I would welcome your definition of what are medical devices and what do not constitute medical devices.

Finally, I attach a link here to your authorisation of a nasal spray which atomises an active ingredient prior to administration, by way of comparison:

[http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC\\_PA0282-090-001\\_20052014123137.pdf](http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA0282-090-001_20052014123137.pdf)

Thank you for taking the time to read this email.

32	Leicester City Council	Organisation	I am pleased to see that you have acknowledged the potential benefit of including electronic cigarettes in your smoking cessation efforts. I manage the Leicester City Stop Smoking Service, and we have been ecig-friendly for almost 3 years. We have seen improved success rates (up to 20% better) among those using e-cigarettes, and reduced costs, because service users have bought their own kit and e-liquid, even if we supply a starter kit. I would encourage you to be optimistic about e-cigarettes, especially for those who tend to relapse; nicotine maintenance via a clean delivery system will keep more people smokefree. Do contact me for info if you would like to hear more about how we achieved this.
33	Irish Pharmacy Union	Organisation	Section 2.1.2.2.2 acknowledges the pharmacy-led smoking cessation service introduced by the IPU in March 2014. The report, however, does not indicate which primary care setting is preferable in which to offer a smoking cessation service. Community pharmacies in Ireland receive 85 million visits a year by members of the public which puts us in an ideal place to address smoking cessation, not only with unselected adults but also with patients with mental health issues and pregnant women. The report acknowledges that efforts to increase the use of combination varenicline and NRT will place additional demands on general practitioner (GP) or nurse prescriber services. Community pharmacists should be able to supply such products to medical card patients without the need to get a prescription from their GP. Indeed, the Health (Miscellaneous Provisions) Bill 2016, which is currently going through the Oireachtas, will facilitate this.

34	Pfizer	Organisation	<p>Policy •Whilst a number of policy measures have been successful to date, to achieve the policy goal of a Tobacco Free Ireland (&lt;5% smoking prevalence or c. 211,400 smokers*) by 2025, an increased urgency and number of measures are needed.(1,2) •We welcome the opportunity to work in partnership with all stakeholders to achieve the policy goal of a Tobacco Free Ireland within this timeframe. Review of Clinical Evidence •We acknowledge varenicline + NRT having the greatest treatment effect relative to control [Table 4.6], but would note that varenicline is not authorized to be used in this way and that Pfizer therefore does not market or recommend it as such.(3) •We would draw attention to the 6 month absolute quit rates of varenicline alone (35%) and varenicline + NRT (32%) and perhaps question prioritisation of the cost-effectiveness of the combination, given the similar absolute quit rates. •We suggest caution in recommending e-cigarettes for smoking cessation as this does not address the challenge of nicotine addiction and may ultimately encourage the smoking of tobacco in the long run, thus compounding the problem of smoking in Ireland. •We would re-emphasise the lack of data supporting the use of e-cigarettes in smoking cessation, with 6 month absolute quit rates worse than control (7% v 11%), as well as long term safety concerns.(4) •Smoking cessation and its management is cyclical, with patients attempting several times to quit smoking; this strategy should be factored into any recommendations. Economic Assessment •We welcome recognition of varenicline as a cost effective smoking cessation intervention. •The increased use of e-cigarettes may be less costly to the HSE - as this intervention is funded through out of pocket expenditure rather than the PCRS. However, with 6 month absolute quit rates reported at less than control,(4) there is considerable uncertainty around the long term success rate and therefore the long term value of this approach in achieving smoking cessation. •We note the comment around barriers to uptake of varenicline and are willing to work with the HSE to address and eliminate barriers to uptake, to ensure that the potential benefits of smoking cessation with varenicline can be realised. Implementation •The policy goal requires a reduction of &gt;65,000 smokers quitting every year over the next 9 years, a total of 600,000 smokers with successful long term quit outcome, to achieve this goal. Experience with smoking cessation interventions to date in Ireland is remains far below the levels required.(1,2) •We propose that the Department of Health considers convening a multi-stakeholder Joint Committee on Smoking Cessation including relevant corporations. This committee would agree practical measures to be implemented, to ensure we're successful in achieving a Tobacco-Free Ireland by 2025. References 1.www.cso.ie Population Tables 2.Prevalence of smokers based on population estimates &gt;12 years and current prevalence of 19% [HSE half yearly update 2016] 3.Champix (varenicline) SmPC 4th August 2016 4.McRobbie H. et al., Cochrane Database of Systemic Reviews 2014 (Issue 12); updated Sept 2016</p>
----	--------	--------------	--

35	Rejuice Ireland	Organisation	<p>Although medication and counselling approaches to treating nicotine addiction are relatively straightforward, most quit attempts today have a success rate of only 2–5%....relapse is the norm.<sup>1</sup> Smoking cessation aids include patches, gums, inhalers etc., but there is a lack of evidence to support the view that these cessation aids are effective and acceptable substitutes to continued tobacco smoking and hence in harm reduction.<sup>2</sup> e-Cigarettes can constitute an effective smoking cessation tool if widespread dissemination of vaping behaviour is encouraged as a successful part of a strategy to reduce smoking and prevent smoking-related diseases, <sup>3</sup> People who do not wish to quit have been shown to be helped to reduce the number of cigarettes they smoke and to quit smoking in the long term, using NRT (e-cigarettes), despite original intentions not to do so.<sup>2</sup> Preliminary findings show that combining availability of appealing e-vapour products for smoking substitution with professional advice from trained staff, it is possible to achieve high and stable success rates. By promoting healthier life-style changes in smokers, vape shops may become valuable allies in the fight against smoking.<sup>4</sup></p> <p>1)The Past, Present, and Future of Nicotine Addiction Therapy. Judith J. Prochaska<sup>1</sup> and Neal L. Benowitz.. Annu Rev Med . 2016 ; 67: 467–486</p> <p>2)Interventions to reduce harm from continued tobacco use. Lindson-Hawley N1, Hartmann-Boyce J, Fanshawe TR, Begh R, Farley A, Lancaster T. Cochrane Database Syst Rev. 2016 Oct 13;10:CD005231.</p> <p>3)Are electronic nicotine delivery systems an effective smoking cessation tool? Lam C, West A. Can J Respir Ther. 2015 Fall;51(4):93-8. Review.</p> <p>4)Quit and Smoking Reduction Rates in Vape Shop Consumers: A Prospective 12-Month Survey Riccardo Polosa’ Pasquale Caponnetto, Fabio Cibella and Jacques Le-Houezec . Int. J. Environ. Res. Public Health 2015, 12</p>
36	Saolta University HealthCare Group	Organisation	<p>I am not sure why HIQA are reviewing this when all the evidence is well established in relation to the efficacy of smoking cessation medications and interventions? Monies would be better spent investing in smoking cessation services which are lacking in a number of counties.</p>
37	Nicopure Labs	Organisation	<p>NICOPURE LABS COMMENTS ON THE HEALTH INFORMATION AND QUALITY AUTHORITY (HIQA)’S HEALTH TECHNOLOGY ASSESSMENT OF SMOKING CESSATION INTERVENTIONS</p> <p>1.Nicopure Labs welcomes HIQA’s recognition of the enormous role that vaping products are playing in moving adult smokers away from smoking and towards safer alternatives – with incontrovertible evidence, from both Ireland and markets around the world, of the explosion in popularity of vaping products amongst smokers</p> <p>2.Nicopure Labs is committed to and remains ready and willing to work closely with the HIQA, the Department of Health and all other public health bodies in Ireland to make sure that clear and accurate information regarding vaping and vaping products can be made available to all smokers seeking to reduce their use of tobacco products</p> <p>3.Nicopure Labs urges the Department of Health to scrutinise the role that can be played by vaping in advancing the Healthy Ireland target of a tobacco free Ireland by 2025</p> <p>About Nicopure Labs Operating since 2009, Tampa-based Nicopure Labs, LLC is an industry leading e-liquid manufacturer with operations in the U.S. and Europe. Nicopure Labs has recently upgraded its 110,000-sq. ft. manufacturing and distribution operations in Gainesville, Florida to include a 10,000-sq. ft. ISO 7 cleanroom. Distributing to over 90 countries worldwide, Nicopure Labs has also expanded its presence with the recent addition of a European headquarters in the Netherlands and offices in England.</p>

38	Person #12	Personal	<p>Key elements of Royal College of Physicians’ report on tobacco harm reduction I would like to draw the attention of the review team to the London-based Royal College of Physician’s 2016 report, Nicotine without smoke: tobacco harm reduction, 28 April 20016, London [1] Five quotes from the report provide an excellent basis for outlining the main issues relating to e-cigarettes, smoking cessation and tobacco harm reduction: 1. On the relative risk of e-cigarettes and cigarettes “Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure”. (Section 5.5 page 87) This carefully worded statement takes the practical approach of focussing on what scientists do know, rather than unknown or unknowable information that will only become available over many decades and only if the right studies are put in place. The judgement of relative risk is based on the completely different physics and chemistry of tobacco smoke and e-cigarette aerosol – some we do not have to wait 50 years for. The former is the product of complex chemical reactions in high temperature combustion of dried tobacco leaf. The latter is the electrical heating at much lower temperature of an inert liquid bearing nicotine and flavourings – there is no combustion. Most of the important harmful toxins in tobacco smoke are products of combustion. For this reason, they are either not detectable in e-cigarette aerosol or present at very low levels. The result is that the overall toxicity of the e-cigarette aerosol is very much lower than cigarette smoke. As one would expect from such an organisation, the Royal College of Physicians has expressed its statement with careful reflection of uncertainties in both directions, but with a steer to make it clear that 5% of the risk of smoking is a conservative estimate. At present, there is no credible evidence to suggest these products will cause any serious disease or premature death. However, the claim is not that they are safe, just very much safer. 2. On population effects “There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking. To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.” (Recommendations) This summary address a number of claims made by tobacco control activists to the effect that the availability of a low-risk alternative to smoking would somehow increase smoking. It is worth recognising just how counter-intuitive these claims are, and as such should require a very credible evidence base before they are accepted as remotely plausible. The RCP draws the opposite, more intuitive, conclusion from the evidence, namely that: (1) people use safer products to reduce their risks; (2) that the promotion of vaping promotes vaping, not smoking; (3) any ‘gateways’ seem more likely to be ‘exits’ from the more harmful to less harmful products. 3. On the impact on smoking cessation “E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking. The RCP makes the important observation that e-cigarettes are consumer products and that their success in part derives from their appeal to those who would never even try to quit smoking via conventional methods or are unwilling or</p>
----	------------	----------	--

unable to quit. E-cigarettes are not medical aids to reduce craving and withdrawal during a quit attempt, but an alternative way of taking the recreational drug nicotine. It is important, therefore, not to treat e-cigarettes as medicines, to misapply concepts like 'efficacy' or to rely on randomised controlled trials that are suited to singular interventions, such as administering a drug. The 'efficacy' of e-cigarettes is not a property of the device and liquid, but the outcome of a complex ecology of behavioural influences, including properties of the product, but also peer support, marketing, beliefs about risk and scare stories in newspapers, local availability, the attitude to smoking/vaping in the social and work environment, and the policy framework – packaging, warnings, restrictions, diversity, marketing, taxation etc. Users tend to progress over time, acquire vaping skills and switch products to more complex configurations, lower nicotine liquids and more diverse flavours as they migrate away from tobacco. A period of dual use may be part of a transition that lasts longer than any RCT ever would, but ends in permanent smoking cessation. Because of their poor efficacy, conventional smoking cessation techniques also involve prolonged "dual use", but this occurs serially with successive quit attempts and relapses back to smoking then the next quit attempt and so on until success, or through an indefinite cycle of cessation and relapse.

4. On unintended consequences of well-intentioned but excessive cautious regulation "A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187) The RCP draws out the most challenging question for regulators. By regulating or communicating with excessive caution, well-intentioned authorities can make the situation worse, cause avoidable harm to consumers and protect the cigarette trade. In forming the EU Tobacco Products Directive provisions on e-cigarettes (and the ban on snus), far too little attention was paid the risk that the measures proposed would have harmful unintended consequences. These could arise by reducing appeal, making the products harder to use, by hampering innovation, by raising prices, by denying the means to communicate and, above all, by creating regulatory barriers to entry that have the effect of protecting the incumbent cigarette trade against disruptive innovation. Ireland's health community should take great care to avoid compounding these errors.

5. On the recommendation of a tobacco harm reduction strategy However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK (Recommendations, original emphasis). Taking all the available evidence into account, the organisation that first reported on Smoking and Health in 1962, endorses a tobacco harm reduction approach including the promotion of e-cigarettes. Ireland's 2025 tobacco policy aims Ireland's ambitious goal to be tobacco-free by 2025 has been translated into achieving a smoking prevalence rate of less than 5%. This goal is very ambitious. It will be exceedingly challenging if the only strategies to be deliberately deployed are complete cessation and reduced initiation. Current rates of decline in smoking are unlikely to come close to meeting this target. However, a third strategy is available, that is to encourage smokers to switch to smoke-free products – primarily e-cigarettes but



			<p>also other nicotine products that does not involve combustion and smoke. Many smokers will find it easier to switch from smoking to vaping than to stop both smoking and nicotine use altogether. The switching strategy only involves giving up part of what is involved in smoking. Switching from smoking to vaping allows the user to continue using nicotine and to maintain several behavioural and sensory aspects of smoking, though with radically reduced risk and a contribution to the attainment of the 2025 smoking prevalence target.</p>
39	JTI Ireland	Organisation	<p>JTI Ireland Ltd, a member of the Japan Tobacco Group of Companies, is Ireland’s leading tobacco manufacturer. JTI Ireland supplies over 4,000 retail outlets nationwide and employs more than 90 people locally. JTI welcomes the launch of this report and we would respectfully ask that our views are considered as part of the consultation process; specifically in relation to electronic cigarettes. JTI supports reasonable and proportionate regulation of electronic cigarettes, and believes Governments and regulators should avoid excessive regulation that prevents adult consumers from choosing these products. The e-cigarette category is an emerging one that needs to be monitored, and be allowed to evolve in Ireland. Electronic cigarettes are consumer products, not tobacco products, as defined by the revised EU Tobacco Products Directive (TPD) (2014/40/EU). Only if manufacturers choose to make a claim that their product can assist with smoking cessation should their electronic cigarette be regulated as a medicinal product or medical device, as is the case for existing medicinal NRT (Nicotine Replacement Therapies). In response to evolving consumer demand for those seeking an alternative option [choice] to smoking, we entered into the e-cigarette category in 2015 and now produce Ireland’s leading e-cigarette brand, Logic. JTI does not make any health claims about our electronic cigarettes, nor do we market electronic cigarettes, or any other nicotine-containing product, to minors or to non-users of tobacco or nicotine-containing products. We very much support a twin track regulatory approach – as prescribed under the revised EU Tobacco Products Directive and recognised in the HIQA report – thereby providing manufacturers with the option to choose TPD electronic cigarettes or medicinal product routes, the latter being subject to pharmaceutical regulation.</p>
40	Irish Cancer Society	Organisation	<p>The Irish Cancer Society welcomes the HIQA health technology assessment (HTA) of smoking cessation interventions in Ireland and the opportunity to respond its draft HTA. The Society broadly welcomes the content of the document and its approach in examining smoking cessation interventions in Ireland. E-cigarettes: In particular, the Irish Cancer Society would welcome a ‘cautionary approach’ to any recommendations regarding electronic cigarettes, as set out on page 275 under section 7.1.2.4, given a lack of evidence on potential long-term risks. While recent studies have shown the potential of e-cigarettes in reducing harm (<a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/E-cigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/E-cigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf</a>), and the Society acknowledges that e-cigarettes are less harmful than tobacco, currently we do not believe they should be recommended as a smoking cessation device until there is further research into the long-term health implications of their use. As noted throughout the consultation document, especially under section 5, there is no long-term evidence as to the safety of these products, and, as per page 69, Section 3.4.2, there is emerging, but as of yet, limited, evidence that for adolescents e-cigarettes may act as a “gateway” to tobacco usage, especially among those in their late teens who otherwise, according to</p>

research, did not intend to smoke tobacco. The Society also maintains concerns, acknowledged in the draft HTA, that the use and marketing of e-cigarettes, may “re-normalise” smoking after a long period of de-normalisation brought about in large part to public health programmes and legislation which have helped changed attitudes towards smoking. The Society hopes that the transposition of the Tobacco Products Directive into Irish law in 2016, and its stricter rules on advertising of electronic cigarettes and refill containers will help mitigate a renormalisation impact somewhat. Recommendation: The Irish Cancer Society recommends that e-cigarettes are not endorsed as a smoking cessation aid until further evidence on the long-term risks becomes available. Community-based interventions, their efficacy and impact on lower socio-economic groups: As noted in the consultation document, on page 275, section 7.1.2.3, the harms that result from tobacco use are not experienced equally by all segments of the population, and smoking prevalence follows a socio-economic gradient. Smoking is the greatest contributor to health inequalities between the richest and poorest sections of society, reflected in table 3.5 of the draft HTA, It is also a significant contributor in gender-based mortality differences. The draft HTA (page 275) acknowledges that “a harm-reducing strategy may fail if net harm is reduced, but in a way that is socially unjust; for example, some socially or economically vulnerable group becomes more at risk of harm or less able to benefit from the harm reduction strategies”. Therefore, the Irish Cancer Society posits that the social gradient associated to smoking means that any policy designed to reduce prevalence should ensure that those in the most deprived areas gain the most from such policies, and should be the focus of targeted supports enabling them to quit. All available evidence suggests that actions should aim to reduce the steepness of the social gradient through the delivery of a universal service on a scale and intensity to the level of disadvantage (Marmot M, Strategic review of health Inequalities in England post-2010). There is emerging evidence pointing to the importance of working in partnership with the community and voluntary services (CVS) in order to deliver smoking cessation support to people living in socially and economically disadvantaged areas. Survey research with CVS in Australia has indicated that community organisations are receptive to supporting smoking cessation, but require additional support to integrate such support into usual care (Bryant, J., Bonevski, B., Paul, C., O’Brien, J., & Oakes, W. (2011). Developing cessation interventions for the social and community service setting: A qualitative study of barriers to quitting). In England, a recent pilot study in Nottingham with low income families found merit in working with Children Centres (centres set up by government to provide services for low income families) which increased referrals to the specialist stop smoking services (McEwen A., Hackshaw L., Jones L., Lavery L., Amos A., Robinson J. Evaluation of a programme to increase referrals to Stop Smoking Services using Children’s Centres and Smokefree Families Schemes. *Addiction* 2012; 107 (Suppl. 2): 8–17. Both the Australian and Nottingham studies demonstrate the potential of community based services as a means to engage with smokers and offering a referral route to specialist services. In the USA, the best evidence of the effectiveness of such community based approaches to working with low income women emerges from the evaluation of the Sister to Sister programme (Andrews, J, Felton, G, Wewers, E et al (2005) Sister to Sister: A pilot study to assist African American women in subsidized housing to quit smoking, *Southern Journal of Online Nursing Research*, 1, 6, 1-20). While the Irish Cancer Society broadly welcomes the draft HTA, it believes that in achieving the desired

outcome of not only reducing smoking prevalence, but enabling people, especially those in deprived and low income communities, to cease smoking, additional consideration in the final HTA should be given to the effectiveness of targeted community level intervention in areas of deprivation. The Irish Cancer Society itself developed a smoking cessation programme for women in 2013 called 'We Can Quit' (WCQ) which was established following a review of the literature conducted by members of the Society's research team. We Can Quit is a 12 week smoking cessation course delivered in the community that offers women 12 weeks of group support, one to one support and free Nicotine Replacement Therapy (NRT). This programme has delivered very positive results thus far and we are seeking to conduct a pilot study that will address the feasibility and acceptability of a community-based smoking cessation intervention the results will inform the design of a future definitive trial. While the draft HTA addresses the current configuration of services, including behavioural supports, and behavioural supports aligned to pharmacological support, which include referral or self-referral, but it has not assessed the effectiveness of targeted support programmes based at reducing the social gradient, something which is recognised as an important cornerstone of smoking cessation policy in the Tobacco Free Ireland policy document, which notes that "targeted and tailored smoking cessation interventions should be used where necessary, for example, in socially disadvantaged areas (<http://health.gov.ie/blog/publications/tobacco-free-ireland/>). Since the publication of "Community engagement: approaches to improve health" in 2008, there has been a substantial increase in the evidence of how community engagement can improve health and wellbeing and reduce health inequalities (<https://www.nice.org.uk/guidance/NG44/evidence>). It is therefore important that reference to this approach be noted in the context of effective smoking cessation interventions. The Society welcomes the recognition (page 281) that the addition of any type of behavioural support to a pharmacological intervention increases the chances of successful quitting, and expresses the hope that further analysis of the effectiveness of targeted community and voluntary supports will be undertaken before the final HTA. Recommendation: The Irish Cancer Society believes that in assessing the cost-effectiveness of an intervention an appropriate weighting should be applied to the societal preference for interventions that are targeted at reducing the smoking rate among deprived groups.

41	Asthma Society of Ireland	Organisation	<p>In less than 10 years the electronic-cigarette industry has grown from one manufacturer in China to an estimated \$3 billion global business with almost 500 brands. Data released earlier this year showed that sale of electronic-cigarettes in Ireland has increased 478 per cent since 2012. Despite this, electronic-cigarettes are totally unregulated in Ireland. This is problematic for a number of reasons. While electronic-cigarettes may not be as harmful as tobacco products, they may still cause serious damage to the user's health. They contain significant levels of nicotine, an addictive toxin which, if consumed in high enough quantities, results in measurable effects on a person's cardiovascular and metabolic systems. It also has the potential to cause kidney damage, nerve and brain dysfunction and respiratory failure. Passive inhalation of e-cigarette emissions may also be injurious to the health of bystanders. In March 2013 researchers from the University of California examined in detail the emission contents of e-cigarettes finding that "many of the elements identified in e-cigarette aerosol are known to cause respiratory distress and disease". According to the WHO, evidence shows that e-cigarette aerosol is not merely "water vapour" as is often claimed in the marketing of these products. Rather, the evidence suggests that exhaled e-cigarette aerosol increases the background air level of some toxicants, nicotine and particles. The WHO is also concerned that e-cigarettes will serve as a gateway to nicotine addiction and, ultimately, smoking, particularly for young people. They are particularly concerned that experimentation with e-cigarettes is increasing rapidly among adolescents, with e-cigarette use in this group doubling from 2008 to 2012. Young people who would never have tried standard cigarettes may try e-cigarettes and migrate later to tobacco use. There is also a serious risk that unregulated availability and marketing of e-cigarettes may reverse the progress that has been made in reducing overall tobacco consumption in Ireland. Experts fear that if electronic-cigarettes remain unregulated smoking could be re-normalised, undermining public smoking bans and undoing years of effort to educate people about its harmful effects. According to the WHO, there is also insufficient evidence to conclude that e-cigarettes help users quit smoking. For these reasons, e-cigarettes should be regulated in the same way as standard cigarettes and tobacco products. This will ensure that e-cigarette users are aware of the risk to their health of using such products and will also protect the public from passive consumption of e-cigarette toxins. It is for the above reasons that the Asthma Society of Ireland feels that incorporating or actively promoting e-cigarettes as a quit aid needs much further research. There are too many variables at the moment which may cause negative health effects in the long term. With greater regulation of e-cigarettes a time might come for their inclusion in quit programmes. The Asthma Society of Ireland is the national charity dedicated to saving lives and improving the lives of people with asthma. We do this by:</p> <ul style="list-style-type: none"> <li>•Providing services such as our free adviceline, workshops for parents and training for health professionals. Anyone can call our adviceline on 1800 44 54 64 and speak to one of our trained respiratory nurses about asthma or COPD. This service is kindly funded by the HSE.</li> <li>•Providing information about asthma management on our website and in printed booklets. Our booklet series includes information on controlling your asthma, managing your child's asthma and exercising with asthma.</li> <li>•Lobbying the Government to improve services for people with asthma.</li> <li>•Supporting research into the causes and treatment of asthma.</li> </ul>
----	---------------------------	--------------	--

42	VIP E-Cigarette	Organisation	<p>"The Department of Health's own research, Healthy Ireland Survey 2016, found that of those who successfully quit smoking, 32% use vaping to do so. However, neither the HSE or Department of Health provide consumers with information or support on vaping products which is just crazy when you consider the above facts. We at VIP would urge the HSE and relevant bodies to look at the Cancer UK, ASH UK and the NHS and see what they are doing with e cigarettes, they are including them in their quit campaigns and are advertising that e cigarettes can help smokers quit. Surely we should look at other well respected bodies and then make a decision to copy this or not and if not to say why not - not to just keep saying - WE DO NOT KNOW THE LONG TERM EFFECTS OF VAPING - we do know the long terms effects of vaping compared to long term effects of smoking and the difference is huge this is what we need to focus on going forward. We have this chance to change people's lives to reduce the harm they cause themselves by smoking - it is too huge to ignore and do nothing. Facts are they are 95% less harmful than smoking, they are not a gateway for children to smoke, they do not normalize smoking, smokers are using them to quit and being successful. VIP UK are doing a pilot programme with the NHS in the UK and supplying smokers with VIP products to get them to stop smoking with a view to rolling it out nationwide. VIP Ireland would be willing to do this with the HSE and work together to help people quit smoking. Thank you Joe Dunne Director VIP E Cigarette Ireland</p>
43	Smoking Cessation Service, Letterkenny University Hospital	Organisation	<p>A: Non- Medical Electronic Nicotine Devices:</p> <ol style="list-style-type: none"> <li>1. The position of electronic non medical nicotine devices in the report: It is unfortunate that this document classifies "e-cigarettes" as a pharmacologic intervention for smoking cessation; products should be identified as non-medical nicotine delivery devices and consumer products - at this point there is only direction on their regulation within the EU and plans are only to regulate some elements of these products. The evidence to support the use of these products as smoking cessation tools is severely limited given participant population numbers and studies available. The Cochrane Tobacco Addiction Group has repeated their 2013 review in a meta-analysis of Non Medical Electronic Nicotine Devices (NMENDs) in 2016 with their findings remaining inconclusive.</li> <li>2. Observations in my clinic are consistent with discussion at the FCTC COP meeting on ENDS/ENNS in November, 2016. The physical, psychological and conditioned behavioural components of tobacco smoking are maintained with the use of non-medical ENDS. Persons who use these devices are not quitting or treating their tobacco use, they are opting for a reduced harm product - an alternative to smoking tobacco "that produces a satisfactory experience to the user in terms of the speedy delivery of sufficient nicotine to mimic the sensory feel of smoking". (WHO, 2016).</li> <li>3. Marketing techniques of the industry have targeted tobacco users and informed consent is not provided at sales point. They now replace tobacco products at the point of sale section in many shops and are marketed as safe and can be used anywhere i.e. not included in the legislation- Public Health (tobacco) Acts. Based on these marketing campaigns- the phenomena I now see in my clinics are;             <ul style="list-style-type: none"> <li>o Dual use - current tobacco users adding ENDS to use in areas where legislation has restricted tobacco smoking.</li> <li>o Switching of tobacco products to ENDS to reduce cost, even with those using hand rolled tobacco products.</li> </ul> </li> </ol>

- o Young people selling on and sharing these devices.
  - o Medical treatment non-compliance- NRT and Varenicline HCL (monotherapy or combinations)- will opt for ENDS use in combination
  - o Use of ENDS instead of licensed treatment - as experienced barriers to access or medicine costs/ GP cost/ not on GMS/not on PCR scheme.
  - o Ex-smokers - those with years in recovery are now using these products.
4. On review in the clinic/bedside these persons' nicotine dependence scores rise, motivation to quit scores reduce and self efficacy in quitting reduces. The use of ENDS becomes constant - reverting back into homes, cars, internal work and social environments. Therefore, the conditioned behaviour becomes more integrated into daily life (and night smoking) and control over product use reduces. Thus in the clinical situation persons' using ENDS - should not be seen as "quitters".
5. Safety, Ethical and Moral considerations: The 4 disease processes used in the cost effectiveness analysis were Lung Cancer, Ischaemic Heart Disease, Stroke and COPD- toxic components of ENDS are reducing the benefits seen with complete cessation and in some cases exacerbate symptoms of disease. Therefore, in the clinical situation patients will receive a prescription or recommendation for licensed treatments as either monotherapy or in combination. Persons attending the clinic who are using ENDS will be transferred to a licensed treatment/s.

