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4/11/2020

To Select Committee on Tobacco Harm Reduction

McNeill Public Submission to the Australian Select Committee on Tobacco Harm Reduction

Thank you for inviting me to submit a response.

A. The treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, New Zealand, the European Union and United States), including but not limited to legislative and regulatory frameworks

In England, the government has adopted an approach to nicotine vaping product regulations which manages the risks (e.g. of youth never smoker uptake) whilst maximising the benefits (smokers using nicotine vaping products to stop smoking). Regulations are therefore in the middle of the regulatory spectrum, eschewing both prohibition (which forces nicotine users to get their nicotine from combustible nicotine sources or medicinal products) and unconstrained market forces. Importantly, our e-cigarette regulations are set against a comprehensive tobacco control strategy which endeavours to maximise regulations for combustible tobacco products – indeed the UK tops the European Tobacco Control Scale (Joossens et al, 2020). The Government recognises the additional contribution that harm reduction approaches make within the tobacco control armoury.

There are two routes to market: consumer and medicinal, but although one product was licensed as a medicine it was never brought to market. UK's nicotine vaping product regulations are implemented within the framework of the Revised European Tobacco Products Directive (European Commission 2016) translated into UK law through the Tobacco and Related Products Regulations (2016) (UK Government, 2016). The Medicines Healthcare products Regulatory Agency (MHRA) acting for the Secretary of Stage for Health is the national competent authority for these regulations. Producers of nicotine vaping products and nicotine containing e-liquids are required to notify the MHRA and submit relevant information (e.g. a list of ingredients in the liquid and emissions, nicotine dose and consistency of dose uptake, toxicology data regarding the products ingredients).

There is also a 'Yellow Card Scheme' for e-cigarettes (similar to that used for medicines) which allows side and adverse effects to be reported by health professionals or consumers and monitored by MHRA:

(https://www.gov.uk/drug-safety-update/e-cigarettes-and-refill-containers-e-liquids-report-suspected-side-effects-and-safety-concerns.)
We give information on the reports to the Scheme in our evidence updates (e.g. McNeill et al, 2020).

The most up-to-date advice on regulations for e-cigarettes is given here:
https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products

The MHRA maintains a database of products that have been notified to them including a list of withdrawn notifications. Such lists could be checked by retailers or consumers if they wish to check that products they are selling or using have been notified to the MHRA.
List of submitted products, companies A to I (MS Excel Spreadsheet, 1.47MB)
List of submitted products, companies J to Z (MS Excel Spreadsheet, 1.74MB)
List of withdrawn UK notifications (MS Excel Spreadsheet, 198KB).

The extent of the notifications (currently ~44,000) suggest that producers of nicotine vaping products comply with this process.

England has implemented additional measures, for example an advertising code restriction, inter alia, the ability of any advertisements to attract adolescents and be confused with smoking (Advertising Standards Authority, 2018) and prohibits e-cigarette sales to under 18 year olds on a par with tobacco.

Additionally, stop smoking campaigns in England highlight the role that nicotine vaping products can play and the importance of completely stopping smoking when vaping. These campaigns portray nicotine vaping products users as middle-aged men and seek to reduce any attractiveness of these products to young people.

In July 2019, a Green Paper, a consultation document (UK Government consultation, 2019), was published which stated an ambition to go smokefree in England by 2030 (achieved when smoking prevalence is 5% or less). In this document the government included an ambition to make smoked tobacco obsolete by 2030 and highlighted that smokers could quit or move to reduced risk products such as nicotine vaping products.

B. The impact nicotine vaping products have had on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption.

In England we monitor the use of nicotine vaping products, attitudes, perceptions, safety issues and the impact on smoking prevalence and cessation as well as the impact of regulations in order to understand how best to regulate the products. We have set out the impact nicotine vaping products have had on smoking rates in England in our evidence updates (McNeill et al. 2018, 2019, 2020), which consistently report that vaping has not undermined the declines in adult smoking. In our most recent report, we explained that smoking among adults in England had continue to decline over the past 10 years and in 2019 was around 15%. Current vaping prevalence (any current use) among adults in England has remained stable since 2014, and in 2019 was between 5% and 7%.

I recently co-authored a study considering the potential impact of nicotine vaping products on smoking prevalence in England using an indirect simulation model (Levy et al, 2020). This indicated that substantial reductions in smoking prevalence occurred in England from 2012 to 2019 which coincided with the growth in nicotine vaping product use. The implied reduction in smoking prevalence from 2012 to 2019 equated to over 165,000 averted deaths by 2052.

C. The established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment.

I would query the language used in this statement as people who smoke do not often or always see e-cigarettes/ nicotine vaping products as a smoking cessation 'treatment'. E-cigarettes are popular because they 'compete' with cigarettes as nicotine delivery systems. So, whilst research trials of e-cigarettes used as a 'treatment' can be illuminating, they are rather limited in what they can say about e-cigarettes. Real-world studies of the impact of e-cigarettes are also important, although somewhat difficult to study and made more complex by a) the heterogeneity of e-cigarettes on the market and b) by perceptions that people have of e-cigarettes. If consumers think that e-cigarettes are equally harmful to tobacco cigarettes (which no study has demonstrated), then they will not be motivated to use e-cigarettes as a way to stop smoking or as a less harmful alternative to smoking. Although complex, I believe that the heterogeneity of e-cigarettes is important as it provides a range of options for smokers to choose from.

