Submission to the consultation of the HIQA draft HTA on smoking cessation interventions

February 3rd 2017

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) see 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 of vaping compared to smoking from 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 smoking that vaping is an acceptable and better thing to do than continuing 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 products 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

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 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.

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 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 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 also welcome any opportunity to aid policy makers in educating on battery safety, including making our specific battery safety leaflet available for reference.