B: Evidence used to support the current situation on smoking cessation in Ireland

It is relative that given the Healthy Ireland 2015 Survey, having the most recent information in existence along with the National Office of Tobacco Control quarterly reports; are used to detail the Irish situation in the document. The concern is with the detail of the questions for the tobacco section and the response set in show cards and the survey as a cross-sectional design was one at a single point in time i.e. Q12 - Possibility of bias is considerably high as some elements of QUIT were listed- however the 1:1 support of clinic and groups were omitted from the list. Dual or combination treatments of licensed medications alone or in combination of behavioural support were omitted, regardless of intensity or location of intervention.

C. Limits of report:

1. Terms of reference cite the general population; though no analysis of smoking cessation interventions in secondary acute hospital service was completed. Over half of the full time smoking cessation practitioners are Clinical Nurse Specialists employed within these settings. This would be of great value, especially as evidence document is to inform a clinical guideline for smoking cessation interventions in the general population, secondary mental health and pregnant women- all are represented and referred to my nurse-led acute hospital smoking cessation service.
2. Mental health secondary care included- 10% of population- smoking cessation interventions are of great value here however, at present we have no smoking cessation personnel in these areas- the patients who show an interest in quitting are referred to community or hospital smoking cessation practitioners. On referral to programme- long term

	<p>intensive behavioural and pharmacotherapy treatment- Combination NRT. A significant proportion of patients reviewed at my clinic or at the bedside; have co-existing mental health or behavioural health co-morbidities and may be in recovery or treatment. During assessment the Hospital Anxiety and Depression score is recorded with patients who have a mental health history or display signs of psychological distress or probable depression.</p> <p>3. Pregnant Women- The context and rationale for tobacco use in pregnancy in Ireland is documented in "A Tobacco - Free Future An All-Ireland Report on Tobacco, Inequalities and Childhood. The document provides details of the impact on perinatal outcomes and is used to inform midwife training in brief advice and brief intervention at LUH. Pregnant women need to be given cessation interventions on confirmation of pregnancy. This cohort of patients prove the most difficult when trying to achieve complete cessation, there is a direct referral system from antenatal booking and the maternity unit to my service- at this point most women are smoking through the first trimester. Most pregnant women are referred from my service onto the community service in Donegal; apart from those attending the high risk clinics in the hospital. Some women decide to delay cessation until after delivery when they can use prescription treatment i.e. combination NRT or Varenicline.</p> <p>4. Behavioural Interventions- the classification of terms, detail level of each intervention and who provides each intervention was identified as difficult in reviewing the randomised control trial (RCT) evidence. While the goal standard for producing evidence are RCTs, there are limits when applied to the clinical situation and possibly observational studies may better inform evidenced based practice and evaluation of a monotherapy therapy or combination therapies.</p> <p>5. Screening, documentation and identification of tobacco use status as a means to improving access to smoking cessation interventions was omitted from the document- these are seen as crucial to improving smoking cessation interventions by all health professionals in any healthcare setting.</p> <p>6. Levels of Smoking Cessation Interventions within the Intensive or dedicated Smoking Cessation Service were omitted from the analysis- as we do not use one intervention alone- multi-component treatments are provided. In my own service I provide eight levels of treatment which includes tailored to quit plans, prescription and withdrawal therapy. In a cost effective analysis of such service provision- only dedicated hours used in delivering cessation services should be used- with many of our current practitioners this may equate to 20 - 80% of their current WTE and such full salary should not be considered the cost for cessation interventions nationally.</p>
<p>44 HSE Drugs Unit Organisation</p>	<p>Following consultation of the HTA on smoking cessation interventions, there were some corrections noted by Primary Care Reimbursement Service (PCRS) as follows;</p> <p><b>Page 33: Section 2.1.1.1</b></p> <p><i>`While all NRT products available in Ireland are <u>now available</u> without a prescription, to be reimbursed through the PCRS they must be prescribed by a doctor or nurse prescriber who is registered with the PCRS'.</i></p> <p>Doctors and nurse prescribers are not registered with the PCRS. They hold a contractor agreement with the HSE in order to prescribe for medical card holders on GMS prescription forms. NRT were always available without a</p>



	<p>prescription (over the counter products) through the pharmacy, the only recent change was the deregulation of certain NRT items from Pharmacy only medications to General Sales List.</p> <p><i>'Beyond Ireland, only the UK fully fund NRT in Europe'</i>. Ireland partially funds NRT for those patients with medical card eligibility under the GMS scheme. NRT is not fully funded.</p> <p><b>Page 238: Section 6.2.9</b></p> <p>This section implies that a patient can obtain up to three months' supply of medication which is not the case. <i>'For those with a Medical Card, up to three months' supply of medication may be prescribed at a time (and dispensed in monthly aliquots)'</i>.</p> <p>NRT cannot be written on a duplicate (3 monthly) GMS prescription form. For those with a Medical Card, NRT must be prescribed on a single monthly GMS form. One month supply is obtained each time. Patients are not limited to a maximum duration of therapy.</p> <p><b>Note:</b></p> <p>2012 PCRS annual report figures used in this section (6.2.9). 2015 PCRS annual report figures are available from <a href="http://www.pcrs.ie">www.pcrs.ie</a>&gt; PCRS Publications&gt; PCRS, Financial and Statistical Analysis.</p>
<p>45 Person #13 Personal</p>	<p>Something that public health, policy makers and the public vitally need to be made aware of is that nicotine has never been proven to be addictive in humans. Experts who work with and study nicotine on a daily basis say it isn't addictive. Vapers routinely find that we gradually lose our tolerance for nicotine with the more innovative, superior devices (non Tobacco Industry devices) and are forced by the body to reduce the amount we use.</p> <p>Vapers can take anything up to around a year to find their personal essential flavours and their right time, before being able to make the switch to vaping exclusively. Some even switch accidentally. I was lucky and switched 100% on the first day - it was so easy for me. I started out on 24mg/ml, having smoked 15-20 cigarettes a day and now use 6mg/ml and 3mg/ml – I found it would suddenly feel a little too strong and less enjoyable. I reduced in 6mg/ml intervals and never even noticed the change. That isn't addiction. This should shut down, once and for all, the oft touted lie that is the gateway to smoking theory. In fact, when pharma applied for and won approval for the long term and concomitant use of NRT with other nicotine containing products, including cigarettes, the FDA gave their approval with no concerns for safety or abuse (addiction), so their pretend concerns about nicotine go against what they already know.</p> <p>I've been vaping for four years and although I know I could go without nicotine, I intend to carry on with it because of its benefits. Aside from the fact that it's proven to be beneficial for various cognitive diseases such as depression, Alzheimer's, Parkinson's, Schizophrenia, as well as Ulcerative Colitis; due to the bacterioidal properties of both nicotine and propylene glycol, I haven't had a single cough, cold or chest infection in my time as a vaper, but I used</p>

to have several a year as a smoker and I've seen many, many others say the same.

The habit of the smoking behaviour is very deeply ingrained, which is another reason I choose to continue to vape and it's a big reason why vaping works; because it mimics smoking and prevents relapse to smoking. However, I also vape because I quite simply enjoy it and certainly more so than smoking, which is important. Also necessary, the myriad of sweet flavours distance vapers from the taste of tobacco, which after vaping exclusively for a week or so, becomes absolutely putrid to taste and smell. Having tried numerous times to quit with pharma's poor cessation offerings, which have a failure rate of 94-98.2%, this is the first time I know for sure I will never smoke again. Regarding flavours, they are not aimed at children ..... the market is millions of smokers. Of the very few youth who vape (the majority being smokers) and often without nicotine, if they were the only ones who used bubblegum and candy floss, it wouldn't be worth manufacturing. Demand = Supply. Vapers get their tastebuds back and it's enjoyable revisiting retro flavours. Vapers also need to switch flavours throughout the day to keep them tasting fresh to the tastebuds, so several different bottles at least are necessary. Anything that helps you make the switch is important.

When NRT came to the market, suddenly the "nicotine is highly addictive; as addictive as cocaine and heroin" was massively ramped up and self reinforced everyday by smokers trying to quit. A public health fail done in order to sell patches and gum for pharma. When you consider that it can be prescribed to 12 year olds, is available over the counter as NRT and was always available in litre bottles and more of 72mg/ml, can ethically be given to never smokers in clinical trials for cognitive diseases, in high doses for six months at a time and nobody became addicted, commonsense tells you that message is completely wrong. Eliquid has been tested and found it was in completely the wrong poison category, alongside cyanide and formaldehyde. In fact it's less dangerous than washing up liquid.

For years it was thought the lethal dose was 60mg. This was based on dubious self experiments from 150 years ago. A little known fact is that we now know that half the lethal dose is 1,000-1,500mg .... 1,500mg having been survived several times. So you can see that the amounts vapers use are tiny and safe and to only allow 20mg/ml which doesn't account for heavier smokers and only in 10ml bottles is completely unnecessary, unfair, expensive and wasteful. In order to commit suicide with nicotine, you would need to be unconscious to stop the vomiting (the body's safety mechanism) and have someone feed about 3,000mg of nicotine intravenously. Also, children would never voluntarily drink nicotine eliquid beyond the first taste because it tastes utterly disgusting, with none of the flavours you get when you vape it. However this is also about parental responsibility, common sense and to my knowledge, the vast majority of bottles are childproof. It's also no problem if you get some on the skin; it's recommended to be washed off within an hour. In fact, everyone tests positive for nicotine as it's part of our daily diet, being in a variety of vegetables, together with tea.

There are two vaping markets. The first and much larger market is made up of small independent businesses selling superior, innovative refillable open system devices and the second is owned by a handful of tobacco companies with their vastly inferior closed system cigalikes. The difference between a smartphone and a 1st generation mobile. With the overly strict regulations in the TPD, the tobacco companies are the only ones who can easily comply and can also afford the expensive costs involved. This hands the monopoly to them, removing the best competition they ever had and protecting cigarettes. Companies close, hundreds of jobs are lost and vapers lose the one thing that finally helped them quit or significantly cut down. Vapers finally have a method that works well and has caused millions worldwide to switch away from lit tobacco - I cannot tell you how wonderful it feels to know that I am finally free from it. All that vaping needs is the usual consumer regulations, 18+ only (though that's debatable for youth smokers), child proof caps, eliquid testing and appropriate warning labels; all mostly done before the TPD came into force.

There's a massive amount of propaganda emanating from the USA, largely to do with outdated ideology, financial agendas and pharma's influence, as vaping is competition to their cessation goods and will curtail smoking related diseases which they treat. Nobody more than vapers want to know all they can on the subject. Along with many others, I have followed the research diligently and we know who and what information we can trust. Below I have added some trustworthy sites for you. We also have a huge amount of shared experiences that we'd love to impart if only public health and policy makers would just engage with us and ask. 20 million+ vape, that's a huge number of cigarettes not smoked. In many millions of hours of use in over ten years on the market, no ill effects, diseases or deaths have occurred when used as intended and its proven there is absolutely no risk to bystanders from the vapour, so no reason for indoor bans. According to the a Royal College of Physicians and Public Health England, vaping is at least 95% safer than smoking and very probably more. The same cannot be said of Varenicline/ Champix/Chantix which, over a five year period in the USA caused 500 suicides, 1,800 attempted suicides and 10,000 serious adverse events, such as severe psychosis with, so far, 3,000 lawsuits settled by Pfizer. Despite this, the FDA deem it safe for use and say the benefits outweigh the risks. Not if you're a smoker!! Vaping is the solution to combustible tobacco, not another problem. Please don't let the perfect stand in the way of the good .... this is the best and only way to have a chance of reaching the endgame in my opinion. We are literally fighting for our lives and the lives of all smokers, please join us.

Is Nicotine Addictive? [http://scanmail.trustwave.com/?c=6600&d=hd6X2ISW-E\\_QCb-gqPlde71PaTnRSSujjHFn5xpqcA&s=226&u=http%3a%2f%2fwww%2eecigarette-politics%2ecom%2fis-nicotine-addictive%2html](http://scanmail.trustwave.com/?c=6600&d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjHFn5xpqcA&s=226&u=http%3a%2f%2fwww%2eecigarette-politics%2ecom%2fis-nicotine-addictive%2html)

Experts' Quotes: [http://scanmail.trustwave.com/?c=6600&d=hd6X2ISW-E\\_QCb-gqPlde71PaTnRSSujjHNns0hteQ&s=226&u=http%3a%2f%2fwww%2eecigarette-politics%2ecom%2fvaping-quotes%2html](http://scanmail.trustwave.com/?c=6600&d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjHNns0hteQ&s=226&u=http%3a%2f%2fwww%2eecigarette-politics%2ecom%2fvaping-quotes%2html)

Chemical a Dependency and Nicotine [http://scanmail.trustwave.com/?c=6600&d=hd6X2ISW-E\\_QCb-](http://scanmail.trustwave.com/?c=6600&d=hd6X2ISW-E_QCb-)

	<p>gqPlde71PaTnRSSujjHJt5Rk7IA&amp;s=226&amp;u=http%3a%2f%2fwww%2ecigarette-politics%2ecom%2fchemical-dependency-and-nicotine%2ehtml</p> <p>Nicotine Without Smoke: Tobacco Harm Reduction. <a href="http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjCBp6E5pJQ&amp;s=226&amp;u=https%3a%2f%2fwww%2ercplondon%2eac%2euk%2fprojects%2foutput%2fnicotine-without-smoke-tobacco-harm-reduction-0">http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjCBp6E5pJQ&amp;s=226&amp;u=https%3a%2f%2fwww%2ercplondon%2eac%2euk%2fprojects%2foutput%2fnicotine-without-smoke-tobacco-harm-reduction-0</a></p> <p>How much nicotine kills a human by Bernd Mayer. <a href="http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjC454x4_Iw&amp;s=226&amp;u=https%3a%2f%2fwww%2encbi%2enlm%2enih%2egov%2fpmc%2farticle%2fPMC3880486%2f">http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjC454x4_Iw&amp;s=226&amp;u=https%3a%2f%2fwww%2encbi%2enlm%2enih%2egov%2fpmc%2farticle%2fPMC3880486%2f</a></p> <p>Ecigarette Eliquid Is Not Highly Toxic - It's Less Dangerous Than Washing Up Liquid. <a href="http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjHE-5UE-dw&amp;s=226&amp;u=http%3a%2f%2fwww%2ecita%2eorg%2euk%2fecita-news%2fe-cigarette-liquid-not-highly-toxic-it%25E2%2580%2599s-less-dangerous-washing-liquid">http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjHE-5UE-dw&amp;s=226&amp;u=http%3a%2f%2fwww%2ecita%2eorg%2euk%2fecita-news%2fe-cigarette-liquid-not-highly-toxic-it%25E2%2580%2599s-less-dangerous-washing-liquid</a></p> <p>Recommended Informative Blogs:</p> <p>Clive Bates, The Counterfactual. <a href="http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjHJr4Etudw&amp;s=226&amp;u=http%3a%2f%2fwww%2eclivebates%2ecom%2f%3f%3d4633">http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjHJr4Etudw&amp;s=226&amp;u=http%3a%2f%2fwww%2eclivebates%2ecom%2f%3f%3d4633</a></p> <p>Dr. Konstantinos Farsalinos - Leading Ecigarette Scientist. <a href="http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjCFn4k5tJw&amp;s=226&amp;u=http%3a%2f%2fecigarette-research%2eorg%2fresearch%2findex%2ephp">http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjCFn4k5tJw&amp;s=226&amp;u=http%3a%2f%2fecigarette-research%2eorg%2fresearch%2findex%2ephp</a></p> <p>Dr Michael Siegel, The Rest Of The Story - uncovering ecigarette junk science: <a href="http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjC5psUtvIw&amp;s=226&amp;u=http%3a%2f%2ftobaccoanalysis%2eblogspot%2eco%2euk%2f">http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjC5psUtvIw&amp;s=226&amp;u=http%3a%2f%2ftobaccoanalysis%2eblogspot%2eco%2euk%2f</a></p> <p>Dr Brad Rodu, Tobacco Truth. <a href="http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjC9q4hpuIA&amp;s=226&amp;u=http%3a%2f%2frodutobaccotruth%2eblogspot%2eco%2euk%2f">http://scanmail.trustwave.com/?c=6600&amp;d=hd6X2ISW-E_QCb-gqPlde71PaTnRSSujjC9q4hpuIA&amp;s=226&amp;u=http%3a%2f%2frodutobaccotruth%2eblogspot%2eco%2euk%2f</a></p>
<p>46 Public Health England Organisation</p>	<p>Thank you for the opportunity to comment on the Health Information and Quality Authority's draft review of smoking cessation interventions. We commend the quality of the work. As in Ireland, smoking in England remains a major public health concern and an analysis of methods available to help existing smokers migrate away from cigarette consumption is valuable.</p> <p>We note that there is currently a form of centralised funding for delivery of very brief advice. Based on the known effectiveness of this intervention we advise on efforts to protect this activity as a method of increasing quit attempts, particularly in primary and secondary care. However, the value of very brief advice in the context of smoking cessation is likely to be enhanced if a greater proportion of smokers are able to swiftly access evidence based behavioural support along with one or more quitting aid/s via HSE smoking cessation clinics.</p>

E-cigarettes (ECs) are the most popular stop smoking aid in England and Public Health England's independent evidence review estimated ECs to be 95% less harmful than cigarettes.<sup>1</sup> Furthermore, the Royal College of Physicians concluded that ECs are unlikely to exceed 5% of the harm from smoking tobacco.<sup>2</sup>

Based on what is known about EC with respect to their constituents, popularity and patterns of use, PHE, along with colleagues in England have developed a consensus which seeks to maximise the public health opportunities and minimise the risks.<sup>3</sup> We note the current position of HSE states that ECs are not advocated as a means of quitting and believe that there might be a role to address misconceptions about relative risks among smokers and support the method of cessation chosen.

In the context of smoking cessation in England, EC use to quit among the general population of smokers remains high (40.6%).<sup>4</sup> Use of EC in local stop smoking services in 2015/16 was low (3%). When ECs were used as a cessation aid with behavioural support, success rates were high (60.7%).<sup>5</sup> We would encourage consideration of the recommendations for practice found in the National Centre for Smoking Cessation and Training's '*Electronic cigarettes: A briefing for stop smoking services*'.<sup>6</sup>

Public Health England. E-cigarettes: an evidence update. <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

Public Health England. E-cigarettes: a developing public health consensus. [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/534708/E-cigarettes\\_joint\\_consensus\\_statement\\_2016.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/534708/E-cigarettes_joint_consensus_statement_2016.pdf)

'The smoking toolkit study': a national study of smoking and smoking cessation in England. <http://www.smokinginengland.info/latest-statistics/>

NHS Digital. Statistics on NHS Stop Smoking Services: England, April 2015 to March 2016. <http://content.digital.nhs.uk/catalogue/PUB21162>

National Centre for Smoking Cessation and Training. Electronic cigarettes: A briefing for stop smoking services. [http://www.ncsct.co.uk/usr/pub/Electronic\\_cigarettes.\\_A\\_briefing\\_for\\_stop\\_smoking\\_services.pdf](http://www.ncsct.co.uk/usr/pub/Electronic_cigarettes._A_briefing_for_stop_smoking_services.pdf)

47	RCPI Public Health	Organisation	See Appendix 11.
48	HSE Mental Health Division	Organisation	<p>The document is a welcome evidence based document outlining the various clinical pharmacological/behavioural therapies available to assist quit programmes.</p> <p>It is comprehensive in its reference to available studies.</p> <p>It will be of use in underpinning the tools currently available/in use and informing clinical guidelines.</p> <p>One comment - I note that there was no Mental Health Divisional representation on the EAG?</p>

## **6. References**

1. QSR International Pty Ltd. NVivo qualitative data analysis software, version 11. 2017.
2. Bullen C, Howe C, Laugesen M, McRobbie H, Parag V, Williman J, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet* (London, England) [Internet]. 2013; 382(9905):[1629-37 pp.]. Available from: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/021/CN-00876021/frame.html>.
3. Caponnetto P, Campagna D, Cibella F, Morjaria JB, Caruso M, Russo C, et al. Efficiency and Safety of an eLectronic cigAreTte (ECLAT) as Tobacco Cigarettes Substitute: A Prospective 12-Month Randomized Control Design Study. *PloS one* [Internet]. 2013; 8(6). Available from: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/653/CN-00904653/frame.html>.
4. Shahab L, Dobbie F, Hiscock R, McNeill A, Bauld L. Prevalence and Impact of Long-term Use of Nicotine Replacement Therapy in UK Stop-Smoking Services: Findings From the ELONS Study. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*. 2016.
5. McNeill A, Brose L, Calder R, Hitchman S, Hajek P, McRobbie H. E-cigarettes: an evidence update. A report commissioned by Public Health England. London, England: Public Health England, 2015.
6. Royal College of Physicians. Nicotine without smoke, Tobacco harm reduction. London: RCP, 2016.
7. Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. *Annals of internal medicine*. 2017.
8. Medicines and Healthcare Products Regulatory Agency. Marketing authorisations granted in November 2015. London: MHRA, 2015.
9. Department of Health (Ireland). Healthy Ireland Survey. Available from the Irish Social Science Data Archive (ISSDA) 2015.
10. Ebbert JO, Hays JT, Hurt RD. Combination pharmacotherapy for stopping smoking: what advantages does it offer? *Drugs*. 2010;70(6):643-50.
11. National Institute for Health Research. A randomised controlled trial to examine the efficacy of e-cigarettes compared with nicotine replacement therapy, when used within the UK stop smoking service London: NIHR; 2014 [Available from: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/12167135/#/>].



## **7. Appendices**

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 1: ASH UK**

# ASH (UK) response: HTA of smoking cessation interventions for public consultation

Health Information and Quality Authority (HIQA): Ireland

**Name :** Deborah Arnott MBA FRCP (Hon)

**Address:**

Action on Smoking & Health  
Suites 59-63, 6<sup>th</sup> Floor, New House  
67-68 Hatton Garden  
London EC1N 8JY

**Contact details:**

e-mail: [deborah.arnott@ash.org.uk](mailto:deborah.arnott@ash.org.uk)

T: 020 7404 0242

M: +44 (0)7976 935 987

F: 020 7404 0850

## Part 1

Reply on behalf of Action on Smoking and Health (UK)

## Part 2

1. ASH (UK) is a health charity working towards the elimination of harm caused by tobacco. ASH receives funding for its full programme of work from the British Heart Foundation and Cancer Research UK. It has also received project funding from the Department of Health to support tobacco control. ASH does not have any direct or indirect links to, or receive funding from, the tobacco industry.
2. ASH (UK) is responding to this consultation because we believe that the UK experience in smoking cessation interventions and assessing the evidence in relation to different forms of intervention (including the use of electronic cigarettes) may be of assistance to the Authority. We of course understand that there may be specific circumstances in Ireland that could require a different policy mix than the optimal one for the UK.
3. In general, we consider the draft HTA to be a thorough and high quality assessment of the available evidence and to contain appropriate recommendations. In particular, we welcome the HTA's conclusion that the available evidence shows that, for the general population, the most effective stop smoking intervention is the provision of varenicline together with NRT and behavioural support (p22, Executive Summary et passim). We agree that, absent other factors applying to individual patients, this should be the model for stop smoking services in Ireland and elsewhere.