The most robust form of evidence synthesis that inform UK health policy are by the Cochrane Review Groups and National Institute for Health and Care Excellence (NICE). The Cochrane Tobacco Addiction Group recently published an update of their widely cited 2016 systematic of electronic e-cigarettes for smoking cessation, whereas NICE are currently undertaking a systematic review to inform an update on their guidance, which is due in July 2021.

The Cochrane review (Hartmann- Boyce et al. 2020) included 50 studies overall (35 new studies since their 2016 review) and reported on both cessation outcomes and adverse events. There was moderate-certainty evidence, from three RCTs including 1498 participants, that quit rates were higher in people randomized to nicotine vaping products compared with people randomized to nicotine replacement therapy (risk ratio (RR) 1.69, (95%CI 1.25 to 2.27)). There was also moderate-certainty evidence, from three RCTs, including 802 participants that quit rates were higher in people randomized to nicotine vaping products compared with non-nicotine vaping products (RR 1.71, 95% CI 1.00 to 2.92). There was also very low-certainty evidence from four RCTs, including 2312 participants, that quit rates were higher in people randomized to nicotine vaping products compared to behavioural or no support (RR 2.50, 95% CI 1.24 to 5.04). These findings are generally consistent with the systematic review by the Joanna Briggs Institute (2019) (commissioned by the Royal Australian College of General Practitioners).

There was no clear evidence of any harmful effects from nicotine vaping products in the trials included in the Cochrane review. The most commonly reported adverse events were throat/mouth irritation, headache, cough, and nausea, which tended to dissipate over time with continued use.

Observational studies, such as those by colleagues at University College London have estimated that nicotine vaping products have contributed to tens of thousands of additional quitters in England. For example, Beard et al. (2019) found that as use of vaping products in quit attempts went up from 2011 onwards, so did the success rate of quitting. When the increase in use of e-cigarettes plateaued around 2015, so did the increase in quit success. Beard et al. estimated that every 1 percentage point increase in use of vaping products in quit attempts resulted in a 0.060 percentage point increase in quit success rate, other things being equal. This led them to estimate that in 2017 around 50,700 to 69,930 smokers had stopped who would otherwise have carried on smoking.

UK research suggests that nicotine vaping products can help in preventing relapse. In one trial where ex-smokers were encouraged to continue to use cessation products if otherwise they might relapse did find ex-smokers vaping for a longer period of time compared to ex-smokers using nicotine replacement therapies (Hajek et al, 2019). There is some evidence that ex-smokers continue to vape for longer than ex-smokers who use NRT to stop.

D. The established evidence on the uptake of e-cigarettes amongst non- smokers and the potential gateway effect onto traditional tobacco products.

We are assessing the 'gateway' effect in our forthcoming 2022 evidence update (McNeill et al, 2022). However, we discussed the gateway theory in our 2015 review and urged caution with the use of the term. The gateway theory is commonly invoked but its definition is contested and the evidential backing for its use in the addiction field is lacking. There are many competing hypotheses for any association between one drug and the subsequent use of another drug (or, in the case of tobacco, drug delivery system). Such hypotheses include shared networks and opportunities to purchase the drugs, and individual characteristics or shared problematic environments. The gateway theory is difficult to test in humans and we urge academics to agree how best to assess the gateway in this field.

However, in our evidence update reports we have examined the uptake of e-cigarettes among non-smokers. In all years, we have observed that whilst non-smokers try e-cigarettes, current or regular vaping is concentrated mainly in people who have experience of smoking. In our 2020 report, for example, we found that less than 1% of 11 to 18 year olds who had never smoked were current vapers. We observed a small rise in the proportion of vapers who had never smoked among adults, but the most recent data (ASH, 2020) indicate that this proportion has declined to 2.9%. There are relatively small numbers of people in English surveys who are current vapers and never smokers making interpretation difficult. We are exploring this in more detail for our forthcoming 2021 report (McNeill et al, 2021).

G. Tobacco industry involvement in the selling and marketing of e-cigarettes

As we reported in our 2020 report (McNeill et al, 2020), about two-thirds of nicotine vaping products on the UK market were currently manufactured by independent companies, so the market in England is not dominated by the tobacco industry. We are exploring this further in our forthcoming 2021 report (McNeill et al, 2021).

Just one further comment on this. I believe that increasing the regulatory burden disproportionately for nicotine vaping products will favour the tobacco industry in two

ways. First, if nicotine vaping products are too tightly regulated it will make it easier for smokers to remain smokers and hence use tobacco industry products. Secondly, a significant regulatory burden on manufacturers will probably result in some of the smaller independent manufacturers being driven out of the business leaving the nicotine market more under the control of the tobacco industry.

I hope this is helpful and I should be happy to provide further information if needed.

Ann McNeill, Professor of Tobacco Addiction

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