4. Our comments are confined to the small parts of the draft HTA which we consider may not be well supported by the available evidence, and to some policy considerations which may not have been fully considered. We consider most of these instances to arise in relation to the use of electronic cigarettes, and by extension other potential “harm reduction” products that may in future be available in Ireland. Our comments should not be taken as implying any negative assessment of the draft HTA taken as a whole.

### **Ethical Considerations**

5. We consider the section of the draft HTA on ethical, societal and legal implications to be particularly important. Page 272 discusses the principle of respect for autonomy – which may be defined in this context as the right of patients to make their own decisions on their healthcare and lifestyle, supported by medical professionals providing them with the best available information and advice. We believe that this principle includes an obligation on medical professionals not to stress the benefits of particular interventions or actions without also informing patients of potential risks, and that it also includes an obligation not to place undue emphasis on risks where the evidence shows a particular intervention or action is much more likely to confer benefits. It is well established that human beings are typically poor judges of risks relative to benefits, and this requires medical professionals to be particularly careful not to describe actual or potential risks in a way that discourages patients from utilising beneficial interventions.
6. On page 272, it is suggested that smoking cessation interventions could “take the form of either a harm reduction strategy or a more absolutist approach” and that “a harm reduction strategy aims to eliminate the damaging effects of a particular behaviour, without eliminating the behaviour itself. A more absolutist approach would seek to eliminate the behaviour entirely. For example drug addiction and prostitution are perceived to be inherently wrong ...”
7. This prompts two comments. First, what is the relevant “behaviour” in the context of this report? Is it the consumption of tobacco, mainly by smoking? Or is it the consumption of nicotine? It is of course the nicotine which creates addiction in smokers, but the smoke that does the overwhelming preponderance of harm. Secondly, we would suggest that not all drug addiction is in fact considered “inherently wrong”. Public beliefs on what is “wrong” in this context are heavily influenced by the legal status of the substance and the harm caused by its use. For example, the UK (and no doubt Ireland) has many people who are dependent on caffeine and could be described as “addicted”. This is not considered “inherently wrong”. The report gives no evidence to support the conclusion that dependence on nicotine should be considered – “inherently wrong”. This is a critical question when considering which health interventions to recommend to smokers, and what to say about them.

### **Health Evidence on Electronic Cigarettes**

8. We agree with the statement of page 37 of the HTA that “There is general agreement that in relation to tobacco smoking, e-cigarette use reduces users’ exposure to toxic substances, and in the UK, support appears to be growing within the public health system for their use.”, with the important rider that public health advocates support

regulation being used to encourage their use by smokers seeking to cut down or quit, and discourage their use by never smokers, particularly young people.

9. Page 76 states that electronic cigarettes have become a popular aid for smoking cessation in Ireland, with the Healthy Ireland survey reporting that 29% of quit attempts were supported through electronic cigarette usage. We consider this to be a positive development, as is the reported higher rate of quit attempts and intentions to quit among current smokers who use electronic cigarettes
10. Page 179 gives rare cases of nicotine poisoning from vials, and some cases of lithium battery explosions and thermal injuries. These suggest a need for product regulation and consumer advice. (For example UK fire services report that fires from electronic cigarette devices generally result from use of the wrong charger.) They do not give grounds for considering electronic cigarettes to be unsafe per se.
11. Page 183 states, in our view correctly, that “it is likely that e-cigarettes are less toxic than cigarette smoke.” It then states that “e-cigarettes are unlikely to be harmless”, which while this is a reasonable statement, is not helpful unless it is accompanied by consideration of what the threshold of risk is for a recommended cause of action to be considered “harmless”. By analogy, physical activity is routinely recommended to the overweight and obese, but most forms of exercise carry risks and might cause harm, for example through physical injury. It should be noted that our research suggests that increasing numbers of people in Great Britain already think e-cigarettes are equally or more harmful than smoking. The ASH Smokefree Great Britain Survey found that between 2013 and 2016 the perception of harm from electronic cigarettes has changed. The general public and smokers are increasingly failing to recognise that electronic cigarettes are less harmful than smoking. In 2016 only 15% of adults correctly identified that electronic cigarettes are a lot less harmful than smoking whereas 21% correctly identified they were a lot less harmful than smoking in 2013. In addition, more than three times as many people in 2016 than in 2013 think they are as harmful or more harmful than smoking.<sup>1</sup> We note that page 181 et passim of the draft HTA gives considerable evidence of the health benefits of substituting electronic cigarettes use for smoking (lower acrolein levels, etc).
12. The conclusion on page 245 that electronic cigarettes are the most cost-effective form of individual smoking cessation interventions, followed by the combination treatment of varenicline and NRT (which is more costly, but also more effective) supports our observations in paragraphs 8 and 9 above.
13. Page 273 states that it is “challenging” for medical professionals to provide information on the risks and benefits of electronic cigarettes, as “comprehensive safety evaluation cannot be made in the face of incomplete evidence, meaning the public cannot be given full information on which to base their decisions”. We consider this an unhelpful formulation. Most medical interventions carry risks, often quantifiable but sometimes not, and interventions frequently have to be recommended in conditions of imperfect information. Medical professionals should be able to explain the potential benefits and

risks of interventions, and include statements of uncertainty where they are relevant, as set out by the Royal College of Physicians (RCP) in London in its 2016 report, “Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.”<sup>2</sup> This does not constitute “the provision of inaccurate information”, as implied by the draft HTA.

14. On page 293 it is stated that “it is reasonable to await the results of ongoing trials before deciding whether to recommend e-cigarettes in preference to combination NRT for populations where varenicline is contra-indicated, not tolerated or not preferred”. Again, we consider this an unhelpful formulation. It would be reasonable for medical professionals to give advice on electronic cigarettes in line with paragraph 8 above, leaving the final decisions to patients, as required by the principle of autonomy. We note that the RCP in London concluded that: “in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK”.

## **Conclusions**

15. We consider that the draft HTA, while an excellent and thorough document in most respects, needs careful review and amendment in relation to the use of electronic cigarettes.
16. We would also point out that electronic cigarettes are not going to be the last potentially harm reducing product offered to smokers. On 30<sup>th</sup> November 2016, Philip Morris International launched IQOS, a potentially ‘reduced risk’ tobacco product in the UK. The device uses compressed tobacco in a ‘mini-cigarette’ form in a vapouriser. Unlike electronic cigarettes which vapourise nicotine suspended in a liquid, the IQOS heats and vapourises tobacco. PMI has submitted extensive evidence to the US Food and Drug Administration seeking approval for iQOS in the US market, and has already launched the product in several other countries including Japan. A plausible (although very tentative) hypothesis at this stage would be that iQOS (and the related products being developed by other tobacco manufacturers) will cause much less harm than smoked cigarettes, although possibly somewhat more harmful than electronic cigarettes. The Irish government, statutory agencies and health professionals will need to consider a general approach to harm reduction that will enable a rational regulatory and policy response to all harm reduction products aimed at smokers, not simply electronic cigarettes.
17. Finally, we note that in the UK, in January 2016, the Medicines and Healthcare Products Regulatory Agency gave a medicinal licence to British American Tobacco’s e-cigarette e-Voke, which enables doctors to prescribe the vaping device as a smoking cessation aid, although it is not yet commercially available. We agree with the MHRA’s statement on this decision: “we want to ensure licensed nicotine-containing products – including e-cigarettes – which make medicinal claims are available and meet appropriate standards of safety, quality and efficacy to help reduce the harms from smoking.”<sup>3</sup> We would

suggest that the Irish government and statutory agencies should consider actively encouraging manufacturers of electronic cigarettes, and other nicotine containing products, to seek medical licensing, so that where the health case is made, such products can be appropriately advertised and promoted to smokers and to health professionals.

---

<sup>1</sup> ASH. Use of electronic cigarettes (vapourisers) among adults in Great Britain. London. May 2016.

<sup>2</sup> [Nicotine without smoke: tobacco harm reduction](#): Royal College of Physicians 28 Apr 2016.

<sup>3</sup> [BAT e-cigarette wins UK medicine licence](#): Guardian 4 Jan 2016

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 2: Phillip Morris Limited**



## Health Information and Quality Authority HTA on Smoking Cessation Interventions

Philip Morris Limited (“PML”) welcomes the opportunity to respond to the Health Information and Quality Authority (HIQA) consultation on its draft Health Technology Assessment of smoking cessation interventions (the HTA).

Philip Morris International (“PMI”) has invested more than US\$3 billion over the past decade to design, develop and assess innovative tobacco and non-tobacco products that have the potential to reduce individual health risks and population harm in comparison to smoking combustible tobacco products. We call these products Reduced Risk Products (RRPs).<sup>1</sup> We are represented in the Irish e-cigarette market via a leading UK e-cigarette manufacturer, Nicocigs, which markets products under the *Nicocig* (formerly *Nicolites*) and *Vivid* brands.

We recognize that combustible tobacco products are dangerous, and the best way to avoid the harms of smoking is never to start, or to quit. Despite declining trends in smoking prevalence, projections by public health experts using World Health Organization data show that there will likely be more than one billion smokers around the globe for the foreseeable future.<sup>2</sup> Much more can and should be done to reduce health risks for those who intend to continue to smoke. Today, a substantial and growing number of public health experts advocate that governments adopt the policy of tobacco harm reduction, which “*focuses on encouraging the use of less dangerous forms of tobacco/nicotine by those who prefer not to abstain from all tobacco/nicotine products,*”<sup>3</sup> to complement the other major strategies for reducing smoking-related harm (i.e., prevention and cessation).

Tobacco harm reduction is not a theoretical concept: Millions of adult smokers around the world, and thousands of smokers in Ireland, have switched from cigarettes to electronic cigarettes and other non-combustible alternatives to cigarettes. Many experts in the public health community view these products as significant public health developments. For example, in 2014 over 50 experts characterized reduced risk alternatives to cigarettes as “*among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives...*”<sup>4</sup> In their view, such products can be an important – perhaps even essential – means to reduce the harm caused by smoking:

*Taken together, these tobacco harm reduction products could play a significant role in meeting the 2025 UN non-communicable disease (NCD) objectives by driving down smoking prevalence and cigarette consumption. Indeed, it is hard to imagine major reductions in tobacco-related NCDs without the contribution of tobacco harm reduction. Even though most of us would prefer people to quit smoking and using nicotine altogether, experience suggests that many smokers cannot or choose not to give up nicotine and will continue to smoke if there is no safer alternative available that is acceptable to them.*<sup>5</sup>

---

<sup>1</sup> Reduced-Risk Products (“RRPs”) is the term we use to refer to products that present, are likely to present, or have the potential to present less risk of harm to smokers who switch to these products versus continued smoking. We have a range of RRP’s in various stages of development, scientific assessment and commercialization. Because our RRP’s do not burn tobacco, they produce far lower quantities of harmful and potentially harmful compounds than found in cigarette smoke.

<sup>2</sup> See *The Lancet*, volume 385, 9972, March 2015.

<sup>3</sup> Kiviniemi M. & Kozłowski L., Deficiencies in public understanding about tobacco harm reduction: results from a United States national survey, *Harm Reduction Journal*, July 2015, available at: <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-015-0055-0>.

<sup>4</sup> Letter from Specialists in Nicotine Science and Public Health Policy, to Dr Margaret Chan, WHO Director General (May 26, 2014), p. 1, available at: <http://nicotinepolicy.net/documents/letters/MargaretChan.pdf>.

<sup>5</sup> *Id.*

Burning tobacco creates smoke which contains high levels of harmful and potentially harmful constituents (“HPHCs”) that are widely recognized to be the most likely causes of smoking-related diseases.<sup>6</sup> Smoke also contains nicotine but experts such as the UK Royal College of Physicians agree that nicotine, while addictive and not risk free, is not the primary cause of smoking related disease:

*“[S]mokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.”<sup>7</sup>*

Similarly, the RCP concluded in 2007 and reiterated in 2016 that *“the health and life expectancy of today’s smokers could be radically improved by encouraging as many as possible to switch to a smoke-free source of nicotine.”<sup>8</sup>*

Electronic cigarettes do not burn tobacco and do not generate smoke. They use battery-powered electronics to heat a nicotine-containing solution to create a vapor with fewer and significantly lower levels of HPHCs than cigarette smoke.<sup>9</sup> There is a growing consensus among public health experts that e-cigarettes present substantially less risk of harm than continued smoking. For example, a 2014 systematic review of all the available evidence on electronic cigarettes concluded that *“[c]urrently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes.”<sup>10</sup>* This and more recent studies led the RCP to conclude that nicotine-containing products that do not involve combustion are likely to be at least 95 percent less hazardous than smoking cigarettes<sup>11</sup>, and to urge governments to *“[p]romote e-cigarettes widely as a substitute for smoking.”<sup>12</sup>*

To that end, we read with interest the discussion in the draft HTA regarding the role of e-cigarettes as an alternative to cigarettes for adult smokers. While the HTA focuses on randomized controlled trials and notes the low number of available e-cigarette trials, multiple analyses of the potential of e-cigarettes as alternatives to smoking for adult smokers have been published in recent years. This data, as well as anecdotal evidence, should not be ignored as HIQA weighs policy options.

---

<sup>6</sup> United States Food & Drug Administration, Center for Tobacco Products, Issue Snapshot: Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products, January 2015, available at:

<http://www.fda.gov/downloads/tobaccoproducts/publichealthsciencesresearch/hphcs/ucm435035.pdf>.

<sup>7</sup> Royal College of Physicians 2007.

<sup>8</sup> Tobacco Advisory Group, Royal College of Physicians, Nicotine without smoke: Tobacco harm reduction, April 2016, p. 2, available at:

<https://www.rcplondon.ac.uk/file/3563/download?token=uV0R0Twz>. See also Royal College of Physicians, Harm reduction in nicotine addiction: Helping people who can’t quit, preface (2007), available at: <http://www.tobaccoprogram.org/pdf/4fc74817-64c5-4105-951e-38239b09c5db.pdf>.

<sup>9</sup> See, for example, Britton J. Bogdanovica I, Electronic cigarettes: A Report Commissioned by Public Health England (2014) (“Producing nicotine vapour from a solution rather than by burning tobacco means that electronic cigarette vapour is free from almost all of the many toxic chemicals that accompany nicotine in cigarette smoke.”), available at:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/311887/Ecigarettes\\_report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf).

<sup>10</sup> Farsalinos K. & Polosa R., Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review, Therapeutic Advances in Drug Safety (2014), available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/>

<sup>11</sup> UK Royal College of Physicians, Nicotine without smoke: tobacco harm reduction (2016),

<https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>; McNeill A, Brose LS, Calder R, Hitchman SC, Hajek P, et al., E-cigarettes: An evidence update, A report commissioned by Public Health England (2015), [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/457102/Ecigarettes\\_an\\_evidence\\_update\\_A\\_report\\_commissioned\\_by\\_Public\\_Health\\_England\\_FINAL.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf)

<sup>12</sup> Royal College of Physicians, Press release, Promote e-cigarettes widely as substitute for smoking says new RCP report, April 28, 2016, available at: <https://www.rcplondon.ac.uk/news/promote-e-cigarettes-widely-as-substitute-smoking-says-new-rcp-report>.

For example, in the UK, e-cigarettes are now the most common means by which smokers quit using combustible tobacco products. Experts have found that smokers are nearly 50% more likely to successfully quit smoking using e-cigarettes than with no aid or over the counter nicotine replacement therapy,<sup>13</sup> and e-cigarettes have already helped millions of people switch from smoking to non-combustible products. ASH UK has concluded that there are “*an estimated 2.8 million adults in Great Britain [who] currently use electronic cigarettes,*”<sup>14</sup> of which approximately 1.3 million are now ex-smokers. Similarly, a recent study found that 6.1 million people in Europe have quit smoking using electronic cigarettes.<sup>15</sup>

Moreover, Initiation of regular nicotine use with e-cigarettes is rare<sup>16</sup>, and regular use is limited almost exclusively to current or former smokers.<sup>17</sup> Furthermore, while “*there have been claims that EC [electronic cigarettes] are acting as a ‘gateway’ to smoking in young people,*”<sup>18</sup> a systematic review by Professor Peter Hajek and others examined that claim and concluded that “*the evidence does not support this assertion. Regular use of EC by non-smokers is rare and no migration from EC to smoking has been documented (let alone whether this occurred in individuals not predisposed to smoking in the first place).*”<sup>19</sup> If anything, e-cigarettes appear to be a gateway out of smoking.<sup>20</sup>

E-cigarettes are not the only product to offer promise as an alternative to smoking for those adult smokers who intend to continue smoking. As recognized by more than 50 of the world’s leading tobacco and nicotine policy experts:

*There are now rapid developments in nicotine-based products that can effectively substitute for cigarettes but with very low risks. These include for example, e-cigarettes and other vapour products, low-nitrosamine smokeless tobacco such as snus, and other low-risk non-combustible nicotine or tobacco products that may become viable alternatives to smoking in the future.*<sup>21</sup>

Innovative products backed by solid science can play an important role in reducing the harms of smoking. PMI is making significant efforts to develop and scientifically assess a range of innovative products that eliminate combustion, generate a vapour in which most of the HPHCs found in cigarette smoke are significantly reduced or eliminated, and which smokers will accept as alternatives to cigarettes.

---

<sup>13</sup> West, R., et al., Estimating the population impact of e-cigarettes on smoking cessation in England, *Addiction*, 2016

<sup>14</sup> ASH Fact Sheet, Use of electronic cigarettes (vapourisers) among adults in Great Britain, May 2016, available at: [http://www.ash.org.uk/files/documents/ASH\\_891.pdf](http://www.ash.org.uk/files/documents/ASH_891.pdf).

<sup>15</sup> K. Farsalinos, press release, New study: 6.1 million Europeans have quit smoking with the use of electronic cigarettes, June 25, 2016, available at: <http://www.ecigarette-research.org/research/index.php/research/research-2016/241-eurob>.

<sup>16</sup> ASH UK Fact Sheet: Use of electronic cigarettes (vapourisers among adults in in Great Britain, May 2016, available at <http://ash.org.uk/information-and-resources/fact-sheets/use-of-electronic-cigarettes-vapourisers-among-adults-in-great-britain/>

<sup>17</sup> UK Royal College of Physicians, Nicotine without smoke: tobacco harm reduction (2016), available at <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>, UK Royal College of General Practitioners, To vape or not to vape? The RCGP position on e-cigarettes, 2016, available at <http://www.rcgp.org.uk/clinical-and-research/clinical-news/to-vape-or-not-to-vape-the-rcgp-position-on-ecigarettes.aspx>; Cancer Research UK, E-cigarettes in stop smoking services, 2016, available at [http://www.cancerresearchuk.org/sites/default/files/e-cig\\_in\\_sss\\_0.pdf](http://www.cancerresearchuk.org/sites/default/files/e-cig_in_sss_0.pdf).

<sup>18</sup> Hajek P. et al., Electronic cigarettes: Review of use, content, safety, effects on smokers, and potential for harm and benefit, *Addiction*, November 2014, available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4487785/>.

<sup>19</sup> *Id.*

<sup>20</sup> ASH UK Fact Sheet – Use of electronic cigarettes among children in Great Britain, October 2016, available at <http://casaa.org/wp-content/uploads/FS34Oct2016-ASH-UK-youth-use-stats.pdf>; Cancer Research UK, Research shows most children do not regularly use e-cigarettes, June 2015, available at <http://www.cancerresearchuk.org/about-us/cancer-news/press-release/2015-06-12-research-shows-most-children-do-not-regularly-use-e-cigarettes>.

<sup>21</sup> Letter from Specialists in Nicotine Science and Public Health Policy, to Dr Margaret Chan, WHO Director General (May 26, 2014), p. 1.

We are not alone in this category. Technological innovation is transforming the tobacco industry: A wide range of non-combustible nicotine products has the potential to significantly reduce health risks when compared to smoking. We have communicated an ambitious goal to our shareholders: ensuring that non-combustible alternatives to cigarettes ultimately replace cigarettes. Indeed, we envision a smokefree Ireland and a smokefree world where a broad range of safer alternatives to cigarettes fully satisfies the continuing consumer demand for tobacco and nicotine products.

As HIQA and the Irish government continue to assess this pressing topic, it is important to be mindful of the rapid pace of innovation in the area of potentially less risky alternatives to cigarettes and ensure that regulation and policies leave room for new developments and do not have the unintended consequence of discouraging adult smokers from switching to scientifically substantiated less risky alternatives to cigarettes.

INTERVIEW

# One day I hope we won't sell cigarettes, says Marlboro boss

Philip Morris chief André Calantzopoulos is puffing up his 'reduced-risk' product. But will the public health lobby listen?

[James Ashton](#)

October 23 2016, 12:01am, The Sunday Times



André Calantzopoulos, pictured at Philip Morris's HQ overlooking Lake Geneva in Lausanne, Switzerland: 'I know what a smoker goes through'

André Calantzopoulos has a confession to make. After more than 30 years, the boss of the world's largest publicly traded tobacco company has finally kicked his pack-a-day habit. "You know, I cannot smoke cigarettes," says the Greek-born chief executive of Philip Morris International, compact and intense as he leans over the table.

Has the Marlboro man really gone on a health drive?

Before anti-smoking campaigners rejoice, Calantzopoulos makes clear that he has merely switched one addiction for another. But, believe it or not, he is on a mission to get millions more smokers to stub out their last fag. He can even see the day when Philip Morris stops selling cigarettes entirely: "Not in my time as chief executive, but in my lifetime, I do hope." It's an amazing statement, given the small matter of the 847bn cigarettes his company sold last year.

The future, according to Calantzopoulos, is on the table in front of us. The iQOS smokeless cigarette, which resembles a cross between a smartphone and a cigarette lighter, has a retractable tube into which a short stick of tobacco is inserted and heated to 300C. The user inhales as normal, getting more smoking-like pleasure than vaping provides, but — the company's research suggests — far fewer toxins than smoking because the tobacco is not burned.

“Professionally, from time to time I have to approve new [cigarette] products, but I immediately go back to iQOS because you get used to a completely different taste and impact,” Calantzopoulos says. He feels better for it: “You see that immediately when you exercise.”

The “reduced-risk” product has gone down a storm in Japan, where Philip Morris has recruited most of its 1m iQOS users to date. It will be on sale in the UK soon, in 20 markets by the year-end and 15 more next year as manufacturing capacity steps up.

Now all Calantzopoulos has to do is to convince regulators, led by the US Food and Drug Administration, that the iQOS is less harmful than traditional cigarettes so he can market it accordingly.

The hunt for a “safe” alternative to cigarettes has been going on for years. If Calantzopoulos has finally cracked it, can he envisage a truce with the public health lobby? “I am not asking them to support my marketing efforts but I am asking them to give me an environment that is conducive to this effort being more successful and faster,” he says in a Mediterranean rasp, every now and then inhaling on his iQOS as if playing a tin whistle.

Beware of Greeks bearing gifts, they say. But a full two decades after big tobacco conceded that smoking causes lung cancer and emphysema and spent billions settling legal claims, Calantzopoulos insists his device is no Trojan horse for snaring a new generation of tobacco addicts. “I hope this genuine effort will be appreciated by society.”

Why bother? Despite everything thrown at the industry — smoking bans, health warnings, plain packaging, soaring excise duties — 1.1bn people around the world still puff away. Volumes are declining, by about 2% a year, but population growth means that smoker numbers will be the same in 2025, the World Health Organisation predicts. Good news for Calantzopoulos, who reckons he can increase pack prices by 3% a year without affecting sales.

No wonder investors view Philip Morris, which commands 29% of the market outside America and China, as more cash machine than ash machine. In the eight years since it was demerged from its American parent, it has returned \$83bn to shareholders through dividends and share buybacks — more than half its \$150bn (£122bn) market value.

Tobacco's enduring appeal is not the only driver of profit across the industry. Consolidation, too, has buoyed returns for shareholders. We spoke just days before British American Tobacco launched a \$47bn offer to take control of Camel owner Reynolds America. The raid appears to have surprised Calantzopoulos. “As you know very well, consolidation in this industry, which is very highly concentrated, is very difficult . . . I know there are constantly rumours, but it is a very complex exercise to achieve,” he says.

Calantzopoulos sees a less foggy future once cigarettes are snuffed out altogether. The profit margin from iQOS is potentially higher and taxation will be lower, he hopes. “These are not cigarettes, so they cannot be taxed as cigarettes. The tax should reflect the lower risk.”



Then there is the competitive advantage. Calantzopoulos forecasts up to 50bn extra unit sales by 2020, net of switching customers. “In principle” all will be smokers of rivals’ brands today. Advances in safer smoking may also help Philip Morris crack China, where the state cigarette company operates a near monopoly and 45% of the world’s tobacco is consumed. Finally, there may be a personal imperative. “Being trashed constantly is not exactly the most pleasurable experience you can have,” he concedes.

We are closeted in a meeting room in Philip Morris’s headquarters in Lausanne, Switzerland, where prints of lush forestry and tobacco leaves decorate the walls and a solitary image of the Marlboro cowboy hangs forlornly in a corridor, a relic of the bad old days. Forty miles away, 300 scientists poached from the pharmaceuticals industry work on research and development. There is much excitement that the iQOS attachment rate has been measured at 70% among Japanese smokers. Far fewer go back to cigarettes compared to those that try vaping.

Philip Morris — whose brands include Parliament, Chesterfield and Nicolites ecigarettes — appears to be leading the heat-not-burn charge. However, British American Tobacco has released its own gadget, the iFuse, in Romania. Calantzopoulos wouldn’t mind if his rivals caught up a bit: “We are running this effort essentially on our own, creating a new category and explaining to consumers and regulators.”

In the perverse world of tobacco, the iQOS can be only so successful. In any other industry, a company that spent millions developing a new product — and aiming to be transparent with the science — would chase as many customers as possible. But, to alleviate unease, Philip Morris is pledging to market only to smokers. Sales assistants in its stores have been trained to politely ask curious non-smokers to leave.

Yet Calantzopoulos knows it is hard to block new customers, who might include his own teenage children. “I would be happy if they didn’t, of course, but if they did, at least they should start with this,” he says, tapping the iQOS. “I say it to any child in the world. They should not start smoking.”

The company’s marketing bind is no odder than its continued sponsorship of the Ferrari Formula One team, at a reported cost of \$160m a year, even though it hasn’t been allowed to display the Marlboro brand on F1 cars since 2007. Calantzopoulos says the relationship is valuable for “promotional reasons” and in markets where the firm “cannot talk to consumers”.

Born near Olympia and raised in Athens, he studied electrical engineering at the Swiss Federal Institute of Technology in Lausanne before entering the electronics industry. He joined Philip Morris in 1985, after taking an MBA at Insead in Paris, and served time in eastern Europe as he climbed the ranks.

When the company split from Altria, which owns Marlboro in the US, he was made chief operating officer. In 2013, he succeeded his close colleague Louis Camilleri as chief executive.

Camilleri, now the chairman, praises Calantzopoulos as “an accomplished leader and human being who admirably balances his superior intellect with his most generous heart”.

Investors speculate that the demerger, devised to free the group’s better-performing overseas arm from the threat of US litigation, could soon be reversed. Consider the smoke signals: most legal actions have been resolved, the pair share technology for reduced-risk products and Altria is flush with cash after its part-owned SAB Miller was bought by brewer AB InBev.

“No, I don’t think that is on the books at all,” says Calantzopoulos quietly, his handler frantically waving her arm.

Going back to his early years, friends questioned why he had joined a dying industry. The gradual decline has not surprised him, not least because of the way smokers have been lectured to from on high.

“I know what a smoker goes through. Sometimes it would be good if people who work on public health spent a little bit of time understanding people’s behaviour. Smokers don’t think they are sick.”

There is just time for a word on Greece, where his mother still lives. Calantzopoulos thinks it is time for the market reforms there to stop and investment to return. “Some stability is needed, but you know it will take years. You need to restore institutional respect.”

Sitting atop big tobacco as he does, it sounds a familiar challenge.

## The life of André Calantzopoulos



Old favourite: Good Will Hunting MOVIESTORE/REX/SHUTTERSTOCK

### Vital statistics

**Born:** December 18, 1957

**Status:** married, with a teenage son and daughter

**School:** 2nd Gymnasium of Athens

**University:** Ecole Polytechnique Fédérale de Lausanne (electrical engineering degree)

**First job:** development engineer at Lavanchy Electronique

**Pay:** \$16.3m (£13.3m) in 2015

**Cars:** several, including a Tesla

**Home:** Chailly in Lausanne

**Favourite book:** Guns, Germs & Steel, by Jared Diamond

**Music:** pop and jazz



**Film:** Good Will Hunting

**Gadget:** iQOS

**Last holiday:** Maldives

**Charity:** "I support those dealing with education and communicable diseases"

### **Working day**

The chief executive of Philip Morris International gets up at 6.30am when a personal trainer arrives at his house. "That forces me to do some exercise otherwise you find all the excuses on earth," André Calantzopoulos says. He drives to the office, arriving by 9.30am. His day is a series of meetings with direct reports, but "there are always unforeseen things — that is the beauty of the job". Lunch is usually something light at his desk. There are few evening engagements if he is in Lausanne. Calantzopoulos aims to be home by 8pm to eat with his family. Half the time he travels, using the company's corporate jet. Most board meetings are in New York.

### **Downtime**

Calantzopoulos winds down with watersports. He skis in winter and scuba dives in summer. As well as cars, he collects fine wine. Weekends are devoted to his wife, whom he met at work, and children: "I spend time as much with them as I can.

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 3: Irish Medical Organisation (IMO)**



IRISH MEDICAL  
ORGANISATION  
Ceardchumann Dochtúirí na hÉireann

IMO Response to the Health Information and Quality  
Authority Consultation

On the Draft Health Technology  
Assessment (HTA) of Smoking Cessation  
Interventions

January 2017

Cian O'Dowd  
Policy and International Affairs Officer  
Irish Medical Organisation

10 Fitzwilliam Place  
Dublin 2

Tel: (01) 6767 273  
Fax: (01) 6612 758  
E-mail: [codowd@imo.ie](mailto:codowd@imo.ie)  
Website: [www.imo.ie](http://www.imo.ie)

## Consultation Response

The Irish Medical Organisation (IMO) welcomes the publication of the draft Smoking Cessation Health Technology Assessment by the Health Information and Quality Authority as an important resource to inform public policy decisions pertaining to smoking cessation. The IMO also acknowledges that this Health Technology Assessment is one of the first of its kind in Europe, and it is hoped that knowledge-sharing across the continent on the evidence base for various smoking cessation interventions can lead to a reduction in the prevalence of tobacco use and improved health policy throughout Europe.

Despite decades of public health measures aimed at reducing the prevalence of smoking, approximately one-in-five Irish people (23%) aged 15 and over smoke.<sup>1</sup> While this figure remains unacceptably high, it nevertheless represents a reduction from the 29% of those aged 15 and over who smoked in 2007.<sup>2</sup> Of concern, however, is that smoking rates are highest among those aged 25 to 34 (33%), and the recruitment of new smokers continues at a high rate, with 20% of those aged under 25 currently smoking.<sup>3</sup> As acknowledged in the draft Health Technology Assessment, approximately 5,500 smokers die each year in Ireland from tobacco-related diseases.<sup>4</sup> The human costs of smoking can be reduced however.

Almost half (48%) of all those who smoked in the past year have made an attempt to quit during that period, whilst three-in-five smokers are at least thinking about quitting.<sup>5</sup> A third of smokers who saw their general practitioner in the past 12 months had discussed ways of giving up smoking.<sup>6</sup> Additionally, it is government policy to reduce the prevalence of smoking in Ireland to below 5% of the adult population.<sup>7</sup> Medical professionals remain integral to improving the rates of smoking cessation, as research indicates that patients who interact with their doctors to achieve smoking cessation attain higher rates of success.<sup>8</sup> Accordingly, the IMO looks forward to the introduction of the findings of this Health Technology Assessment into medical practice in Ireland, which it is hoped will assist in raising the rates of successful smoking cessation.

The IMO also welcomes the conclusion of the draft Health Technology Assessment, that a “high level of uncertainty surrounding both the clinical effectiveness and costs of” e-cigarettes or non-medicinal nicotine delivery systems, a view expressed by the IMO in its submission to the Department of Health Consultation on Legislation in Relation to the Sale of Tobacco Products and Non-Medicinal Nicotine Delivery Systems in January 2015. In this submission, the IMO stated:

“While academic debate surrounding e-cigarettes remains lively, the emerging consensus is that these products are largely safer to use, at least in terms of immediate or short-term health consequences, than traditional combustible cigarettes. Nevertheless, apart from containing nicotine, a highly addictive substance that may carry its own health risks or

---

<sup>1</sup> Ipsos MRBI, *Healthy Ireland Survey 2016: Summary of Findings*, Dublin, The Stationery Office, 2016, p. 2.

<sup>2</sup> K. Moran *et al.*, *SLÁN 2007: Survey of Lifestyle, Attitudes & Nutrition in Ireland: Main Report*, Dublin, Department of Health and Children, 2008, p. 74.

<sup>3</sup> Ipsos MRBI, *Healthy Ireland Survey 2016: Summary of Findings*, Dublin, The Stationery Office, 2016, p. 15.

<sup>4</sup> Health Service Executive, *Smoking – The Facts*, available at: <http://www.hse.ie/eng/about/Who/TobaccoControl/KF/>.

<sup>5</sup> Ipsos MRBI, *Healthy Ireland Survey 2016: Summary of Findings*, Dublin, The Stationery Office, 2016, p. 15.

<sup>6</sup> *Ibid.*

<sup>7</sup> Department of Health, *Tobacco Free Ireland Action Plan*, Dublin, Department of Health, 2014, p. 1.

<sup>8</sup> L.F. Stead, G. Bergson, T. and Lancaster, ‘Does advice from doctors encourage people who smoke to quit’, *Cochrane Database of Systematic Reviews*, Issue 2, 2008.

encourage the use of other nicotine products, there are indications that e-cigarettes contain similar toxicants as ordinary tobacco smoke, albeit at lower levels.

For this reason caution must be exerted, particularly as question marks still exist as to whether e-cigarettes have the potential to appeal to current non-smokers who may become habitual e-cigarette users, developing nicotine dependency as a result. Similarly, risks exist that the perceived comparative safety of e-cigarettes may encourage former smokers to engage in their use. Such habitual e-cigarette use or nicotine dependency may act as a gateway to traditional combustible cigarette use. Furthermore, a public perception that e-cigarettes are safe or an uptake in their use by non-smokers or former smokers may serve to re-normalise smoking in the public eye, an undesirable result considering the strong and successful efforts that have been made to raise awareness of smoking's drawbacks by public health and non-governmental bodies, including the IMO, over the past several decades.”<sup>9</sup>

Accordingly, e-cigarettes, or non-medicinal nicotine delivery systems, should not be recommended for use as part of smoking cessation efforts until reliable scientific evidence suggests a clear clinical and public health benefit associated with their use as smoking cessation aids which do not encourage or normalise the use of tobacco products.

---

<sup>9</sup> Irish Medical Organisation, *Irish Medical Organisation Submission to the Department of Health Consultation on Legislation in Relation to the Sale of Tobacco Products and Non-Medicinal Nicotine Delivery Systems*, Dublin, January 2015,

# IMO



IRISH MEDICAL  
ORGANISATION

10 Fitzwilliam Place  
Dublin 2 Ireland  
Telephone  
(01) 676 72 73  
Facsimile  
(01) 661 27 58  
E mail: imo@imo.ie  
Website: www.imo.ie

23 March 2017

Dr. Máirín Ryan  
Deputy Chief Executive and Director of Health Technology Assessments  
Health Information and Quality Authority  
Unit 1301  
City Gate  
Mahon  
Cork  
Co. Cork  
T12 Y2XT

Dear Dr. Ryan,

I write to you in reference to the Health Information and Quality Authority's recently published Draft Health Technology Assessment (HTA) of Smoking Cessation Interventions. As you may be aware, the Irish Medical Organisation submitted a response to your organisation's public consultation on this Draft HTA, which commented on some of the Draft HTA's clinical aspects and welcomed its publication.

It has come to my attention, however, that some incorrect figures have been included in your organisation's Draft HTA, under section "6.2.9 Cost parameter estimates". In particular I refer to the estimate set out on page 238 of the Draft HTA, in which it is stated that "[t]he average cost per visit [is] . . . €55.63 for the GMS population". This costing is in part based on estimates of general practice visits per patient provided in the Living in Ireland Survey, a survey series which concluded in 2001. This survey relied on retrospective reporting by survey respondents, who were asked to recall how many visits to general practice they had undertaken during the past twelve months. This method of estimation has been criticised due to its potential for memory error, which cannot be easily mitigated or controlled for (Short *et al.*, 2009; Wolinsky *et al.*, 2007). The most recent Living in Ireland Survey estimated that General Medical Services (GMS) scheme patients visit their general practitioner 5.3 times annually, on average. However, a more recent examination of visitation rates in Irish general practice, based on actual practice records rather than patients' recall over the past twelve months, concluded that GMS patients visit their general practitioner approximately 7.7 times annually, on average (Behan *et al.*, 2013). Such a calculation is based on a more reliable account of visitation rates, and is therefore a preferable basis from which to derive subsequent calculations. Accordingly, reliance on statistics drawn from the Living in Ireland Surveys to calculate practice income per GMS patient visit are likely to result in incorrect conclusions.

It must also be pointed out that placing a unit cost on an individual consultation in general practice is not easily achieved. The figure of €483.14m in Primary Care Reimbursement Service (PCRS) payments made to general practitioners in 2012 encompasses payments across a spectrum of practice areas. This total payment to general practitioners includes out-of-hours payments,

CEARDCHUMANN  
DOCHTÚIRÍ na hÉIREANN

payments for special items of service, practice supports for various staff, contributions to indemnity insurance, and other miscellaneous payments, in addition to ordinary capitation payments for the care of GMS patients. Accordingly, it is not possible to accurately deduce a unit cost for a consultation in general practice by simply dividing the total of all annual payments made to general practitioners under the PCRS by the estimated total number of consultation with GMS patients per year.

Additionally, it must be pointed out that, while consultations in general practice may discuss patients' lifestyle habits and their contribution to patients' health, there currently exists no agreement for general practitioners to provide targeted smoking cessation interventions or services under the GMS contract. As a result, references to the provision of smoking cessation services in general practice should be caveated by acknowledgement that no agreement presently exists for their provision under the GMS contract.

It is my hope that you will see fit to amend the final publication of the HTA on Smoking Cessation Interventions in view of the concerns that I have raised, and I am happy to provide additional information to you on any of the aforementioned matters.

Yours sincerely,



Cian O'Dowd  
Policy and International Affairs Officer  
Irish Medical Organisation



## **Appendix 4: Irish Vape Vendors Association (IVVA)**



## **IVVA Submission**

The IVVA would like to first acknowledge the considerable amount of work that has gone into the research and preparation of this assessment by the evaluation team from the HTA Directorate and the multidisciplinary Expert Advisory Group, and also to thank HIQA for making it available for public consultation.

### **Background to the Irish Vape Vendors Association**

The IVVA is the only trade association in Ireland for businesses in the vaping industry that is independent of tobacco or pharmaceutical companies.

Our member companies were established by entrepreneurial ex-smokers who successfully switched to vaping from smoking. They are owner-operated, and they and their staff interact daily with smokers looking to switch to vaping, and provide advice, service and support to their customers directly.

Our submission comprises of general comments, along with some more direct responses to portions of the draft HTA, of which we have quoted the relevant paragraphs below.

### **Submission to the consultation**

#### **Overview**

We fully acknowledge that in the context and terms of reference of this HTA, vaping is only regarded as a method of smoking cessation. The IVVA, many ex-smokers who have switched to vaping, and indeed public health professionals in other countries (England for example) sees vaping as harm reduction tool.

Harm reduction can be briefly explained as the substitution of a harmful behaviour (the use of nicotine through smoking combusted tobacco) with that of a less risky one (the use of a safer form of nicotine through vaping).

Given the differences in safety profile of these two forms of nicotine use, with vaping being scientifically proven to be at least 95% safer, it is never preferable for a smoker to continue to smoke rather than to switch to vaping.

If current smokers cannot or do not wish to stop smoking by any other means, they should be actively encouraged and supported to make the switch to vaping.

In response to points raised on page 21 of the draft HTA, it should be re-iterated that increased rates of switching to vaping by smokers will only happen if the conditions for smokers to do so are amenable.

The IVVA's view is that there are policies currently in place in Ireland which are having, and will continue to have, a negative effect on the numbers of smokers who switch, regardless of the conditions which lead to the switch (self-initiated, or recommended by a smoking cessation service provider or health professional).

Accurate and balanced information on the relative safety compared to smoking by smoking cessation/health providers is one such condition.

Currently, media 'scare stories' are appearing with what seems like increasing frequency, and while the IVVA will continue to provide the media with accurate information and comment to try and counteract the more egregious misinformation, there is little additional response by health or public health professionals in evidence.

If there were, it would go a long way towards allaying smokers' concerns and would inspire their confidence in the product. Some smokers will likely never initiate a visit to a smoking cessation provider, or may have previously tried all other ways to stop smoking, and may be thinking about switching to vaping but is put off by misleading media reports. To make it clear to this cohort of smokers that vaping is an acceptable and better thing to do than continue to smoke, this should be addressed as a matter of urgency.

Regulation is another such condition. If more smokers are to switch to vaping in order to bring about the reduction in smoking rates and cost saving to the state as per the draft HTA, this will not happen if products are made less available, more expensive, less effective, or less attractive to use.

Currently, EU regulation transposed by the Department of Health (S.I. 271 of 2016) restricts the nicotine content of liquid refills to 20mg per ml, which will affect the uptake by heavier or more long term smokers who may need a higher nicotine strength to make the switch.

It heavily restricts advertising to adult smokers, making it almost impossible for independent businesses like our members to advertise their products, or their business, to the adult smokers in their local communities.

It restricts the size of liquid refill containers to 10ml, and the size of the tanks used to 2ml, producing more packaging waste and a less 'user friendly' experience for smokers. It requires the products to carry a warning about nicotine, but makes no allowances to communicate the relative safety compared to smoking.

Transposition of the EU regulation is not harmonised throughout all EU states. For example, a six month wait period between a product being placed on the central EU notification system and being allowed to go on sale applies to Ireland, but not to the UK or France. It is difficult to envisage how uptake of vaping by Irish smokers will reach the same rates as England in the near future, given how quickly products evolve and improve, and that Irish smokers will have to wait 6 months to access to new, or improved (in terms of efficacy or safety) existing products.

Another condition that makes uptake of vaping by smokers amenable, is price. There is currently a proposal by the EU Commission to amend the directive on manufactured tobacco products (Directive 2011/64/EU), and include a harmonised rate of excise duty on vaping products.

Assuming where vaping products are not subsidised by the state, and discounting how vaping products are not a tobacco product and do not contain tobacco, this would in effect be a punitive measure on smokers who have already switched to vaping and make switching less attractive for adults who still smoke.

It would have more of a negative effect on smokers with low incomes, and may drive those who would likely switch to the informal economy, in order to save money. This would not only have an impact on VAT returns, but also ensuring consumer safety. The IVVA's view is that the draft HTA's conclusions as to the cost savings to the state be communicated to the Department of Finance, in the above context.

The final condition of amenability we would like to mention, is that of adults being able to use their vaping product in public places. Currently, there is a lack of policy framework which informs owners and operators of public places or workplaces to make the distinction between smoking and vaping. Although the previous Minister for Health chose not to include vaping in the workplace smoking ban, there is none the less a confusing situation for smokers where on the one hand they may be aware that there is no significant risk to bystanders from vaping, but a premises' or organisation's policy says the opposite.

The IVVA would welcome clarification for the public in this regard e.g. :

<https://www.gov.uk/government/news/vaping-in-public-places-advice-for-employers-and-organisations>

More specifically, we would encourage the removal of the ban on vaping on HSE campus grounds. It is our view that hospitals and health facilities are the ideal opportunity to make smokers aware that switching to vaping is preferable to smoking, and some NHS Hospital Trusts in England have already taken this step, recognising that those who are quitting smoking should be supported, regardless of the method used.

### **Direct responses to specific points raised**

**Page 14** : However, HSE smoking cessation services provide support to smokers who choose to use e-cigarettes in their quit attempt in the form of the provision of information and behavioural interventions as appropriate to the individual smoker.

#### **Response:**

Anecdotal evidence from our members' customers who have previously interacted with a smoking cessation provider, as well as calls to our office requesting information about products from smoking cessation advisors, would indicate that there are wide ranging differences in the quality of information about vaping products supplied to smokers by individual service provider staff.

We see it a priority therefore, that the quality of the information about vaping provided to smokers be assessed. Our association would endorse the use of the NCSCT guidance on e-cigarettes:

[http://www.ncsct.co.uk/usr/pub/Electronic\\_cigarettes.\\_A\\_briefing\\_for\\_stop\\_smoking\\_services.pdf](http://www.ncsct.co.uk/usr/pub/Electronic_cigarettes._A_briefing_for_stop_smoking_services.pdf)

We would also like to make available our technical expertise on the products in aiding the creation of any future technical or safety information that might be helpful to HSE smoking cessation service providers or other policy makers or regulators.

**Page 19 :** Researchers have speculated that reducing the risks of smoking, rather than cessation, may be a better initial focus for the mental health population due to the higher nicotine dependence and greater burden of disease compared with the general population

**Response:**

There is evidence emerging from the introduction of vaping to people on mental health wards by Leicester Stop Smoking Service in England, that mental health populations are amenable to vaping with the necessary support from care workers, and we would encourage this to be mirrored in Ireland.

In their shops, our members have previously assisted carers and community health workers in helping people with mental health issues to choose vaping devices that are easy to use, and will satisfy their specific needs. We are willing to offer this kind of technical and product advice to any health care facility or provider that requires it.

**Page 22/23 :** Alternatively, if e-cigarette use in Ireland (26%) rose to maximum levels currently reported in England (45%), and smokers choose this option without seeking medical advice, the number of prescriptions required could fall by nearly 40%. E-cigarettes are unusual as they are the only intervention in this analysis that is not advocated by HSE QUIT services or funded through the public health system. If the results reported so far are confirmed in subsequent trials and e-cigarette use continues to rise, there is a risk that an ever greater number of people will attempt to quit smoking without involving any trained smoking cessation staff and the potential benefit of providing this treatment in conjunction with behavioural support interventions may be lost.

**Response:**

The IVVA's view is that while we agree with the general point made above, it does not acknowledge the differences in experience for a smoker purchasing a vaping product in, say, a convenience store versus a dedicated vape shop. The two transactions are very different.

Almost exclusively, staff employed in dedicated, independently owned vape shops are ex-smokers themselves and will have successfully gone through the experience of transitioning from cigarettes to vaping. They assess, from the customer's patterns of smoking, which will be the best nicotine strength and flavour to start with, and through discussion of their day to day lifestyle, the best device for them. (people who work outdoors for example, may need a sturdier device, etc.). Through conversation and training in how to use the product, they will have discussed and trouble-shot foreseeable barriers the smoker may encounter in making the transition, how to maintain their device, vitally important battery safety information, and tips and tricks to get back on track if they find themselves craving to smoke again.

The IVVA is open to helping any smoking cessation service provider with this sort of information if they think it would be helpful, and would be open to work on, say, a general information leaflet for the smokers who wish to use a vaping product alongside their services

**Page 26 :** Although the available results for e-cigarettes are promising, there is insufficient evidence to demonstrate their effectiveness as an aid to smoking cessation at present. It would be appropriate to await the results of ongoing trials before deciding whether e-cigarettes should be recommended for those for whom varenicline is contraindicated, not tolerated or non-preferred.

**Response:**

We refer to our general point at the beginning of our submission: due to the relative safety of vaping compared to smoking, it should never be the case where vaping is not considered if all other methods to stop smoking are exhausted.

**Page 31 :** It is also important to note that each of the included interventions is of interest only insofar as they help increase the chances of long-term smoking cessation. This HTA does not examine the impact of the interventions in terms of any potential harm reduction associated with their use, such as helping people to reduce the number of cigarettes smoked per day, reducing exposure to second-hand smoke, or relapse prevention measures.

**Response:**

We acknowledge the parameters of the terms of reference of the HTA in regards to the point above. However, it is the IVVA's view that if vaping is only recommended to smokers in the context of an explicit quit attempt, it will fail to reach the cohort of smokers who are resistant to the idea of quitting and who may see it as an unattractive proposal for them. Many smokers who have stopped smoking have not set out to use their vaping product specifically to "quit", but to reduce their harm from smoking, or reduce the amount of cigarettes they smoke, and who have subsequently gone on to quit smoking anyway.

By the acknowledgement of the harm reduction potential of vaping, alongside the message that using their vaping product exclusively will have better outcomes, it may well turn out to be the case where this cohort of smokers who might not otherwise have made an explicit quit attempt, achieves smoking cessation.

**Page 63 :** The Healthy Ireland and Smoking Tracker surveys do not collect information in relation to pregnancy and diagnosed mental health conditions, and therefore do not provide data on those distinct subgroups of the population.

**Response:**

There is more than one trial looking at the efficacy of vaping in pregnancy currently ongoing in the UK, and there are now guidelines available for smokers who are pregnant on vaping:

<http://www.smokefreeaction.org.uk/SIP/files/SIPe-cig%20infographic.pdf>

It is therefore the IVVA's view that it would be prudent for the research knowledge gap identified above to be filled, if it is the case that these populations may benefit from direct advice about switching to vaping when all other options have been exhausted.

**Page 69 :** A recent and substantial change to the smoking cessation landscape has been the development of electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS), also known as e-cigarettes. As they are not a tobacco product, they are not subject to tobacco control legislation, and in many jurisdictions are therefore not expressly banned in indoor public spaces and can be advertised in mainstream media. Use of e-cigarettes is controversial for many reasons. There are concerns that they act as a gateway to cigarette smoking in adolescents, that the adverse effects and safety profile are not well known, and, as they are unregulated, the composition and effects of the inhaled vapour are not well known.

**Response:**

As an aside to the point above, vaping products have never been unregulated. Previous to their inclusion in the revision of the EU Tobacco Products Directive, they were subject to a range of provisions under the general Products Safety Directive, as well as other EU and Irish regulations including those specific to batteries, chemicals and weights and measures.

With the introduction of the provisions under the revised directive, composition and aerosol emissions are included in the required pre-market notification scheme.

**Page 110 :** Given the widespread provision of supportive therapy in other pharmacological trials, the minimal support in the e-cigarette trials may partly explain the low absolute quit rates observed.

**Response:**

While acknowledging the point above, it is our view that there are also other compounding factors involved. Devices vary greatly, and the particular device or combination of device, nicotine strength and flavour will have had an effect.

The focus on trials for efficacy may need to shift to looking at a combination of relative risk communication and after-market population level studies instead. It is likely that this approach, with careful methodology and survey questions, will give a clearer picture of the efficacy of vaping products.

**Page 179 :** 5.3.5 Device explosion and fires

**Response:**

The IVVA takes consumer safety extremely seriously, and supplies its members with best practice advice and resources to fully educate their customers on aspects of lithium ion battery safety, and by ensuring that our members sell batteries with safety cases/sleeves.

The adverse incidents arising from battery failure are extremely rare, and are overwhelmingly in the majority caused by user error, either by the incorrect storage/transportation, or inferior electrical chargers. The independent vaping industry, through product standards and consumer education is attempting to eradicate the incidents of batteries failing. It is our view that this be backed up by due enforcement by regulatory authorities, and we would welcome any opportunity to aid policy makers in educating on battery safety, including making our specific battery safety leaflet available for reference.

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 5: Irish Pharmaceutical Healthcare Association (IPHA)**





## IPHA Submission on HIQA's Consultation on smoking cessation

03<sup>rd</sup> Feb 2017

### GENERAL

The Irish **Pharmaceutical Healthcare** Association (IPHA) represents the international research-based companies who are responsible for developing, manufacturing and bringing innovative medicines to the Irish market.

We support the need for evidence based decision making, welcome the principle of a review of smoking cessation methods and applaud the government's efforts to prevent and reduce the use of tobacco. We support the continued availability of treatments that are **scientifically proven** as being effective in reducing and preventing tobacco use.

However, IPHA has serious concerns at the way in which e-cigarettes are portrayed in this Health Technology Assessment (HTA) report and were portrayed in the press release to its publication. E-cigarettes are not regulated as medicines, have no robust safety and efficacy data, and cannot make any health claims about reducing and preventing the use of tobacco. Under the 2014 EU Tobacco Products Directive (TPD), these products are regulated as "tobacco related products" and forbidden from making any type of health claims. Moreover they are prohibited from sales in pharmacies by our national regulator, prohibited from making smoking cessation claims by the FDA not recognized by the World Health Organization (WHO) as a product to reduce tobacco use are owned primarily by tobacco companies (according to WHO) and which are rapidly being adopted by children.

### BACKGROUND

IPHA seeks to collaborate with governments, regulatory authorities and healthcare organizations to establish and promote policies and guidelines that improve public health whilst reducing the negative impacts of ongoing tobacco use. We particularly support those policies and guidelines that encourage wider access to proven smoking cessation services and therapies. We also support consumer access to, choice of, and information about the variety of healthcare products and services that have scientifically proven safety and efficacy in helping to reduce and stop the use of tobacco.

We appreciate that HIQA may have included e-cigarettes in its HTA in order to reflect what is happening in the market and to future proof its guidance, despite it not having been explicit that they would be considered as smoking cessation therapies/interventions within the

original terms of reference. However, we find that the degree of emphasis and weight that has been given to e-cigarette throughout the guidance and the fact that e-cigarettes were considered equally alongside established, licensed pharmaceutical smoking cessation aids with robust evidence of efficacy and safety for the purposes of this review to be of serious concern.

IPHA has serious concerns about the way in which e-cigarettes are treated within the HIQA HTA, because of the following non-exhaustive list of issues around e-cigarettes:

- There are no e-cigarettes licensed as smoking cessation aids in Ireland
- There is a worrying lack of evidence on the efficacy or long-term safety of e-cigarettes
- The **regulator of pharmacies and pharmacists in Ireland**, the Pharmaceutical Society of Ireland (PSI), **does not permit e-cigarettes to be sold in pharmacies** in Ireland as to do so would infer, incorrectly, that their safety and efficacy had been assessed and can be assured.
- The **WHO** advises that unless e-cigarettes are deemed safe and effective in reducing and stopping smoking and become of acceptable quality, **governments should prohibit** manufacturers and third parties from making health claims for e-cigarettes, including that they are smoking cessation aids.
- A systematic review on the use of e-cigarettes for smoking cessation by one of the most well respected internationally acclaimed review bodies (Cochrane<sup>1</sup>) graded the quality of the two randomised controlled **e-cigarette studies referred to in the HIQA report as “low” and “very low”**.
- E-cigarettes **are not recommended by the HSE** as a means of smoking cessation on the grounds that *“the Health Service can only endorse products that are proven to be safe, and proven to be effective; e-cigarettes have not yet achieved either test.”*
- The relevant legislation requires that any e-cigarette presented for smoking cessation<sup>2</sup> should be regulated as a medicinal product and the competent authority responsible for overseeing the implementation of Article 20 of the revised 2014 EU TPD in Ireland would be **required to intervene** should an e-cigarette manufacturer present or promote their product as a medicinal product unless it was licensed as a medicine. Under that law e-cigarettes are classified as “tobacco-related products”, forbidden from health claims on any impact on reducing and preventing smoking and must carry significant health warnings. Any and all products that have scientifically proven safety and efficacy should be classified as medicines and subject to national and international law.

---

<sup>1</sup> The Cochrane review is a well-respected, internationally acclaimed review and its evidence should be given due weight, which is not evidenced in the HIQA HTA (page 134, line 8-9) etc. These Cochrane reviews are systematic reviews of primary research in human health care and health policy and are internationally recognized as the **highest standard** in evidence-based health care resources.

<sup>2</sup> The revised EU TPD (2014/40/EU), which entered into force on 19.05.14 and became applicable in the EU Member States on 20.05.16, requires that any e-cigarette presented as a medicinal product (i.e. for smoking cessation or tobacco/nicotine dependence) should be regulated as a medicinal product for human use under the auspices of Directive 2001/83/EC.

## SUMMARY

We support the need for evidence based decision making including the principle of a review of smoking cessation methods, and proportionate solutions to ensure that Ireland's citizens have the greatest access to scientifically proven safe and effective treatments to help reduce and prevent tobacco use.

The current draft report, and associated press release strongly, and against international evidence, infers the efficacy and safety of e-cigarettes. The regulator of pharmacy in Ireland (PSI), WHO, FDA, Cochrane review etc. all have serious concerns about e-cigarettes, which are unregulated devices. We strongly recommend that the HIQA report is amended to give due weight to evidence to scientifically-proven therapies and remove the unwarranted endorsement of e-cigarettes, which have no clinical evidence of safety and efficacy in reducing tobacco use, do not use internationally-recognized good manufacturing and quality standards, are not licenced as smoking cessation aids, are a serious potential health risk, are owned primarily by tobacco companies and which are rapidly being adopted by children. Current e-cigarette use among US high school students has increased from 1.5% in 2011 to 16% in 2015 (> 900% increase).

The safety and efficacy of NRT for smoking cessation has been long established as confirmed by, amongst others, the Cochrane Collaboration and the National Institute for Health and Care Excellence (NICE) in England, The WHO has also listed both NRT patch and gum in their Model List of Essential Medicines and their use is endorsed in the WHO Implementation Guideline for Article 14 of the WHO Framework Convention on Tobacco Control. Importantly, in the Irish context, the National Standard for Tobacco Cessation Support Programme published by the HSE also recommends the use of NRT.

## SPECIFIC CONCERNS

In IPHA's opinion the overall conclusion and tone of the HIQA report in relation to e-cigarettes is not appropriate for a product whose dangers not only include the toxins that they emanate, but also their lack of safety data and their ability to encourage smoking commencement in the general population.

E-cigarettes are unregulated devices that the PSI has advised should not be sold in pharmacies. This is because selling them in a pharmacy would infer that their safety and efficacy has been assessed and can be assured. In fact, neither their efficacy nor their safety can be assured unless they are classified and regulated as medicinal products with scientifically-based evidence of safety and efficacy, and thus the PSI, the national regulator of pharmacies and pharmacists, does not permit their sale or display in pharmacies.

Additionally, the WHO has collected international evidence on this topic confirms that e-cigarettes are now owned primarily by tobacco companies<sup>3</sup>. The WHO report indicates that

---

<sup>3</sup> The 2012 WHO [report](#) advises as follows: *The ENDS market, initially dominated by companies with no links to the tobacco industry, is increasingly owned by the tobacco industry. All main transnational tobacco companies sell ENDS and one of them is launching legal proceedings over patents against its rivals as they become increasingly aggressive in the battle for the fast-growing e-cigarette market. The increasing concentration of the ENDS market in the hands of the transnational tobacco companies is of grave concern in light of the history of the corporations that dominate that industry'...Most ENDS products have not been tested by independent scientists but the limited testing has revealed wide variations in the nature of the toxicity of contents and emissions.*

there is little evidence of safety and on the contrary the WHO advises that the toxins in e-cigarettes are similar to those of smoking.

Furthermore, these devices are appealing to children. A survey supported by the United States Food and Drug Agency and the Centers for Disease Control and Prevention showed that, over the past decade, there has been a significant drop in the use of traditional cigarettes among young people but their use of other tobacco products is rising. Current e-cigarette use among US high school students has increased from 1.5% in 2011 to 16% in 2015 (> 900% increase).

It is generally understood and even detailed in the HIQA report itself that *'If e-cigarette use becomes socially acceptable, it could lead to new use of nicotine by people who have never smoked before, later migration to tobacco cigarettes, long-term nicotine dependency, and other potential as yet unknown harms.'*

- The HIQA report states on page 105 that:

*The 10 interventions in the network of pharmacological treatments were analysed in terms of their likely ranking (from best treatment to worst treatment) (Figure 4.5)...E-cigarettes and cytosine both had wide ranges of potential rankings, **highlighting the uncertainty in relation to their effectiveness.***

- The HIQA report states on page 134 that

*The Cochrane review of e-cigarettes for smoking cessation described the level of evidence as **low**.*

However, the Cochrane review is a well-respected, internationally acclaimed review and its evidence should be given due weight, which is not evidenced in the HIQA report (page 134, line 8-9 etc). "Low" by GRADE standards indicates that further research is very likely to have an important impact on confidence in the effect estimate, and is likely to change the estimate itself. Thus, we consider the efficacy of e-cigarettes to be largely uncharacterized. In contrast, NRT treatments have been studied in over 100 clinical trials involving tens of thousands of smokers, and have been proven effective in reducing smoking rates and improving quit rates.

- The EU Smoking Cessation Guideline (page 124 extracted below) is quite different to HIQA's approach:

#### 4.2.7 E-cigarettes

E-cigarettes are a new product which are being marketed more frequently and which are presented both as a tobacco replacement product and as a smoking cessation product. Most sales of cartridges for e-cigarettes contain nicotine at various undefined levels. The smoke-like vapour produced by ethylene glycol or glycerol is an irritant when exposure is repeated, but is not a severe toxin in short-term use.

With disposable cartridges, e-cigarette have become more economical than regular cigarettes per nicotine puff absorbed and experimentation with e-cigarettes by young people is becoming more and more common throughout Europe. The e-cigarette has now become a tobacco initiation product, a product for consumption in non-smoking areas, a product to promote smoking. However, it is also presented as a smoking cessation or harm reduction product.

The lack of reliable studies had led most national authorities to prohibit the promotion of this product as a smoking cessation product. Currently, there is no clear-cut response by doctors with regard to this ambiguous product. There is no evidence of frequent or severe adverse effects, but there is likewise no evidence of efficacy for smoking cessation, so in view of the absence of studies health professionals should not recommended this product, but there is no strong argue to contradict a patient's choice if the patient chooses to use e-cigarettes as an adjuvant to other smoking cessation articles.

Emissions of total suspended particulate matter (TSP) derived from e-cigarettes are around 60 mcg/m<sup>3</sup>, 10-15 times lower than those of conventional cigarettes For each of the different fractions of PM, (PM<sub>1</sub>, PM<sub>2.5</sub>, PM<sub>7</sub>, PM<sub>10</sub>), there is a lower density (ranging from 6 to 21 times) for e-cigarettes compared to conventional cigarettes, but the levels still slightly exceed WHO outdoor air quality guideline values<sup>1</sup>.

E-cigarettes were found to have immediate adverse physiologic effects after short-term use that are similar to some of the effects seen with tobacco smoking; however, the long-term health effects of e-cigarette use are unknown but potentially adverse and worthy of further investigation<sup>2</sup>.

We believe that the importance of the aforementioned bulleted facts were not given due consideration and in some cases no consideration in the report and particularly in the conclusion. The [HIQA Corporate Plan](#) specifically advises that HIQA has statutory responsibility for *'Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities'*. We believe that the tone of the conclusion of the current HIQA report, and elements of the content, do not enable the best outcome for patients as it does not provide enough prominence to the WHO, PSI and EU Smoking Cessation Guideline concerns about e-cigarettes nor the body of evidence to support Nicotine Replacement Therapy (NRT) or varenicline.

We therefore, suggest the following changes to the report:

#### PROPOSED CHANGES

- The HIQA report states on page 101 that:

*The data on e-cigarettes is less clear, influenced by the small number of studies and comparisons available. Relative to control there was statistically significant treatment*

*effect, although the confidence bounds were wide. Relative to NRT monotherapy there was a small, but not statistically significant treatment benefit.*

*IPHA proposes that HIQA change this to the following more accurate statement that is in line with the WHO etc.:*

The data on e-cigarettes is less clear, influenced by the small number of studies and comparisons available. ~~Relative to control there was statistically significant treatment effect, although the confidence bounds were wide.~~ Relative to NRT monotherapy there was ~~a small, but not~~ no statistically significant treatment benefit.

- The HIQA report states on page 134 that:

*The Cochrane review of e-cigarettes for smoking cessation described the level of evidence as **low**.*

*IPHA proposes that HIQA change this to the following more accurate statement that reflects the standing of the Cochrane review:*

The Cochrane review of e-cigarettes for smoking cessation described the level of evidence as **low**. However, the Cochrane review is a well-respected, internationally acclaimed review. “Low” by GRADE standards indicates that further research is very likely to have an important impact on confidence in the effect estimate, and is likely to change the estimate itself. Thus, we consider the efficacy of e-cigarettes to be largely uncharacterized. In contrast, NRT treatments have been studied in over 100 clinical trials involving tens of thousands of smokers, and have been proven effective in reducing smoking rates and improving quit rates.

- Under ‘wider implications’ the HIQA report comments as follows:

*If e-cigarette use becomes socially acceptable, it could lead to new use of nicotine by people who have never smoked before, later migration to tobacco cigarettes, long-term nicotine dependency, and other potential as yet unknown harms.*

However, on page 20 under ‘safety’ the HIQA report states that:

*Safety data on e-cigarettes is limited to two small short-term clinical trials. Mild, temporary adverse drug reactions were found, such as throat and respiratory irritation and dry cough. Toxicological studies have demonstrated that while toxic chemicals may be present in e-cigarette vapour, they are at a lower concentration than in cigarette smoke. E-cigarettes have only been in use for a short time, and so data on long-term toxicity is not yet available. While the clinical effect of long-term e-cigarette use is unknown, the risk to bystanders from ‘passive vaping’ appears to be very low. The safety of e-cigarettes is*



*an evolving area of research; while believed to be safer than smoking, evidence on long-term safety has yet to be established.*

*Therefore, IPHA proposes that HIQA modify page 20 to the following more accurate statement that is in line with international opinion:*

Safety data on e-cigarettes is limited to two small short-term clinical trials. Mild, temporary adverse drug reactions were found, such as throat and respiratory irritation and dry cough. ~~Toxicological studies have demonstrated that while toxic chemicals may be present in e-cigarette vapour, they are at a lower concentration than in cigarette smoke.~~ E-cigarettes were found to have immediate adverse physiologic effects after short-term use that are similar to some of the effect seen with tobacco smoking<sup>4</sup>. E-cigarettes are not regulated as medicines, have no robust safety and efficacy data, and cannot make any health claims about reducing and preventing use of tobacco. Under the 2014 EU TPD, these products are regulated as “tobacco related products” and forbidden from making any type of health claims. Moreover they are prohibited from sales in pharmacies by our national regulator and not recognized by the World Health Organization as a recognized product to reduce tobacco use. They are noted by the FDA as being rapidly adopted by young people<sup>5</sup>. If e-cigarette use becomes socially acceptable, it could lead to increased uptake of nicotine products by people who have never smoked before, later migration to tobacco cigarettes, long-term nicotine dependency, and other potential as yet unknown harms. Therefore, the use and normalisation of these products should not be encouraged. While the clinical effect of long-term e-cigarette use is unknown, the risk to bystanders from ‘passive vaping’ is also unknown and may be substantial ~~appears to be very low.~~ The safety of e-cigarettes is an evolving area of research and ~~while believed to be safer than smoking,~~ evidence on long-term safety has yet to be established. Most e-cigarettes have not been tested by independent scientists but the limited testing that has been carried out has revealed wide variations in the nature of the toxicity of contents and emissions<sup>6</sup>.

- On Page 21 under ‘economic evaluation’ the HIQA report states that:

*A comparison of alternatives to the current mix of smoking cessation interventions used in Ireland was carried out using international data as an indicator of plausible changes in the usage of the most cost-effective cessation interventions. This included a scenario where combination varenicline and NRT use was maximised, and a scenario where e-cigarette uptake reached levels recently reported in England. This analysis found that maximising the uptake of varenicline and NRT in combination is the most cost-effective strategy. However, it is unclear to what extent policy initiatives can influence overall smoking cessation preferences, particularly in light of the high use of e-cigarettes in Ireland in the*

---

<sup>4</sup>Page 63 of the [EU Smoking Cessation Guideline](#) produced by the European Network for Smoking & Tobacco Prevention.

<sup>5</sup> [US FDA](#): Young people are rapidly adopting e-cigarettes, however, young people who use e-cigarettes are heavier (not lighter) smokers. E-cigarette use among high school students has increased from 1.5% in 2011 to 16% in 2015 (> 900% increase). E-cigarettes contain candy flavours (e.g., cherry, chocolate, Turkish delight).

<sup>6</sup> WHO report

*absence of any explicit endorsement by quit services. Based on the currently available evidence, an increase in the uptake of e-cigarettes to rates of 45% currently reported in England is likely to improve the cost-effectiveness of the overall mix of cessation interventions in Ireland, by increasing the number of successful quit attempts, again at an acceptable cost.*

At this time the use of varenicline and NRT in combination is not supported by the labelling of either varenicline or NRT. The off-label nature of this combination means that there is no recognised posology or safety record on which to make treatment recommendations and therefore they should not be included in the cost effectiveness analysis for use in combination. A statement that they are “best value for money” as a smoking cessation intervention constitutes a tacit recommendation, and implies an established, accepted benefit versus risk assessment in this indication when that is not supported by evidence at this time, nor is it supported by present product labelling. Additionally, without established efficacy or safety, and given the HSE does not advocate their use in combination for smoking cessation, a cost-effectiveness analysis and implied recommendation is not justified.

*Therefore, IPHA proposes that HIQA should modify page 21 as follows to remove any inference that HIQA is promoting the off label use of medicines.*

A comparison of alternatives to the current mix of smoking cessation interventions used in Ireland was carried out using international data as an indicator of plausible changes in the usage of the most cost-effective cessation interventions. This included a scenario where combination varenicline and NRT use was maximised, and a scenario where e-cigarette uptake reached levels recently reported in England. ~~This~~ While this analysis found that maximising the uptake of varenicline and NRT in combination is the most cost-effective strategy the ~~safety of such off label use of these medicines has not been assessed and therefore cannot be endorsed.~~ However, it is unclear to what extent policy initiatives can influence overall smoking cessation preferences, particularly in light of the high use of e-cigarettes in Ireland in the absence of any explicit endorsement by quit services. Based on the currently available evidence, an increase in the uptake of e-cigarettes to rates of 45% currently reported in England is likely to improve the cost-effectiveness of the overall mix of cessation interventions in Ireland, by increasing the number of successful quit attempts, again at an acceptable cost suggests that e-cigarettes could become socially acceptable. However, if e-cigarette use becomes socially acceptable, it could lead to increased uptake of nicotine products by people who have never smoked before, later migration to tobacco cigarettes, long-term nicotine dependency, and other potential as yet unknown harms from devices that are not regulated, are not manufactured under GMP and cannot be sold in pharmacies due to the lack of evidence demonstrating their safety and efficacy.

- Page 22 of the HIQA report states that:

*The government has an ethical duty to ensure that the media portrayal of the product is appropriately aligned with its known degree of risk. This is dealt with in the recent EU TPD,*



*which aims to harmonise the quality and safety requirements of tobacco products and e-cigarettes for the benefit of consumers. **Although negative health effects from the use of e-cigarettes are currently unknown, there is concern that potential legal liability may be possible if future research finds that negative effects do result from their use. Provided appropriate warnings and information leaflets containing accurate information are included with the sale of any such product, it is difficult to see how a legal action might successfully be taken if this were to occur...***

IPHA is of the opinion that the tone of the report is biased towards the use of e-cigarettes and this bias is not supported by available evidence. E-cigarettes are not regulated as medicines, have no robust safety and efficacy data, and cannot make any health claims about reducing and preventing use of tobacco. The safety of the inhalation of glycerine and propylene glycol, contained in e-cigarettes, is not well established other than when heated and oxidised propylene glycol can form propylene oxide, which is a known carcinogen. Under the 2014 EU TPD, these products are regulated as “tobacco related products” and forbidden from making any type of health claims. Moreover they are prohibited from sales in pharmacies by our national regulator and not recognized by the World Health Organization as a recognized product to reduce tobacco use. They are noted by the FDA as being rapidly adopted by young people<sup>7</sup>. If e-cigarette use becomes socially acceptable, it could lead to increased uptake of nicotine products by people who have never smoked before, later migration to tobacco cigarettes, long-term nicotine dependency, and other potential as yet unknown harms. Therefore, the use and normalisation of these products should not be encouraged.

E-cigarettes cannot be presented as smoking cessation aids unless they are classified as medicinal products, subject to Irish pharmaceutical laws and standards, and such products would be required to be the subject of a marketing authorisation before being placed on the market in Ireland.

Furthermore, the position of the PSI is that it would not be appropriate for any of these products to be offered for sale or supply in retail pharmacy businesses in Ireland. Members of the public have a right to expect that the quality, safety and efficacy of any products supplied in pharmacies have been appropriately established and independently assured. As detailed in the PSI position paper on e-cigarettes, pharmacists are required to ensure that products supplied to patients do not pose a hazard to a patient’s health or wellbeing, as may be the case if a person were to resort to a particular product in respect of which the safety and efficacy had not been established against other products and treatments that have met the required standards of safety and efficacy.

Only products with demonstrated safety and efficacy of reducing and stopping smoking should be registered as medicinal products and be allowed to make smoking cessation claims. However, in contrast to the WHO recommendation the HIQA report appears to be endorsing e-cigarettes.

---

<sup>7</sup> [US FDA](#): Young people are rapidly adopting e-cigarettes, however, young people who use e-cigarettes are heavier (not lighter) smokers. E-cigarette use among high school students has increased from 1.5% in 2011 to 16% in 2015 (> 900% increase). E-cigarettes contain candy flavours (e.g., cherry, chocolate, Turkish delight).

*IPHA suggests that the current wording be replaced with the following wording:*

The government has an ethical duty to ensure that the media portrayal of the product is appropriately aligned with its known degree of risk. This is dealt with in the recent EU TPD, which aims to harmonise the quality and safety requirements of tobacco products and e-cigarettes for the benefit of consumers. ~~Although negative health effects from the use of e-cigarettes are currently unknown, there is concern that potential legal liability may be possible if future research finds that negative effects do result from their use. Provided appropriate warnings and information leaflets containing accurate information are included with the sale of any such product, it is difficult to see how a legal action might successfully be taken if this were to occur...~~ E-cigarettes are not regulated as medicines, have no robust safety and efficacy data, and cannot make any health claims about reducing and preventing use of tobacco. The safety of the inhalation of glycerine and propylene glycol, contained in e-cigarettes, is not well established other than when heated and oxidised propylene glycol can form propylene oxide, which is a known carcinogen. Under the 2014 EU TPD, these products are regulated as “tobacco related products” and forbidden from making any type of health claims. Moreover they are prohibited from sales in pharmacies by our national regulator and not recognized by the World Health Organization as a recognized product to reduce tobacco use. They are noted by the FDA as being rapidly adopted by young people<sup>8</sup>. If e-cigarette use becomes socially acceptable, it could lead to increased uptake of nicotine products by people who have never smoked before, later migration to tobacco cigarettes, long-term nicotine dependency, and other potential as yet unknown harms. Therefore, the use and normalisation of these products should not be encouraged.

- The HIQA report states on page 36 that:

*E-cigarettes do not contain tobacco, but provide sensations that are similar to cigarette smoking. This may help smokers achieve long-term abstinence by alleviating some of the sensory and behavioural challenges associated with smoking cessation, as well as helping to reduce nicotine withdrawal symptoms (in cases where the liquid also contains nicotine).*

*There is no citation quoted and thus this statement should be removed.*

There is also no discussion or comment regarding use of Glycerin (also called glycerol) for human inhalation. It has been approved for use in food and cosmetics, is also not explicitly approved for human inhalation (German Cancer Research Center, 2013). The discussion is incomplete. A complete discussion can be found on page 16 of the WHO background paper on E-cigarettes (Annex I).

Regarding inhalation, a Master Data Safety Sheet, guidance for the industrial use of propylene glycol by Sciencelab.com, Inc., states it can cause eye and respiratory irritation and “Prolonged or repeated inhalation may affect behaviour/CNS (with symptoms similar to ingestion) and spleen.”(Sciencelab.com Inc., 2013). A major manufacturer of propylene

---

<sup>8</sup> [US FDA](#): Young people are rapidly adopting e-cigarettes, however, young people who use e-cigarettes are heavier (not lighter) smokers. E-cigarette use among high school students has increased from 1.5% in 2011 to 16% in 2015 (> 900% increase). E-cigarettes contain candy flavours (e.g., cherry, chocolate, Turkish delight).

glycol, the Dow Chemical Company, states in its product safety materials that the “inhalation exposure to [propylene glycol] mists should be avoided” (Dow Chemical Company, 2013) and the American Chemistry Council warns against its use in theatre fogs due to its potential to cause eye and respiratory irritation (The American Chemistry Council, July 2001). When heated and vaporized, propylene glycol can form propylene oxide, an IARC class 2B **carcinogen** (Laino T *et al.*, 2012) and glycerol forms acrolein, which can cause upper respiratory tract irritation (U.S. EPA, Henderson TR *et al.*, 1981). Major injuries and illness have resulted from e-cigarette use, which may be related to lack of basic safeguards in the product design and manufacturing process, as well as the contents of the solution.

- The HIQA report states on page 72 that

*The 2015 Healthy Ireland survey collected data on quit attempts in the last 12 months by current and former smokers. Of current smokers or those that had smoked within the previous 12 months, half (50.0%) had stopped smoking for a day or more in the previous 12 months as part of an attempt to quit smoking. Within the survey, respondents could report the cessation approach they took, choosing from the range of options outlined in Table 3.6...*

However, no reference is provided. Please provide reference cited in Table 3.6.

- The HIQA report states on page 76 that

*From the Healthy Ireland survey data it is apparent that e-cigarettes have become a popular aid for smoking cessation, with almost 29% of quit attempts supported through e-cigarette usage. Unfortunately, these data on e-cigarette use in cessation are limited to a snapshot, and it is therefore not possible to analyse the trends in relation to cessation in Ireland. UK data suggest the use of e-cigarettes for cessation is increasing. Almost all (98%) of e-cigarette users are smokers and former smokers, with the prevalence of e-cigarette usage at approximately 6% in both groups. There is no evidence to suggest that the quantity of cigarettes smoked is less in smokers who also use e-cigarettes compared with smokers who do not use e-cigarettes. Seventy one percent of current smokers who also use e-cigarettes attempted quitting in the previous 12 months, compared with 43% of current smokers who do not use e-cigarettes. Similarly, 66% of current smokers who also use e-cigarettes are either trying to or actively planning to quit, compared with 30% of smokers who do not use e-cigarettes. It is not possible to state whether the higher intention to*

However, no reference is provided. Please provide the reference cited—Healthy Ireland survey data.

- The HIQA report states on page 254 that

*The survey also asked about the dual use of e-cigarettes and tobacco smoking, and found that approximately 15% of smokers also reported using an e-cigarette in the previous 12 months. A systematic review of unassisted quitting in Australia based on 19 Australian*

*studies reported that 54% to 69% of ex-smokers quit unassisted and 41% to 58% of current smokers had attempted to quit unassisted. This indicates that unassisted quitting is the most popular method of quitting. The authors concluded that public health would benefit from a greater understanding of why so many smokers choose not to use smoking cessation aids.*

This survey was taken from <http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129549848>. The statement indicated that 15% of smokers used e-cigarettes in the previous 12 months. Full citation is required to ensure that a full picture is shared. The statement could mislead readers that you could choose e-cigarettes or unassisted quitting and obtain the stated outcome. The Australian Government has previously expressed concerns about the use of e-cigarettes, as the impact of wide scale use of these devices on tobacco use is unknown, and the outcome in the community could be harmful. The Therapeutic Goods Administration (TGA) indicates that use of e-cigarettes may be dangerous and that there has been no assessment of their effectiveness in helping smokers quit. Given their unclear safety profile, e-cigarettes are not currently approved for sale in Australia. This has not been indicated in the citation. A balance view in this case is required.

*Refer to Annex 4 for further information*

- The Conclusion section of the HIQA report states that

*Smoking cessation services should seek to increase the uptake of the use of varenicline (alone or in combination with NRT or bupropion) among smokers wishing to use some type of pharmacological support in their attempt to quit. Although the available results for e-cigarettes are promising, there is insufficient evidence to demonstrate their effectiveness as an aid to smoking cessation at present. It would be appropriate to await the results of ongoing trials before deciding whether e-cigarettes should be recommended for those for whom varenicline is contraindicated, not tolerated or non-preferred. The addition of any type of behavioural support is associated with a beneficial effect on quitting outcomes.*

IPHA believes that the HIQA conclusion should reflect the current concerns around unregulated therapies more accurately and rely on evidence based conclusions. NRT is highly regulated as a medicinal product, follows GMP during manufacture and is sold in pharmacies. E-cigarettes are not regulated, are not manufactured under GMP and cannot be sold in pharmacies due to the lack of evidence demonstrating their safety. Therefore, IPHA believes that HIQA should not endorse a product that may carry significant risks to the user and bystanders and that may also have as yet unknown significant side effects. Additionally, the possibility that they may encourage the smoking of cigarettes by children or other adults means that the use and normalisation of these products should not be encouraged.

*IPHA suggests that the current wording be replaced with the following wording:*

Smoking cessation services should seek to increase the uptake of the use of varenicline (~~alone or in combination with NRT or bupropion~~) or NRT among smokers wishing to use some type of pharmacological support in their attempt to quit. The safety and efficacy of NRT for smoking cessation has been long established as confirmed by, amongst others, the Cochrane Collaboration and the National Institute for Health and Care Excellence (NICE) in

England, The WHO has also listed both NRT patch and gum in their Model List of Essential Medicines and their use is endorsed in the WHO Implementation Guideline for Article 14 of the WHO Framework Convention on Tobacco Control. Importantly, in the Irish context, the National Standard for Tobacco Cessation Support Programme published by the HSE also recommends the use of NRT.

The addition of any type of behavioural support is associated with a beneficial effect on quitting outcomes. ~~Although the~~ The available results for e-cigarettes are promising, there is insufficient evidence to demonstrate their any effectiveness as an aid to smoking cessation at present. ~~It would be appropriate to await the results of ongoing trials before deciding whether e-cigarettes should be recommended for those for whom varenicline is contraindicated, not tolerated or non-preferred. The addition of any type of behavioural support is associated with a beneficial effect on quitting outcomes.~~ E-cigarettes are not regulated as medicines, have no clinical evidence of safety and efficacy in reducing tobacco use, do not use internationally-recognized good manufacturing and quality standards, are not licenced as smoking cessation aids, are a serious potential health risk, are owned primarily by tobacco companies and are rapidly being adopted by children. Under the 2014 EU TPD, these products are regulated as “tobacco related products” and forbidden from making any type of health claims. Moreover they are prohibited from sales in pharmacies by our national regulator and not recognized by the World Health Organization as a recognized product to reduce tobacco use. They are noted by the FDA as being rapidly adopted by young people<sup>9</sup>. If e-cigarette use becomes socially acceptable, it could lead to increased uptake of nicotine products by people who have never smoked before, later migration to tobacco cigarettes, long-term nicotine dependency, and other potential as yet unknown harms. Therefore, the use and normalisation of these products should not be encouraged.

## CONCLUSION

As licenced medicines, varenicline, bupropion or NRT products have scientifically proven safety and efficacy profiles, both in relation to individual products and published data supported by a number of years use worldwide, and are manufactured using internationally recognized good manufacturing and quality standards.

E-cigarettes have no such evidence, are owned by tobacco companies, are unregulated, are increasingly being used by children, are actively prohibited from sale in pharmacies by the pharmacy regulator, have no robust evidence of efficacy and have concerns around their safety.

Therefore, we strongly recommend that the HIQA report reflect the aforementioned facts when referring to e-cigarettes. The current inference is that there is an economic benefit to the government in the promotion of the use of e-cigarettes or the promotion of the off-label use of varenicline and NRT in combination. However, there is no such national or international evidence in relation to e-cigarettes by highly esteemed review bodies,

---

<sup>9</sup> [US FDA](#): Young people are rapidly adopting e-cigarettes, however, young people who use e-cigarettes are heavier (not lighter) smokers. E-cigarette use among high school students has increased from 1.5% in 2011 to 16% in 2015 (> 900% increase). E-cigarettes contain candy flavours (e.g., cherry, chocolate, Turkish delight).

regulators, WHO etc and the use of varenicline and NRT in combination is off label use and the legislation prohibits the promotion of this by pharmaceutical companies. In particular, and in regard to e-cigarette safety, simply not knowing the risk does not mean that there is no risk. In particular, there is no economic benefit to promoting e-cigarette use when their use may increase, not decrease, the number of smokers, lead to significant health and safety issues and lead to a whole new generation of young people becoming addicted to tobacco.

We request that the changes advised in our submission are made to the HIQA report and the associated press release.

## APPENDIX 1

### EVIDENCE BASED RECOMMENDATIONS

As HIQA deliberates the value and benefits of smoking cessation interventions, we recommend consideration of the value and benefits to public health and the impact on healthcare systems of existing interventions. The following data is demonstrable of the impact of consumer access to NRT medicines.

- Increased access to NRT for all smokers could result in 6 million people giving up smoking in one year, globally, of which 1 million would avoid dying from smoking-attributable causes over their lifetimes.<sup>i</sup>
- In 2009, the WHO placed two forms of NRT on its list of “Essential Medicines,” transdermal patches and chewing gum. The WHO examined 13 reviews of the effectiveness of NRTs in reducing and ending tobacco use, and found an increased probability of cessation with NRTs, usually in combination with another cessation strategy.<sup>ii</sup> Specifically, the WHO found that NRTs increase the chances of quitting tobacco use successfully by 58% (Cochrane Review, 2008).<sup>iii</sup>
- Thirty-one countries have national guidelines for smoking cessation treatment, which recommend NRT as an appropriate, evidence-based therapy for smoking cessation.<sup>iv</sup>
- A Cochrane review found that commercially available NRT products are effective methods of smoking cessation, increasing cessation rates by 50-70%.<sup>v</sup>

It is well established that varenicline, NRT or bupropion can reduce the cravings and withdrawal symptoms that occur when stopping smoking, and can increase the likelihood of a successful outcome in those motivated to quit. As licenced medicines, varenicline, bupropion or NRT products have a well-supported safety and efficacy profile supported by a number of years use worldwide. This includes data from a number of placebo-controlled studies reviewed under the medicinal product regulatory framework which have showed them to be effective.

In the absence of a similar level of data and assurance, e-cigarette manufacturers have been unable to address the major issues including:

#### 1. Efficacy Concerns

- Relative to NRT monotherapy no statistically significant treatment benefit has been demonstrated for e-cigarettes.

#### 2. Safety concerns

- There is an absence of studies on the safety of long-term use of e-cigarettes particularly in terms of contribution towards a substantial reduction in cardiovascular risk factors and respiratory symptoms.
- There are no GMP or minimum standards concerning the quality of for e-cigarette ingredients or control of final product.
- There are no Pharmacovigilance or risk management plan activities in place for e-cigarettes.

### 3. Promotion concerns:

- Possible promotion of relapse among quitters by suggesting that e-cigarettes are relatively safe.
- Possible increased initiation of smoking, especially amongst young people, by suggesting that e-cigarette smoking (vaping) is safe.
- A large proportion of NRT is used under the supervision of a pharmacist or healthcare professional, with behavioural support being a critical part of the quit attempt. Placing e-cigarettes on the same platform as NRT legitimises its use without any of the same standards or proof of concept.

## KEY REGULATOR & OTHER GROUP OPINIONS ON E-CIGARETTES

### 1. WHO

- The WHO supports the establishment of laws and regulations for Electronic Nicotine Delivery Systems (ENDS), including e-cigarettes. Until they are deemed safe and effective in reducing and stopping smoking and are deemed to be of acceptable quality by national health regulatory bodies, the WHO recommends governments prohibit manufacturers and third parties from making health claims for ENDS, including that ENDS are smoking cessation aids.
- Only products with demonstrated safety and efficacy of reducing and stopping smoking should be registered as medicinal products and be allowed to make smoking cessation claims.

*Refer to Annex 1 for further information*

### 4. TGA Australia

- The Australian Government is concerned about the use of e-cigarettes in Australia. The impact of wide scale use of these devices on tobacco use is not known and there is concern that they could be harmful.

*Refer to Annex 2 for further information*



## 6. [EU Smoking Cessation Guideline](#)

- The lack of reliable studies had led most national authorities to prohibit the promotion of this product as a smoking cessation product.

*Refer to Annex 3 for further information*

## 9. **British Medical Association ([BMA](#)) position**

- “While e-cigarettes have the potential to support tobacco harm reduction, any benefits or disadvantages to public health are not yet well established. This reflects the lack of conclusive evidence of their effectiveness as a smoking cessation aid, concerns regarding the variability of the components of e-cigarette vapour, and the absence of a significant health benefit associated with dual use of e-cigarettes and tobacco cigarettes”

### Annex 1



WHO  
ecig\_Report\_Dec201

### Annex 2



ASMI Media  
Statement on Lancet

### Annex 3



ENSP-ESCG\_FINAL.pdf

### Annex 4



ASMI Media  
Statement on Lancet

---

### References

- <sup>i</sup> WHO. (March 2009). “Proposal for Inclusion of Nicotine Replacement Therapy in the WHO Model List of Essential Medicines.” [http://www.who.int/selection\\_medicines/committees/expert/17/application/NRT\\_inclusion.pdf](http://www.who.int/selection_medicines/committees/expert/17/application/NRT_inclusion.pdf)
- <sup>ii</sup> WHO. (March 2009). “Proposal for Inclusion of Nicotine Replacement Therapy in the WHO Model List of Essential Medicines.” [http://www.who.int/selection\\_medicines/committees/expert/17/application/NRT\\_inclusion.pdf](http://www.who.int/selection_medicines/committees/expert/17/application/NRT_inclusion.pdf)
- <sup>iii</sup> WHO. *Tobacco Free Initiative (TFI)*. [http://www.who.int/tobacco/quitting/summary\\_data/en/](http://www.who.int/tobacco/quitting/summary_data/en/)

- 
- <sup>iv</sup> Raw M and Slevin C. (Dec 7, 2007). "A survey of tobacco dependence treatment guidelines and systems in 45 countries." <http://www.treatobacco.net/en/uploads/documents/Publications/Raw%20&%20Slevin%202007%20survey%20on%20treatment%20guidelines%20and%20services%20in%2045%20countries.pdf>
- <sup>v</sup> Stead LF, Perera R, Bullen C et al. *Cochrane Database Syst Rev.* (2012). "Nicotine replacement therapy for smoking cessation." <http://www.cochrane.org/reviews/en/ab000146.html>

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 6: Royal College of Physicians of Ireland (RCPI) Tobacco Policy Group**



# Consultation Response

## HIQA Draft HTA of smoking cessation interventions

February 2017

This document is a response from the Policy Group on Tobacco of the Royal College of Physicians of Ireland to a HIQA Public Consultation on a health technology assessment of smoking cessation interventions, announced in January 2017.

## Introduction

The Royal College of Physicians of Ireland (RCPI) has a longstanding record of leadership in the area of public health policy. We have a number of policy groups comprised of members, fellows and trainees from a range of medical specialities within RCPI, representatives from other medical and healthcare professions, and relevant advocacy organisations.

In 2014, RCPI established a policy group on tobacco. This multidisciplinary group is comprised of physicians from a range of specialties, including Public Health Medicine, Paediatrics, Obstetrics and Gynaecology, and Occupational Medicine. The group has published a policy statement in 2014, and has developed pre-budget submissions, consultation responses and briefing statements for Oireachtas committees.

In 2014 the group published a policy statement "*Towards a Tobacco-Free Ireland*" which detailed a number of solutions to reduce the negative impacts of tobacco on Irish society. A number of these referred to smoking cessation interventions, under the title "offering help to quit". The statement emphasised that there is evidence for the effectiveness and cost-effectiveness of brief interventions for all smokers. The statement highlighted the importance of support to pregnant women in quitting smoking.

The 2014 statement also reviewed evidence available at the time on e-cigarettes; looking at their potential use in smoking cessation, and at possible harms. Because of the limited research available, the group position was that further research was necessary to determine their utility in smoking cessation and harm reduction, and any long term adverse effects.

## 1. General Comments on the HTA

- The RCPI Policy Group on Tobacco welcomes this health technology assessment and views it as a comprehensive and positive contribution to the evidence base around smoking cessation interventions.
- This document should serve as a guideline to influence both HSE and Government policy and funding for smoking cessations therapies. It should also be used to identify areas of tobacco control research where there is paucity of data from an Irish perspective. Funding should be made available to further research these areas.
- In particular, the inclusion of e-cigarettes in this health technology assessment is welcomed. The use and interest in e-cigarettes has increased rapidly in recent years, and while they are likely safer than conventional cigarettes for the individual user with regard to tobacco-related morbidity and mortality,

there are not risk-free products and their potential as a cessation aid has been unclear. The results of this HTA in relation to e-cigarettes highlight that:

- E-cigarettes were twice as effective as control, but this was based on only two trials.
- The evidence base for e-cigarettes will evolve as further trials are completed.

## **2. Comments on specific sections of the report**

### **2.1. Range of interventions (p30)**

The HTA evaluated the following interventions for smoking cessation:

Pharmacological interventions:

- Nicotine Replacement Therapy
- Electronic Cigarettes
- Anti-depressants (bupropion)
- Nicotine receptor partial agonists (varenicline)

Non-pharmacological interventions

- Acupuncture
- Behavioural interventions including motivational interventions, brief advice, telephone based interventions, internet-based interventions, mobile phone based interventions, individual behavioural counselling, group behaviour therapy and the Alan Carr method.
- Financial incentives for pregnant women.

The chosen interventions are comprehensive and encompass many of the common smoking cessation methods currently used in Ireland. The HTA provides a good argument for leaving out other interventions.

### **2.2. Epidemiology of smoking and smoking related illness in Ireland(p 48)**

**Smoking in pregnancy (pg 52).**

- Additional harms associated with smoking in pregnancy which are not mentioned in the HTA report include:
  - Asthma<sup>1 2</sup>
  - Risk of miscarriage may be included, as there does appear to be an association between cigarette smoking and miscarriage. However there is lack of evidence as to a direct causal effect.

### **E-cigarette usage in Ireland- clarification**

- Section 3.4.5 (p75) states that 29% of quit attempts are supported through e-cigarette usage. Elsewhere it is reported that e-cigarette use is 26% (p280). It is unclear where this statistic comes from and whether it refers to the % of the population who have ever tried e-cigarettes or whether this refers to regular usage. The 2015 Healthy Ireland Survey stated that 42% of smokers had tried e-cigarettes at some point with, while 6% were currently using them, while 6% of ex-smokers and 0.1% of never smokers reported using e-cigarettes.

### **Section 3.4.5 Inequalities in smoking cessation (page 78)**

- “An effort to reduce cessation inequalities will require other approaches to be considered...”The data in this section highlights the impact of lower socioeconomic status on the success of smoking cessation. These points should be taken into account when developing future HSE guidelines and government policies on promoting different cessation techniques.

### **Effects of second-hand smoking in children**

- The section on the effects of second-hand smoking on children is much smaller than in many similar documents. “For children, exposure to second-hand smoke increases the risk of sudden infant death syndrome, acute respiratory infections, ear problems and more severe asthma. Furthermore, exposure to second-hand smoke slows lung growth” (page 54 of the draft HTA document). There are large sections on pregnancy and mental health and similar emphasis on children would have been welcome. Second-hand smoking is a major cause of morbidity in children and the effect of this can be a useful stimulus for tobacco cessation in parents.

## **2.3. Effectiveness of available smoking cessation interventions (p81)**

The HTA reviewed clinical effectiveness through considering studies in three distinct population groups- General Adult Population, People attending secondary mental health services and pregnant women.

The presentation of the data analysed is thorough and clearly laid out. The focus on people attending secondary mental health services is welcomed. A disproportionate number of people with severe mental illness are regular smokers and die from smoking related diseases. A US study found that people with mental health issues were about twice as likely to smoke compared to people with no mental health illness.<sup>3</sup>

The focus on pregnant women is also welcomed. The effectiveness of the more successful interventions identified should be highlighted to all the Maternity Hospital groups to help increase cessation rates among pregnant women.

## **2.4. Safety (p172)**

### **E-cigarettes – additional safety aspects:**

In section 5.3.13 on E-cigarette use in youth and initiation of smoking, there is no mention of the damaging effects of nicotine on children and adolescence. Nicotine (and by inference ENDS) is associated with alterations in both lung and neurological development<sup>4</sup>. We would suggest that this point is added to this section.

## **2.5. Economic Analysis/Cost effectiveness of interventions (p206)**

The detailed cost effectiveness analyses should be commended for its meticulousness and attention to detail (Page 267). The point that “the utility gain from smoking cessation is likely to be an underestimate” should be highlighted along with an emphasis on the astronomical costs of smoking related diseases on our healthcare system.

## **2.6. HTA report conclusions**

The conclusions of the HTA are balanced and have our support:

- Smoking cessation services should seek to increase the uptake of varenicline (alone or in combination with NRT or bupropion among smokers wishing to use a form of pharmacological support to quit
- There is insufficient evidence to demonstrate effectiveness of e-cigarettes as a cessation aid- appropriate to await results of ongoing trials before deciding whether e cigarettes should be recommended for those for whom varenicline is contraindicated, not tolerated or non-preferred.
- The addition of any type of behavioural support is associated with a beneficial effect on quitting outcomes
- High intensity interventions combining pharmacotherapy and behavioural support have been shown to improve quit outcomes in people attending secondary mental health services.
- Among pregnant women, behavioural support interventions such as counselling, health education and the use of financial incentives can significantly improve quit outcomes during pregnancy.



**We suggest the conclusions would also include the following**

- **A recommendation from the HTA should be to target these people who wish to quit but decide not to use cessation aids available in Ireland.** This relates to section 3.4.4 Smoking cessation in Ireland (Page 72). It is stated that “The most common approach, used by half (50%) of respondents, was to have no help”.

In addition, section 3.4.5 Inequalities in smoking cessation (page 78) says: “It should be borne in mind that 79% of quit attempts do not involve State-supported interventions,” Perhaps this is an indication that people who wish to quit either don’t believe cessation aids work or they are not aware of all of the options out there. More research into why such group would choose “willpower” alone may better inform us of the best smoking cessation aids to use for these people.

- **The importance and value of Brief Interventions could be highlighted much more in the document.** The need for smoking cessation to be raised at all relevant health encounters, through Brief Interventions should be emphasised in the conclusions.

## Members of the RCPI Policy Group on Tobacco

<b>Name</b>	<b>Representing</b>
Dr Des Cox	Group chair, Consultant in Paediatric Respiratory Medicine
Prof Tom Clarke	Faculty of Paediatrics
Dr Linda Coate	Irish Society of Medical Oncology
Siobhan Kelly	Irish College of Ophthalmologists
Dr Donal Murray	Irish Cardiac Society
Dr Peter Noone	Faculty of Occupational Medicine
Dr Siobhán Nicholson	Faculty of Pathology
Ann O'Shaughnessy	Head of Education, Innovation and Research, RCPI
Dr Carmen Regan	Institute of Obstetricians and Gynaecologists
Dr Peter Wright	Faculty of Public Health Medicine

## References

---

- <sup>1</sup> Cheraghi M, Salvi S. Environmental tobacco smoke (ETS) and respiratory health in children. *Eur J Pediatr* 2009;168:897–905.
- <sup>2</sup> Hollams, de Klerk, Holt, et al. Persistent Effects of Maternal Smoking during Pregnancy on lung function and asthma in adolescents. *AJRCCM* 2014 Feb 15;189(4):401-7
- <sup>3</sup> Lasser, K, J W Boyd, S Woolhandler, D U Himmelstein, D McCormick, and D H Bor. “Smoking and Mental Illness: A Population-Based Prevalence Study.” *JAMA: The Journal of the American Medical Association* 284, no. 20 (November 22, 2000):2606–2610.
- <sup>4</sup> Nicotine and the Developing Human: A Neglected Element in the Electronic Cigarette Debate *Am J Prev Med.* 2015 August ; 49(2): 286–293).

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 7: Johnson & Johnson Ireland Ltd**

Johnson & Johnson (Ireland) Ltd. has been researching and developing treatments for tobacco dependence for more than 40 years\*. Nicorette® Gum, the first pharmacotherapy to effectively aid smoking cessation, was first marketed in 1978. Since then new nicotine replacement products have been developed and marketed, and Johnson & Johnson (Ireland) Ltd. continues to work to further improve and enhance nicotine replacement products.

In Ireland, Johnson & Johnson (Ireland) Ltd. markets the Nicorette® range of nicotine replacement therapy (NRT) and the Marketing Authorization Holder is McNeil Healthcare (Ireland) Ltd. Nicorette® Gums, Patches, Inhaler, Lozenge, and QuickMist are all available in Ireland as both prescription and over-the-counter (OTC) smoking cessation treatments. All have a general sales list (GSL) OTC status except the 25mg patch which has a pharmacy only medicine (P) status.

Johnson & Johnson (Ireland) Ltd. seeks to collaborate with governments, regulatory authorities, and healthcare organizations to establish and promote policies and guidelines that improve public health whilst reducing the negative impacts of ongoing tobacco use, particularly those that encourage wider access to proven smoking cessation services and therapies.

Johnson & Johnson (Ireland) Ltd. welcomes the opportunity to comment on the “Health technology assessment (HTA) of smoking cessation interventions” published by the Health Information and Quality Authority on 5<sup>th</sup> January 2017. As a major researcher, developer, manufacturer and supplier of smoking cessation pharmacotherapies, Johnson & Johnson (Ireland) Ltd. hopes that its experience and understanding of smoking cessation treatment will be of value to the Health Information and Quality Authority.

Johnson & Johnson (Ireland) Ltd. would also welcome the opportunity to expand on any of the areas highlighted in this response or to answer any questions that arise from it.

\*This period includes the years during which Pfizer Consumer Healthcare and other legacy companies owned and marketed Nicorette®, and prior to the acquisition of Pfizer Consumer Healthcare by Johnson & Johnson in 2006.

In response to the consultation on the “Health technology assessment (HTA) of smoking cessation interventions” published by the Health Information and Quality Authority (HIQA), Johnson & Johnson (Ireland) Ltd. (“JJI”) is submitting comments focussed on three domains:

1. The strong recommendation in favour of off-label use of licensed smoking cessation pharmacotherapies.
2. The inclusion of e-cigarettes in the assessment and the safety, efficacy and quality data available as a basis for inclusion (or not).
3. The proven efficacy of licensed nicotine replacement therapies.

### **1. The strong recommendation in favour of off-label use of licensed smoking cessation pharmacotherapies.**

The first statement from HIQA in the report conclusions is that “Smoking cessation services should seek to maximise the uptake of varenicline (alone or in combination with NRT or bupropion) among smokers wishing to use some type of pharmacological support in their quit attempt.”

At this time the use of varenicline and NRT in combination is not supported by the labelling of either varenicline or NRT. The off-label nature of this combination means that there is no recognised posology or safety record on which to make treatment recommendations. “JJI” therefore proposes that they should not be included in the cost effectiveness analysis for use in combination. A statement that they are “best value for money” as a smoking cessation intervention constitutes a tacit recommendation, and implies established, accepted benefit:risk in this indication when that is not supported by evidence at this time, nor is it supported by present product labelling.

Without established efficacy or safety, and given the Health Service Executive (HSE) does not advocate their use in combination for smoking cessation, a cost-effectiveness analysis and implied recommendation is not justified.

If this analysis is to produce viable, cost-effective treatment recommendations, these should be compatible with product labels, and be supported by established efficacy and safety profiles for recommended treatments. We would ask that this is considered.

In addition, “JJI” would like to make the following observations around the studies cited in support of varenicline and NRT use in combination which we would ask to be considered:

- The concept behind the evaluation and recommendation of varenicline and NRT use in combination is questioned. There is no posology for Varenicline and NRT use in combination in the product label for

varenicline or NRT, although it is noted that the varenicline summary of product characteristics (SmPC) does refer to an increased risk of adverse events with the combination.

- The cited studies assess a varenicline and NRT patch in combination; however the treatment recommendation in the report conclusions makes no reference to any particular format of NRT. It is likely given difference in nicotine pharmacokinetics between formats that a higher risk of adverse events could result from the use of faster release nicotine formats other than patch.
- Given the off-label nature of this combination, the treatment recommendation is made on the basis of two studies with demographics that do not allow this to be established. Ramon (2014), studying a group of smokers smoking 20 or more cigarettes per day, fails to demonstrate an efficacy advantage for the primary abstinence endpoint - but does indicate difference in subgroup analyses. This distinction is not mentioned. Koegelenberg (2014) did find an efficacy advantage in a different smoker group (those smoking 10 or more cigarettes per day), however even this manufacturer (Pfizer) funded study referred to the need for further studies to assess long-term efficacy and safety.

It is also of note that should the conclusion about the use of varenicline and NRT in combination remain as published in the draft report it is likely to lead to confusion and uncertainty in the real world. Manufacturers of licensed medicines are only able to communicate about the use of their products in ways consistent with the product label, and frequently they need to respond to questions about product use from healthcare professionals. If guidance from HIQA states such combination use is effective and cost effective whilst manufacturers have to state that they cannot recommend such use due to product labelling there is the potential for confusion, not to mention questions on liability should there be any negative consequences.

## **2. The Inclusion of e-cigarettes in the draft report and the safety, efficacy and quality data available as a basis for inclusion (or not).**

In the press release of January 10<sup>th</sup> 2016 titled “HIQA to carry out HTA of smoking interventions” it was stated that:

The Terms of Reference of the HTA are to:

- describe the range of smoking cessation therapies available
- review the effectiveness and safety of the available smoking cessation interventions and their impact on long term quit rates

- describe the epidemiology of smoking and smoking related-illness in Ireland
- compare the cost-effectiveness of interventions that are associated with improved rates of smoking cessation and to estimate the costs associated with these interventions within the public health system in Ireland
- examine any other relevant issues associated with potential changes to the provision of smoking cessation services by the HSE that may affect patients, staff or the organisation of existing services
- advise on the optimal use of smoking cessation interventions by the HSE, based on this assessment.

Throughout these terms of reference there is a stated focus on smoking cessation therapies or interventions. In the report it is also stated that “Smoking cessation interventions that were evaluated in this HTA include both Pharmacological and non-pharmacological interventions. The pharmacological interventions assessed were: nicotine replacement therapy (NRT), electronic cigarettes (e-cigarettes), antidepressants (specifically bupropion) and nicotine receptor partial agonists (NRPA).” As such e-cigarettes are clearly described as a pharmacological smoking cessation therapy or treatment by HIQA

Article 1 of Directive 2001/83/EC as amended defines a “medicinal product” as:

- “Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; [the first/presentational limb]
- Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis” [the second/functional limb]

The therapies or interventions identified as pharmacological in this report are being used functionally in order to manage tobacco/nicotine dependence for those undertaking a smoking cessation attempt, which are both internationally recognized as a disease state. Nicotine Dependence is recognized as a medical condition in the Diagnostic and Statistical Manual (DSM) of the American Psychiatric Association and Tobacco Dependence is recognized by the WHO in the International Classification of Diseases (ICD-10).

To describe something as a pharmacological smoking cessation therapy or intervention by function and to present it as a treatment for a recognized disease state therefore positions it as medicinal by both presentation and function. As



such e-cigarettes are being described as a medicine for human use and should be subject to medicinal licensing according to Directive 2001/83/EC

With regard to e-cigarettes, it is also important to note that the revised EU Tobacco Products Directive (TPD) (2014/40/EU), which entered into force on 19 May 2014 and became applicable in the EU Member States on 20 May 2016, states that:

“Electronic cigarettes and refill containers should be regulated by this Directive, unless they are - due to their presentation or function - subject to Directive 2001/83/EC of the European Parliament and of the Council (2) or to Council Directive 93/42/EEC (3). Diverging legislation and practices as regards these products, including on safety requirements, exist between Member States, hence, action at Union level is required to improve the smooth functioning of the internal market. A high level of public health protection should be taken into account when regulating these products. In order to enable Member States to carry out their surveillance and control tasks, manufacturers and importers of electronic cigarettes and refill containers should be required to submit a notification of the relevant products before they are placed on the market.”

This requires that any e-cigarette presented as a medicinal product (i.e. for smoking cessation or tobacco/nicotine dependence) and being described as pharmacological by function should be regulated as a medicinal product for human use under the auspices of Directive 2001/83/EC.

At this time there are no e-cigarettes licensed as medicinal products for human use in Ireland or for which the manufacturer has clinical evidence to support its product being used as a pharmacological smoking cessation treatment. Therefore, presently available e-cigarettes do not meet the formal definition of a pharmacological smoking cessation therapy or intervention. Indeed, it would be expected that the competent authority responsible for overseeing the implementation of Article 20 of the revised EU Tobacco Products Directive (TPD) in Ireland would be required to intervene should an e-cigarette manufacturer present or promote their product as a medicinal product unless licensed as a medicine.

It is also notable that in a systematic review on the use of e-cigarettes for smoking cessation, Cochrane graded the quality of the two randomised controlled studies available to evaluate this as “low” and “very low”. Also, in the draft report being consulted upon, HIQA concedes that on the basis of its own review there is insufficient evidence to demonstrate the effectiveness of e-cigarettes in this indication (Page 25). Nor are e-cigarettes recommended by the HSE as a means of smoking cessation on the grounds that “the Health Service can only endorse products that are proven to be safe, and proven to be effective; e-cigarettes have not yet achieved either test.” The position of the Pharmaceutical Society of Ireland (PSI) is also of note in this regard, they

advise that e-cigarettes should not be sold in pharmacy in Ireland as to do so would infer, incorrectly, that their safety and efficacy had been assessed and can be assured.

Other comments that “JJI” would like to make on e-cigarettes in the context of the draft report are as follows:

- It is not apparent that HIQA has considered the lack of any treatment protocol for the use of e-cigarettes in smoking cessation, and hence the potential that they will drive long-term substitution of cigarettes (partially or wholly) with e-cigarettes rather than supporting the cessation of tobacco and nicotine. We can only conclude that HIQA has assumed in their assessment that real world use of e-cigarettes will be in line with the protocols used in cited smoking cessation trials. “JJI” believes that is unlikely when users of unlicensed e-cigarettes are outside the setting of a clinical trial.
- There appear to be incongruous observations within the report, notably that e-cigarettes offer “best value for money” in smoking cessation (Page 24) despite effectiveness not having been demonstrated (Page 25) and the long-term safety being as yet unknown (page 20).
- It is stated that nitrosamines are present in e-cigarette vapour in comparable amounts as in pharmaceutical nicotine products (we assume the comparator to be the Nicorette Inhalator) and a reference is cited (reference 19) in paragraph 3 on Page 36. Upon review of this cited reference our reviewer did not find data supporting this statement. It is also notable that more recent studies have specifically found that the Nicorette Inhalator does not contain nitrosamines (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4154473/>).

“JJI” does appreciate that HIQA may have included e-cigarettes in its HTA in order to reflect what is happening in the market and to future proof any guidance given, despite it not having been explicit that they would be considered as smoking cessation therapies/interventions within the original terms of reference. However, it finds the degree of emphasis and weight they have been given throughout the guidance to be surprising considering there are no such products licensed as smoking cessation aids in Ireland and given the present lack of evidence on their efficacy or long-term safety. Despite those facts it appears from the outset that e-cigarettes were considered equally alongside established, licensed pharmaceutical smoking cessation aids for the purposes of this review.

“JJI” acknowledges that in both its conclusions and recommendations HIQA has been cautious about the present role of e-cigarettes as a result of the present

lack of evidence on their efficacy or long-term safety. However, this was not the headline taken from the report upon its publication and that was published by multiple media outlets and a wide range of other stakeholders. This is concerning given the following quote taken from the draft report:

- “The government has an ethical duty to ensure that the media portrayal of the product is appropriately aligned with its known degree of risk. This is the dealt with in the recent EU Tobacco Products Directive, which aims at harmonising the quality and safety requirements of tobacco products and ecigarettes for the benefit of consumers. Although negative health effects from the use of e-cigarettes are currently unknown, there is concern that potential legal liability may be possible if future research finds that negative effects do result from their use. Provided appropriate warnings and information leaflets containing accurate information are included with the sale of any such product, it is difficult to see how a legal action might successfully be taken if this were to occur.”

There is no doubt that a proportion of smokers are using e-cigarettes as a means to cut down or quit smoking. However, as e-cigarettes are not yet proven as effective or safe, are not yet recommended by the HSE, and cannot be legally promoted as such, we propose that they should not be included in the cost effectiveness analysis at this time. A statement that they are “best value for money” as a smoking cessation intervention constitutes a tacit recommendation, and implies established, accepted benefit:risk in this indication when this report makes clear that this is not the case.

### **3. The proven efficacy of licensed nicotine replacement therapies.**

The safety and efficacy of NRT for smoking cessation has been long established as confirmed by, amongst others, the Cochrane Collaboration and the National Institute for Health and Care Excellence (NICE) in England, The WHO has also listed both NRT patch and gum in their Model List of Essential Medicines and their use is endorsed in the WHO Implementation Guideline for Article 14 of the WHO Framework Convention on Tobacco Control. Importantly, in the Irish context, the National Standard for Tobacco Cessation Support Programme published by the HSE also recommends the use of NRT.

The first statement from HIQA in the report conclusions is that “Smoking cessation services should seek to maximise the uptake of varenicline (alone or in combination with NRT or bupropion) among smokers wishing to use some type of pharmacological support in their quit attempt.” What this conclusion, and the report more generally, does not appear to have fully considered is the efficacy and cost effectiveness of the use of NRT combination therapy as an

alternative to varenicline, i.e., NRT use that is supported by the product labelling for licensed NRT products.

The effectiveness of NRT combination therapy is established and accepted practice. Optimising nicotine substitution by increasing the level of nicotine delivered via one or more NRT formats (combination therapy), means it is possible to increase the efficacy of NRT in achieving quit success. The objective of combination therapy is to use a steady release NRT format such as a nicotine patch, which is designed to supply a steady continuous amount of nicotine throughout the day, with any intermittent cravings that smokers experience being addressed with faster, flexible formats such as nicotine gum or inhalator.

In addition, the AHFS, an American pharmacopoeia, states, “If pharmacotherapy with a single first-line drug does not enable patients to quit smoking, clinicians should encourage the use of transdermal nicotine combined with a self-administered form of nicotine replacement (i.e., either buccal nicotine polacrilex or nicotine nasal spray) that they administer independently to themselves. Nicotine replacement therapy in such combination is more effective than when administered as a single nicotine preparation.”

A search of the published literature has identified a number of articles which discuss the combined use of different NRT products, a number, although not all are as follows:

- The available data for combination therapy suggest that in situations where a smoker is unable to successfully stop smoking using a single form of NRT, a combination of different formats can be both efficacious and well tolerated. The objective of combination therapy is to help address the intermittent cravings that many patients suffer from that can lead to failed quit attempts. Authors have discussed that combination pharmacotherapy is indicated for highly nicotine-dependent smokers, patients who have failed with monotherapy, and patients with breakthrough cravings. They also comment that an additional form of NRT or an addition of a non-nicotine replacement therapy oral medication (bupropion or varenicline) may be helpful.
- The ASH Guidance (2005) entitled ‘Nicotine Replacement Therapy – Guidance for Health Professionals on Changes in the Licensing Arrangements for Nicotine Replacement Therapy’ states:
  - *“More than one form of NRT can now be used concurrently. Patients with a history of failure of quit attempts using a single form of NRT should be offered a prescription for combinations of patch plus gum, patch plus inhalator or other combinations, but*

*any smoker who wishes to use a combination and is willing to purchase one of the forms themselves should be encouraged to do so.”*

- The NICE Clinical Knowledge Summary on Smoking Cessation states:
  - *“NRT may be combined to gain better control of withdrawal symptoms. This is usually done by providing a steady delivery of nicotine using a patch, with an intermittent formulation (such as the gum, lozenges, or inhalator) to provide relief from breakthrough cravings.”*
- Stead et al conducted a systematic review on NRT for Smoking Cessation on behalf of the Cochrane Collaboration. As part of this review, the authors investigated the efficacy of combination NRT use. Nine trials were included in the review. These studies assessed combination therapy using a nicotine patch along with nicotine gum, nicotine inhalator, nicotine nasal spray or nicotine lozenges.
- Pooling all nine trials suggested a statistically significant benefit for combining a nicotine patch with a rapid delivery form of NRT (Risk Ratio 1.34, 95% Confidence Interval; 1.18 to 1.51). It was concluded from this review that, “the evidence suggests that using a combination of NRT products is better than one product alone. Two recent trials have increased the evidence base. Both compared a combination of patch and lozenge with either alone. The trials showed fairly consistent effects, with a range of different comparators. The combined therapies all included the patch and an acute dosing type...”. The Cochrane review did not recommend particular acute dosing forms to be used in combination.
- Mills et al performed a systematic review and meta-analysis to compare the effect of high-dose NRT and combinations of NRT for increasing smoking abstinence rates compared to standard dose NRT patch, varenicline and bupropion on smoking abstinence. Ten electronic databases were searched (up to January 2012) for randomised controlled trials of standard-dose ( $\leq 22$  mg) or high-dose nicotine patch therapy ( $> 22$  mg), combination NRT (e.g. nicotine patch + nicotine inhaler), bupropion, and varenicline. Analysis consisted of random-effects pairwise meta-analysis and a Bayesian multiple treatment comparison (MTC). The authors identified 146 randomised controlled trials (65 standard-doses of the nicotine patch ( $\leq 22$  mg); 6 high-dose NRT patch ( $> 22$  mg); 5 high versus standard-dose NRT patch; 5 combination NRT versus inert controls; 6 combination versus single NRT patch; 48 bupropion; and 11 varenicline). The MTC found that all therapies offered treatment benefits at most time points over controls. Combination NRT

and higher-dose NRT did not demonstrate consistent effects over other interventions. With the exception of varenicline, the benefits of treatments over standard-dose NRT were not retained in the long term. The authors concluded that all pharmacologic treatments were significantly more effective than inert controls.

- Cahill et al conducted network meta-analyses, comparing pharmacological interventions for smoking cessation. The analyses covered 267 studies, involving 101,804 participants. Combination NRT outperformed single formulations. The authors also concluded that combination NRT and varenicline are equally effective as quitting aids.
- Furthermore, a study by Fagerstrom et al demonstrated that combination therapy was significantly better at managing cravings compared with patch alone.

Based upon this information and data, “JJI” asks that HIQA give greater consideration to the role of combination NRT therapy as an alternative first line smoking cessation treatment alongside varenicline.

Johnson & Johnson (Ireland) Ltd. is grateful to have the chance to respond to the draft report “Health technology assessment (HTA) of smoking cessation interventions” published by HIQA. Please note that “JJI” would be very willing to engage in further dialogue on these topics and to answer any questions resulting from this response. It looks forward to continued engagement in the process of developing a smoking cessation guideline that will support smokers in Ireland on the journey to a life free from tobacco and nicotine and to advancing public health in Ireland.

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 8: Vape Business Ireland (VBI)**

## **Draft Health technology assessment (HTA) of smoking cessation interventions - public consultation**

### **Vape Business Ireland response**

Vape Business Ireland (**VBI**) welcomes the opportunity to respond to the Health Information and Quality Authority (**HIQA**) on its draft “Health technology assessment (HTA) of smoking cessation interventions” draft report (**Draft Report**).

VBI is a business alliance committed to securing and facilitating open debate about vaping products in Ireland, ensuring that the vaping sector is properly represented and that the interests of consumers are recognised. Our membership spans the vaping product supply chain from manufacture to sale.

We support regulation of vaping products that is balanced and evidence-based and which upholds the principles of consumer choice for adults, particularly for adult smokers who wish to find an alternative to tobacco products.

VBI is encouraged by the findings of the Draft Report from which we draw the following conclusions and observations:

- 1.** The Draft Report recognises the role of vaping as a viable alternative to smoking. VBI agrees with this conclusion, given the growing number of international studies already available in this regard.
- 2.** The Draft Report acknowledges that continued research is required going forward to monitor the impact of vaping products on consumers and the population as a whole. In this respect, we would urge the HIQA to provide more clarity on what it considers is required in terms of further research and, from this, we recommend that the Department of Health commission such research and continue this on an annual basis.
- 3.** The Draft Report recognises the fact that a growing number of smokers are choosing to use vaping products as a means of quitting smoking, and advocates the need for information on vaping products being made available in our opinion without further delay, whether through Quit.ie, or otherwise, so that consumers are fully informed.
- 4.** The Department of Health should examine the role that can be played by vaping in advancing the Healthy Ireland target of a Tobacco Free Ireland by 2025 and publish its findings to clarify the potential role that vaping can play in reaching that target.



Given that the Healthy Ireland 2015 survey found that between 100,000-150,000 adults in Ireland use vaping products (e-cigarettes) and 32% of those who do quit using vaping to do so, we welcome HIQA including vaping products in their considerations when assessing availability and effectiveness of quitting tools and viable alternatives to cigarettes. At the same time, it is important to note that the revised Tobacco Products Directive (TPD2) contemplates Member States applying an approach whereby vaping products which contain up to 20mg per ml of nicotine can be sold as a regulated consumer products and products containing over 20mg per ml of nicotine will need to be licensed as medicines. This distinction should be maintained.

In the context of vaping products, the Draft Report is based on a range of comprehensive studies such as the Public Health England "E-cigarettes: an evidence update"<sup>1</sup> and relevant Cochrane studies from the database of systematic reviews. We acknowledge that no research of vaping in Ireland exists, but HIQA does use a range of international studies to arrive at its conclusions around vaping and we welcome its use of same. The Royal College of Physicians' report, 'Nicotine without smoke: tobacco harm reduction'<sup>2</sup>, concluded that vaping products are likely to be beneficial to public health and it is important to promote the use of vaping products as widely as possible as a substitute for smoking. The RCP Report emphasised that *"it is inherently unlikely that nicotine inhalation itself contributes significantly to the mortality or morbidity caused by smoking. The main culprit is smoke and, if nicotine could be delivered effectively and acceptably to smokers without smoke, most if not all of the harm of smoking could probably be avoided."*

In respect of the concern raised in the Draft Report that vaping product use among non-smokers may act as a precursor or 'gateway' to smoking, the RCP Report it should be noted concluded that: *"[r]enormalisation concerns, based on the premise that e-cigarette use encourages tobacco smoking among others, also have no basis in experience to date"*. A recent systematic review also noted that *"[f]our population survey studies found that tobacco use rates among youth were declining as vapour device prevalence increased. The two regression analysis studies provided the strongest evidence that vapour device use does not lead to tobacco use among youth, as US adolescents with access to vapour devices had lower rates of tobacco uptake than those who were banned from the legal purchase of*

---

<sup>1</sup> E-cigarettes: an evidence update. (2015) Public Health England. <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

<sup>2</sup> Nicotine without smoke: Tobacco harm reduction. (2016) Royal College of Surgeons <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

vapour devices.”<sup>3</sup> In our view therefore the concerns raised in the Draft Report regarding the potential gateway effect of vaping products do not sufficiently recognise the weight of current evidence.

It is also relevant to note the UK’s Institute of Economic Affairs (IEA) discussion paper on Understanding the Basics Economics of Tobacco Harm Reduction published in 2016.<sup>4</sup> This paper states that the best first option for those looking to quit smoking is to use alternatives such as vaping products rather than quitting without any aid.

We believe that these studies, on which policy around vaping products has been formed in other jurisdictions, are sufficient to assess the role of vaping products in providing viable alternatives in Ireland. The only Irish ‘research’ on vaping products and the role they play is the Department of Health’s annual Healthy Ireland survey which provides specific data on the use of vaping products and the role they play in Ireland. This survey found that in 2016, 99% of those who use vaping products are ex-smokers and of those who quit 32% used vaping to do so compared to 48% who used willpower alone. In comparing the results of the 2015 and 2016 Healthy Ireland survey we see that 2% more smokers are using vaping in an attempt to quit which shows that not only are many consumers finding vaping a viable alternative to smoking but that the use of vaping products is on the increase. There has also been much research done within the EU on the effectiveness of vaping products being used as an alternative to smoking, a sample of which can be found at the end of this submission.

In our view the growing evidence on vaping products indicates that appropriate regulation that supports adult access to products, while incorporating mandated quality standards and disclosure of information on products, can yield potential public health benefits over and above existing tobacco control measures.

However, we also agree that continued research going forward is an essential component of any sensible strategy. We believe that HIQA could begin this process in the final HTA by clearly defining the scope of further research it believes is required. We note that the Draft Report states many times that “*there is insufficient evidence to demonstrate their effectiveness as an aid to smoking cessation at present*”. As this is a theme throughout the Draft Report in relation to vaping products, we provide below what we hope are some constructive examples of work that can be done by the Department of Health to ensure adequate research is carried out on vaping products.

---

<sup>3</sup> See O’Leary et al. (2017), Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices: Victoria, BC: Centre for Addictions Research of BC.).

<sup>4</sup> Institute of Economic Affairs (IEA) discussion paper on Understanding the Basics Economics of Tobacco Harm Reduction <https://iea.org.uk/publications/understanding-the-basic-economics-of-tobacco-harm-reduction/>

**1. Research:** We suggest that the Department of Health, should undertake these studies to assess the role played by vaping products in achieving Ireland's 2025 tobacco control goals and the more overarching longitudinal studies on vaping products as a category in Ireland on an ongoing basis.

**2. Consumer information:** We note that the Draft Report, recognises that despite no endorsements by quit services, the HSE, Department of Health or the Government, the use of vaping products as an alternative to smoking continues to rise in Ireland. The Draft Report also confirms that: “[g]iven the increasing use of e-cigarettes, it is of vital importance that their potential benefit and harms continue to be discussed with smokers to ensure informed decision-making in relation to their use”. Therefore, VBI considers that Ireland’s quit smoking service, Quit.ie, should include information on their website about vaping products as another alternative to smoking so that consumers are fully informed. We note that such information is provided by the NHS in the U.K. (see: [http://www.nhs.uk/Conditions/Smoking-\(quitting\)/Pages/Treatment.aspx#e-cigarettes](http://www.nhs.uk/Conditions/Smoking-(quitting)/Pages/Treatment.aspx#e-cigarettes)).

**3. Healthy Ireland Study:** Another way in which the Department of Health can enhance the knowledge regarding how vaping products are being used in Ireland is by expanding the sample size and questions in the Healthy Ireland survey. Widening the sample size and scope of questions will allow the Department of Health to more effectively gauge the potential that vaping products can play in providing an alternative to smoking in Ireland.

To ensure that the final HTA is used to full effect it is important that the HTA offers constructive ideas on what public health bodies in Ireland can do to ensure Irish smokers and vaping product users are being supplied with legitimate and up-to-date information.

#### Other relevant research/studies:

**1. Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries – Farsalinos, et al,** (here<<http://onlinelibrary.wiley.com/doi/10.1111/add.13506/abstract>>)

Researchers conducted an analysis of EU data and found that 6.1 million (35.1%) smokers quit smoking cigarettes using e-cigarettes.

**2. A longitudinal study of electronic cigarette use among a population-based sample of adult smokers: association with smoking cessation and motivation to quit – Biener, L., et al** (here<<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4375383/>>)

Researchers surveyed representative samples of two US metropolitan areas about their use of novel tobacco products. Follow-up interviews were conducted and assessed their smoking status and history of e-cigarette use. The study found that intensive users of e-cigarettes (used e-cigarettes

daily for at least one month), were more likely than non-users/tryers to report that they quit smoking. The study concluded, “daily use of electronic cigarettes for at least 1 month is strongly associated with quitting smoking at follow-up.”

3. **Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study** – Brown, J., et al  
(here <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4171752/>)

The study assessed the effectiveness of e-cigarettes when used to aid smoking cessation compared with over-the-counter NRT and with unaided quitting. The study found that, among smokers who have attempted to stop without professional support, those who use e-cigarettes are more likely to report continued abstinence than those who used over-the-counter NRT or no aid to cessation.

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 9: Tobacco Free Research Institute (TFRI)**

Date 31.01.2017

Dear Dr. Moran,

Thank you for giving me the opportunity to comment on the HTA of smoking cessation interventions. It is a very comprehensive assessment. Mostly it seems to take a fresh look at what is already available in the literature especially meta-analyses, more especially Cochrane reviews which are familiar to those involved in smoking cessation but as per your terms of reference may inform others of these considerations. However we feel the report sometimes loses sight of the status and role of smoking cessation in the overall aim of creating a Tobacco Free Ireland. There also seems to be a lack of an in-depth look at Smoking Cessation Services in countries other than UK. If this was required the Pesce and EQUIPP reports referenced below may have helped.

We have a number of reservations about aspects of the draft report but have specific concerns about the approach to Ecigs as a smoking cessation intervention which, as you concede, is not yet acceptable or accepted.

Also Varenicline + NRT as a treatment regimen shows promise but has not been evaluated in any known Smoking Cessation Service to date nor has a pricing structure for such a regimen been published or experienced. Mechanistically this combination is counter intuitive so needs careful examination.

Our main comments refer probably mainly to **Chapters 6 and 7** but we have made a number of comments in tracked changes in the full document about other chapters which I attach to this email and also record some of them below but we think they may be easier to relate to in the tracked changes.

### **Efficacy of Ecigs**

With regard to Ecigs their efficacy, effectiveness and indeed their role in Smoking Cessation and in Tobacco Control is far from a settled issue.

We are therefore surprised at the superficiality of the discussion - that you do not discuss the Surgeon General's report or other important USA publications or the worries that many in Tobacco Control, including in this country, have about the role of Ecigs in general and in particular the risk involved with Tobacco Industry ownership of Ecigs and its relationship to FCTC Article 5.3. We are surprised that when discussing Ecigs in young people you do not report on the existing Irish report (refs below) There is also the citation of the "95% safer" figure as if it had accepted scientific merit when in fact an even superficial reading of the report and subsequent criticism of it internationally make it clear that it is a figure without a firm scientific basis and derived from an inadequate data set.

Your own report on the efficacy of Ecigs has similar problems. There are very few data and those that exist provide no certainty about anything and are therefore unreliable for assessing efficacy or

---

#### **TobaccoFree Research Institute Ireland**

Focas Research Institute, D.I.T. Kevin Street, Dublin 8.

Ph: 087 6887678 EMAIL [tobaccofreeireland@gmail.com](mailto:tobaccofreeireland@gmail.com)

[www.tri.ie](http://www.tri.ie)

Ms Valerie Duncan, Mr. Ivor Fitzpatrick (Chair), Prof. Pat Goodman, Mr Kevin Halpenny,  
Registered in Ireland. Focas Research Institute, DIT Kevin Street, Dublin 8. Co Reg No 351908



effectiveness. You cannot therefore give credence to a cost-effectiveness analysis based on existing data. This is all very disappointing as you identified these problems and stated them in the body of the text and then went ahead as if they did not exist or you had the solution

### **Cost effectiveness analysis of Ecigs**

With regard to the cost effectiveness analysis itself it has the usual difficulties which we also encountered in the SimSmoke model. Obviously there are 3 important blocks in the model:

#### 1. Smoking population

**Comment:** We had to adopt a similar approach in SimSmoke. For example, mortality rate by smoking status, age and gender was from US Surgeon General's report, CSO and HI 2015. Prevalence of smoking-related illness is from National Cancer Registry Ireland, and international literature etc.

2. The relative clinical effectiveness estimate for each of the smoking cessation interventions and the baseline absolute quit rate associated with unassisted quitting were reported in the clinical effectiveness chapter (Chapter 4).

**Comment:** As far as I can see there are no Irish data used in this?

Our own paper below and the annual reports from HSE lead me to believe that your assumptions are unreliable in general for Ireland.

However when we come to Ecigs we suggest the results from 2 fairly inconclusive RCT should not be used to make national recommendations.

It may be said that the report does not make recommendations but your misleading press release and the failure to correct it in subsequent interviews suggest that you are offering the report as a way forward including a role for Ecigs and this does not seem appropriate at present.

#### 3. The cost of various smoking cessation interventions.

**Comment:** A difficult estimate. Your costings seem to suggest that Ecigs will be used for 3 months as might occur in an RCT. There is no evidence that when Ecigs are used ad libitum that they will only be used for only 3 months. So I cannot understand how a decision to assume 3 months usage was made or agreed. As far as I know even in UK the duration of usage in their 'real world' estimates no such assumption is made? Your costs are therefore unreliable and may be misleading

So you neither know the effectiveness nor the cost of Ecigs in an Irish Smoking Cessation setting, casting doubt on your results which needs to be made clear in summaries and press releases. Did you not consider that maybe the reason that there were no similar analysis of Ecigs cost-effectiveness to yours was that there are inadequate data available on which to base such an analysis? You risk causing severe damage to the smoking cessation service if action were to be taken on the basis of this estimate.

**References relevant to these comments:**

**U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults.** A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

**A systematic review of health effects of electronic cigarettes**

Preventive Medicine, Volume 69, Issue null, Pages 248-260

Charlotta Pisinger, Martin Døssing

**Electronic cigarettes and nicotine dependence: evolving products, evolving problems**

Caroline O Cobb, Peter S Hendricks, and Thomas Eissenberg corresponding author

BMC Med. 2015; 13: 119.

Published online 2015 May 21. doi: 10.1186/s12916-015-0355-y PMID: PMC4440602

**EUROPEAN SCHOOLS SERVICE PROJECT ON ALCOHOL AND OTHER DRUGS (ESPAD) 2015.**

Luke Clancy, Keishia Taylor, Kate Babineau, Sheila Keogan, Ellen Whelan ISBN. 978-0-9557528-2-7 [www.tri.ie](http://www.tri.ie) (particularly Chapter 4)

**E-cigarettes: effective cessation tools or public health threat?**

L. Clancy and K. Babineau QJM: An International Journal of Medicine, 2016, Vol. 109, No. 2

**Electronic cigarette use among Irish youth:**

A cross sectional study of prevalence and associated factors. Babineau K, Taylor K, Clancy L (2015). PLoS ONE 10(5): e0126419. doi: 10.1371/journal.pone.0126419

**EQUIPP: Europe Quitting: Progress and Pathways, London, 2011  
Bridgehead International**

**PESCE General Practitioners and the economics of smoking cessation in Europe** (EU Grant Agreement 200 5319) Executive Project Summary May 2008

**Harm Reduction and e-Cigarettes: distorting the approach**

Moore, M; McKee, M; Daube, M; (2016)

Journal of public health policy. ISSN 0197-5897 DOI: 10.1057/s41271-016-0031-2

**Irish healthcare staff-smoking, training and activity in treatment of tobacco dependence - an online survey.**

Sheila Keogan, Annette Burns, Kate Babineau, Luke Clancy

Tob. Prev. Cessation 2016;2 (September):66 <http://www.dx.doi.org/10.18332/tpc/64946>

**TobaccoFree Research Institute Ireland**

Focas Research Institute, D.I.T. Kevin Street, Dublin 8.

Ph: 087 6887678 EMAIL [tobaccofreeireland@gmail.com](mailto:tobaccofreeireland@gmail.com)

[www.tri.ie](http://www.tri.ie)

Ms Valerie Duncan, Mr. Ivor Fitzpatrick (Chair), Prof. Pat Goodman, Mr Kevin Halpenny,  
Registered in Ireland. Focas Research Institute, DIT Kevin Street, Dublin 8. Co Reg No 351908





### **Varenicline + NRT**

With regard to treatment with Varenicline + NRT this is interesting but as you point out there are only 2 RCT neither of them seems to have reported results at 1 year. Studies referenced below cast doubt on those findings. We are not aware of any SCS that is using this combination. If this were a recognised treatment regimen, which it is not, the 'real world' costs might be quite different from your estimated costs. So again are you confident that it is appropriate to report this as if it is reliable?

### **Refs to be considered further**

#### **Is a combination of varenicline and nicotine patch more effective in helping smokers quit than varenicline alone? A randomised controlled trial**

Peter Hajek, Katie Myers Smith, Al-Rehan Dhanji and Hayden McRobbie

Hajek et al. BMC Medicine 2013, 11:140 <http://www.biomedcentral.com/1741-7015/11/140>

#### **Combining varenicline and nicotine patches: a randomized controlled trial study in smoking cessation.**

Josep M Ramon, Sergio Morchon, Antoni Baena and Cristina Masuet-Aumatell

Ramon et al. BMC Medicine 2014, 12:172 <http://www.biomedcentral.com/1741-7015/12/172>

### **Other points concerning the report:**

#### **Chapter 6.5 re Key points-Preference of smokers receiving SC service advice:**

Preference is often due to convenience and availability. If 'Nurse Practitioners' were available in every clinic it seems likely that this would have marked effect or at least I think it would be valid to raise the issue.

#### **Chapter 7.1.2.1**

Were the papers referenced below from Nutt et al. and from Moore et al. considered as regard this discussion?

Perhaps they should have been as they show that the basis for '95% safer' claim and how it is seriously flawed as the authors know the data available is inadequate for an accurate estimate and therefore may be misleading and still published widely.

#### **Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach**

David J. Nutt, Lawrence D. Phillips, David Balfour, H. Valerie Curran, Martin Dockrell, Jonathan Foulds, Karl Fagerstrom, Kgosi Letlape, Anders Milton, Riccardo Polosa, John Ramsey, David Swenor  
Eur Addict Res 2014; 20:218–225 DOI: 10.1159/00036022

And see also the following which assesses some of these points

#### **Harm Reduction and e-Cigarettes: distorting the approach**

Moore, M., McKee, M. & Daube, M. J Public Health Pol (2016). doi: 10.1057/s 41271-016-0031-2

---

### **TobaccoFree Research Institute Ireland**

Focas Research Institute, D.I.T. Kevin Street, Dublin 8.

Ph: 087 6887678 EMAIL [tobaccofreeireland@gmail.com](mailto:tobaccofreeireland@gmail.com)

[www.tri.ie](http://www.tri.ie)

Ms Valerie Duncan, Mr. Ivor Fitzpatrick (Chair), Prof. Pat Goodman, Mr Kevin Halpenny,  
Registered in Ireland. Focas Research Institute, DIT Kevin Street, Dublin 8. Co Reg No 351908



**In the terms of reference for the report** it states

*“Examine any other relevant issues associated with a decision to change the provision of smoking cessation services by the HSE that may affect patients, staff or the organisation of existing services.”*

With regard to the existing service and your presentation of it there seems to be a missed opportunity. When discussing prescription it is said this may be by a Nurse prescriber or a doctor which of course is true but how many registered nurse prescribers of smoking cessation pharmacotherapies are there in the service at present? When we surveyed the SCS there was only one Nurse Prescriber in the service. If you have up to date figures for this we feel you should publish them and if as low as we feel then recommendations on this matter would be appropriate. If all SCS practitioners were registered prescribers we believe it would transform the service and would result in smokers getting the best available treatment in many more interactions.

### **References for -Wider Implications on service- Chapter 7.2**

#### **An evaluation of the range and availability of intensive smoking cessation services in Ireland.**

Currie, L. M., Keogan, S., Campbell, P., Gunning, M., Kabir, Z., Clancy, L. (2009). *Ir J Med Sci.* 2009 Jun 27. <http://www.ncbi.nlm.nih.gov/pubmed/19495838>

#### **Irish healthcare staff-smoking, training and activity in treatment of tobacco dependence -an online survey.**

Sheila Keogan, Annette Burns, Kate Babineau, Luke Clancy

*Tob. Prev. Cessation* 2016; 2 (September):66 <http://www.dx.doi.org/10.18332/tpc/64946>

**When considering inequalities in smoking** we found that PLWHA were very badly served and feel this might be mentioned under this topic especially as so much resource is spent on treating HIV and so successfully but mortality from smoking in PLWHA is greater than from HIV infection.

#### **Smoking Behaviour among People Living with HIV and AIDS: A Sub-Group Comparison**

K Babineau, S O Dea, G Courtney, L Clancy. *IMJ* 2016

Yours sincerely,

Prof Luke Clancy, BSc, MB, MD, PhD, FRCPI, FRCP (Edin), FFOMRCPI  
Director General  
TobaccoFree Research Institute Ireland

---

#### **TobaccoFree Research Institute Ireland**

Focas Research Institute, D.I.T. Kevin Street, Dublin 8.

Ph: 087 6887678 EMAIL [tobaccofreeireland@gmail.com](mailto:tobaccofreeireland@gmail.com)

[www.tri.ie](http://www.tri.ie)

Ms Valerie Duncan, Mr. Ivor Fitzpatrick (Chair), Prof. Pat Goodman, Mr Kevin Halpenny,  
Registered in Ireland. Focas Research Institute, DIT Kevin Street, Dublin 8. Co Reg No 351908

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of smoking cessation interventions.

## **Appendix 10: Purplebox Vapours Ltd**

## **purplebox vapours Response to HIQA Public Consultation on Smoking Cessation Interventions in Ireland**

To whom it may concern;

My name is Steve Barrett, I am the owner of a small independent vaping business known as purplebox vapours, located in Temple Bar, Dublin 2.

This is my response to the request from HIQA for public consultation to its report on *Smoking Cessation Interventions in Ireland* with direct reference to Vaping products / electronic cigarettes.

### **Background**

In July 2013 I embarked on my research into the phenomena that is vaping and electronic cigarettes. I started from a skeptical viewpoint that e-cigarettes would be as harmful as regular cigarettes and that nicotine per se was one of the many toxic elements involved in smoking.

During seven months of exhaustive research – finding the initial studies into the vapour production from these devices and the available research from many health bodies into, not only the harmless aspects of nicotine, but the uses of nicotine in treating many medical conditions, my opinions changed dramatically. In fact, Robert West, Professor of Health Psychology and Director of Tobacco Studies at the Cancer Research UK Health Behaviour Research Centre, called the concept “revolutionary” and I agreed with him.

I decided to invest in this new sector, with no vested interests or big backers I opened purplebox vapours with the simple mission to help people stop smoking and guide them on how to use this revolutionary new product that could give the nicotine stimulus without the harmful aspects of smoking.

### **Vaping as a Smoking Cessation Aid**

Currently smoking cessation methods and NRT's (Nicotine Replacement Therapies) include:

- Nicotine patches, chewing gums or spray
- Zyban tablet medication
- Hypnosis
- Cold turkey
- Vaping / e-cigarette use

The 2007 *Cochrane Review* of NRT's (Cochrane is a global independent network of researchers, professionals, patients, carers, and people interested in health) found that initially NRT's have reasonable success in helping people to stop smoking:

- Nicotine patches and chewing gum – 31%
- Nicotine sprays – 42%
- Zyban medication – 30%
- Cold turkey – 5%

However, despite the initial success only 5% of those tested were smoke free 12 months later.

The 2016 study of e-cigarette and Vaping as a cessation aid conducted by the *International Journal of Environmental Research and Public Health* concluded that even after one year 40.8% of smokers who had used vaping to quit had eradicated tobacco from their lives

completely and a further 15.5% had dropped their cigarette intake by over 80%. A further 10% had reduced their smoking habit by 50%.

The scientists conducting the survey concluded that "smokers purchasing e-cigarettes from vape shops with professional advice and support can achieve high success rates".

In 2016 the *Journal for the Society on the Study of Addiction* also backed the findings of The International Journal. Furthermore, it concluded that relying on the expert advice from a specialist supplier of vaping products was more likely to result in success, owing to the ability to purchase the correct equipment, obtain the correct strength of nicotine within the e-liquid and psychologically feel part of the Vaping community.

### **The Psychological Aspects to Vaping Success**

As shown by many studies, NRT's such as patches, gums and sprays enjoy initial success as smoking cessation devices, however, their success is minimal when studied long term (over a 12-month period). This is because whilst they may satisfy a nicotine dependence they do not solve the psychological elements involved in stopping smoking. These include the habitual traits of smokers having developed a hand to mouth habit; smokers looking for the stress relief feeling of smoking and the exhalation of a 'smoke' is a substantial mental barrier if using the stated NRT methods.

Dr Lynne Dawkins, Senior Psychology Lecturer at the University of East London comments: *"The hand-to-mouth action of smoking through associative learning mechanisms can become a deeply entrenched habit. The habitual act of reaching for a cigarette, coupled with reduced impulse control during a quit attempt, may constitute a strong relapse factor. Any smoking cessation aids which more closely resemble a cigarette could help more smokers to quit."*

Vaping is successful in combating all of these psychological aspects and is therefore proven to be much more successful over a long term period.

Many smokers fail to quit or relapse after smoking due to being in unavoidable social situations with other smokers. Vaping is again successful in this situation as the smoker has something to turn to and not feel 'left out' with friends in smoking areas.

### **Vaping/e-Cigarette Safety Should Be Unanimously Supported**

HIQA has a very real opportunity to make a substantial difference to tobacco addiction in Ireland with its Smoking Cessation report by fully supporting the use of vaping devices. It is now abundantly clear that vaping is completely safe and that the level of toxicity of e-cigarette vapour is absolutely minimal.

The most recent study published in *Regulatory Toxicology and Pharmacology* showed what exactly is in e-cigarette vapour compared to the contents of cigarette smoke. Scientists concluded that the toxins in e-cigarette vapour were quite similar to the normal toxins found in regular room air.

Instead of deadly toxins, the e-cigarette vapour only contained propylene glycol, water, and small traces of flavoring and nicotine additives. In order to register any degree of toxicity, the scientists had to use 99 puffs of an e-cigarette to get even the tiniest measurement of 0.18 milligrams of HPHC's. To put that in perspective, a single puff of a Marlboro Gold cigarette measured 30.6 milligrams. In a puff-to-puff comparison, the cigarettes had 2000 times more toxins than the e-cigarettes.

This study makes it clear that vaping is a far better alternative for smokers. They are now scientifically proven to have harm reduction properties and there is no way that lawmakers can argue that public vaping is harmful after looking at these findings.

Dr Michael Mosley, very publicly tested vaping in his programme *Trust Me I'm a Doctor* for the BBC and discovered very similar conclusions to the Regulatory Toxicology and Pharmacology tests.

Professor Linda Bauld (Professor of Health Policy at the University of Stirling, Deputy Director of the UK Centre for Tobacco and Alcohol Studies and holds the CRUK/BUPA Chair in Behavioural Research for Cancer Prevention at Cancer Research UK), alongside the Royal College of Physicians and the Royal College of General Practitioners, believes that it is important to promote the use of e-cigarettes, along with other non-tobacco nicotine products to smokers looking to stop.

She believes that scare stories perpetuated in the media regarding vaping are based on poor science and ulterior agendas of the tobacco industry and various Big Pharma companies who have a vested interest in seeing these vaping products over-regulated into obscurity.

These industries have enormous power and influence with regulatory bodies and as investigative journalist Greg White says on *NewsTarget.com* "As is typical in politics, the driving force behind regulating e-cigarettes has everything to do with money and nothing to do with legitimate concerns over public health".

Linda Bauld has stated, "I believe that e-cigarettes have huge potential to save lives by providing an alternative to smoking. Yet this can only be realised if we address negative harm perceptions and communicate honestly with the public".

It is the responsibility of organisations such as HIQA, the HSE, HPRA and CORU to publicly state the benefits, safety and value of vaping and e-cigarettes as a smoking cessation aid and assist in modifying public opinion to counteract the scaremongering surrounding the vaping sector.

### **Conclusion**

With many health bodies, eminent health professionals, such as Professor Peter Hajek, Professor Robert West, Dr Michael Mosley and others, and many Anti-Smoking Institutions such as Cancer Research UK and the NHS now endorsing Vaping as a viable and the most successful method of quitting smoking and with non-partisan studies highlighting how safe Vaping is an alternative to smoking it seems contrary to common sense to over regulate such a revolutionary industry.

The industry is very much led by independent vape companies and despite their efforts the tobacco industry is having limited success in the market – this is their reason for spreading the scaremongering stories to quash the rise of vaping amongst smokers.

According to the experts vaping has the power to save millions of lives and in the process save the health industry millions of euro in treating smoking related diseases - in Ireland alone this could equate to up to two billion euro.

The fact that vaping has incorrectly fallen under the banner of the Tobacco Products Directive legislation is nullifying its potential positive effect on society. I find it inexplicable that legislative bodies seem to be doing their best to thwart the efforts of independent vaping companies to help rid society of tobacco – paradoxically banning informative advertising and restricting to an absurd degree the size of available e-liquid bottles. These measures will only ensure smokers stay smoking.

It seems lawmakers are regulating a concept rather than anything physical – by classifying Vaping (a concept with no relationship to tobacco) under the Tobacco Directive, it would seem they are classifying nicotine and therefore should be classifying patches, gums and sprays under the same Directive. If not, then are simply allowing the tobacco industry to gain further leverage over the independent vaping sector.

I sincerely hope that HIQA will see the benefits vaping is having on society in general and smokers in particular. *purplebox vapours* has witnessed many clients, who were smoking in excess of 30, 40 or 50 a day successfully eradicate tobacco from their lives. History will surely judge this pivotal moment in the fight against tobacco.

### **Anecdotal Evidence**

At *purplebox vapours* we devised a S.T.E.P. initiative (Switch To Electric Programme) that assisted smokers to make the life change to vaping. We talk with the customer regarding their existing habit and devise a strategy that gives them the best starter kit and the right e-liquid for them. We then monitor their progress over a period of time and help them eliminate tobacco from their lives for good. To give some examples:

*Customer A smoked between 50 – 70 cigarettes per day. He had be warned by his doctor that he may have less than a year to live if this continued. At 46 he had never played football with his children and had difficulty even climbing a set of house stairs. With the correct advice he reduced his habit over two weeks to 30-40 per day and then to between 10-20 and eventually stopped after 6 weeks. After his first game of 5-a-side with his boys he came in to share his delight.*

*Customer B is a woman who was smoking between 20-30 per day, this was increasing with the stress of her son getting very sick. With our assistance she has now been smoke free for a whole year despite the incredible strain of dealing with personal issues.*

We also find that 30ml bottles of e-liquid are key to people sticking to vaping as 10ml bottles can run out quickly and become an inconvenience. 30ml is the perfect size that will last approximately 2-3 weeks and ensures people have enough liquid handy to not relapse to cigarettes if liquid runs out. The new restrictions on bottle size to just 10mls will have a very negative impact on vaping success for new starters.

Without official support the proven safety of vaping will remain hidden and whether to vape or not will remain a dilemma for many smokers. It is time for health organisations, legislative bodies and government departments to step from under the cloud of the tobacco industry and Big Pharma – save lives and save health care budgets. Vaping should not be steeped in self-consciousness and negativity but be celebrated as the revolutionary step that it is.

Witnessing the joy and sense of pride in our customers who switch to vaping and stop smoking is hugely rewarding for us both as individuals and as a business. Should representatives from HIQA wish to spend the day at *purplebox vapours* you are most welcome.

Steve Barrett  
Managing Director  
*purplebox vapours*  
087 250 8731

## **Appendix 11: Royal College of Physicians of Ireland (RCPI) - Faculty of Public Health Medicine**





**FACULTY OF  
PUBLIC HEALTH  
MEDICINE**

ROYAL COLLEGE OF  
PHYSICIANS OF IRELAND

Royal College of Physicians of Ireland  
Frederick House  
19 South Frederick Street, Dublin 2  
Telephone: +353 1 863 9700  
Facsimile: +353 1 672 4707  
Website: [www.rcpi.ie](http://www.rcpi.ie)

HIQA

**Subject: Consultation on HTA of smoking cessation interventions**

**Response from Faculty of Public Health Medicine of Royal College of Physicians of Ireland.**

To whom it may concern,

I understand that the Tobacco Policy group of the Royal College of Physicians is providing a comprehensive response to the report.

On behalf of the Faculty of Public Health Medicine (PHM), I wish to welcome this excellent and comprehensive HTA. We commend the wide consultation and opportunity to comment. It is very good to see such a thorough evidence based approach. We look forward to the development of clinical guidelines on the foot of this work.

The Faculty has a long and continuing concern about the impact of tobacco and smoking on the health of the population. Hence it fully supports and reinforces the need for a substantial investment in an area of such proven cost effectiveness.

Two Fellows of the Faculty have been very prominent in advocating for control of Tobacco: Dr Fenton Howell, as National Tobacco Control advisor to the Department of Health and Dr Patrick Doorley, Chair of ASH Ireland. I know that both will also be commenting on the HTA.

On another note, may I also take the opportunity to complement the Chair of the EAG, Dr Mairin Ryan, for her excellent, authoritative, clear and understandable interview on radio during the week.....an excellent communicator and advocate!

Please do not hesitate to contact us should you require any clarification or support.

Eliz

Prof Elizabeth Keane MCRN 005903  
Dean, Faculty of Public Health Medicine,  
Royal College of Physicians of Ireland,  
Frederick House,  
19 South Frederick Street,  
Dublin 2

Health Information and Quality Authority

Dublin Regional Office

George's Court

George's Lane

Smithfield

Dublin 7

Phone: +353 (0) 1 814 7400

URL: [www.higa.ie](http://www.higa.ie)

© Health Information and Quality Authority 2017