Consultation statement:

Input to the next 'Folkehelsemelding'¹ dated 11 March 2022

Contents:

- <u>The role of reduced risk products in tobacco harm reduction</u>
- <u>The new Norwegian approval regulation and Nicotine Pouches</u>
- <u>Maximum 20 pcs in a cigarette pack</u>
- Taxation and pricing as an instrument for reducing consumption
- Final remarks to the consultation

Introduction

Reference is made to the consultation letter of 2 March 2022 with an invitation to provide input to the next Public Health Report to be issued by the Norwegian Government.

BAT Norwayis a member of the British American Tobacco group of companies ("**BAT**"). BAT is at the forefront of the development and sale of a range of nicotine and smoke-free reduced risk products ("**RRPs**")² that provide an alternative to smoking without burning tobacco. To this end, BAT has invested heavily in its own research and development ("**R&D**") activities, and has continued to incrementally increase these investments with in particular an increase in 2021 of £377 million compared to 2020 (itself an increase on 2019 of £346 million). BAT's growing portfolio of RRPs includes oral tobacco-free nicotine pouches, e-cigarettes and tobacco heating products.

We, BAT, fundamentally support the Government's policy objective of preventing the use of tobacco and nicotine products by the under-aged. We agree that tobacco and nicotine products should only be used by adults. As the same time, we also believe that the key to reducing adult smoking rates, and related illnesses, is the transformation of the tobacco market to one that offers adult consumers a range of RRPs. Accordingly, the Government should focus on developing a balanced regulatory regime that supports the RRP market for adult consumers, while protecting against youth usage of any tobacco or nicotine products.

Along with the industry, governments and the public health community have a key role to play in maximising the potential for RRPs to contribute to harm reduction. For these products to be a

¹ Hereafter referred to as the "Public Health Report."

² Based on the weight of evidence and assuming a complete switch from cigarette smoking. These products are not risk free and are addictive. This applies to all references in this document to a "less harmful product" or a "reduced risk product" any variation thereof.

success, they must be supported by effective regulatory and policy regimes that enable responsible growth and promote informed consumer choice. This must then be complemented by responsible practices by the industry.

Around 8 per cent of the Norwegian population between the ages of 16 and 74 smoked daily in 2021, about 9 per cent among women and 6 per cent among men.³ In total, this corresponds to about 360.000 persons. In addition, around 8 per cent smoke occasionally.⁴ This means that around 720.000 Norwegians smoke occasionally or on a daily basis. According to the Norwegian Health Directorate, approximately 15 percent of the entire adult population, or about 670.000 persons (2021), state that they use snus daily. Therefore, RRPs can play an important role for these smokers and snus users, and from an overall public health perspective in Norway.

The role of reduced risk products in tobacco harm reduction

It is accepted worldwide that most of the harm associated with tobacco is due to inhalation of the smoke produced by burning the tobacco, not the nicotine itself. Public health agencies such as the UK Royal College of Physicians recognise that: 'the harm of smoking is therefore caused not by nicotine, but by other constituents of tobacco smoke. Non-tobacco nicotine products that reproduce the nicotine delivery and behavioural characteristics of smoking, without the many other toxins in tobacco smoke, therefore have the potential to allow smokers to continue to use nicotine and avoid the significant harm to themselves and others that smoking causes."⁵

While BAT's non-combustible products are not authorised cessation devices under the applicable pharmaceutical legislation, nor are they marketed as such, RRPs, such as nicotine pouches, e-cigarettes, and tobacco heating products, are being used by many smokers as a substitute for traditional cigarettes:

• Nicotine pouches and e-cigarettes do not contain tobacco, and they do not involve any combustion. As a result, no tobacco smoke and no tobacco tar are produced. Therefore, these products do not expose consumers to the vast majority of toxins contained in tobacco smoke. It can be concluded that, based on the weight of the evidence and assuming a

³ https://www.ssb.no/en/helse/helseforhold-og-levevaner/statistikk/royk-alkohol-og-andre-rusmidler

⁴ https://www.ssb.no/en/statbank/table/05307/tableViewLayout1/

⁵ Royal College of Physicians (2016), Nicotine without smoke: Tobacco harm reduction at p. 184.

complete switch from cigarettes, nicotine pouches⁶ and e-cigarettes⁷ pose a lower risk than combustible tobacco products and even less of a health risk than snus products – which the scientific evidence shows are far less harmful than combustible tobacco.

• While THPs contain tobacco, their properties and mode of operation mean that they are very different to conventional combustible tobacco products, including cigarettes. As the tobacco is only heated there is no combustion and no smoke, the aerosol produced by THPs contain far fewer and lower levels of toxic chemicals than conventional cigarette smoke. The emerging scientific evidence suggests that THPs are reduced risk compared to traditional combustible cigarettes.⁸

These products therefore offer a potential tobacco harm reduction benefit by eliminating cigarette smoke inhalation for people who continue using nicotine.

The concept of tobacco harm reduction is embedded in the WHO Framework Convention on Tobacco Control ("**FCTC**"). Specifically, in defining tobacco control, Article 1(d) of the FCTC recognises that "tobacco control" concerns not just "a range of tobacco supply, demand" measures, but also the adoption of "harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke."

The findings of the 2007 report of the UK Royal College of Physicians were unequivocal: "*in this report we make the case for harm reduction strategies to protect smokers. We demonstrate that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that*

⁶ Epidemiological studies have shown snus to be a significantly reduced risk product relative to smoking and that it plays a constructive role in a tobacco related harm reduction strategy. For example, the U.K. Royal College of Physicians has concluded that "[o]n toxicological and epidemiological grounds, some of the Swedish smokeless products appear to be associated with the lowest potential for harm to health" (see Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007); and the WHO Scientific Advisory Committee on Tobacco Product Regulation has concluded that "[a]mong the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes" (see The scientific basis of tobacco product regulation: second report of a WHO study group (WHO technical report series; no. 951), p273). Oral nicotine pouches can be expected to have an even greater impact on tobacco harm reduction relative to snus, given that they do not contain tobacco. Chemical analysis has also demonstrated that toxicant levels in tobacco-free oral nicotine pouches were significantly lower than a scientific reference cigarette and snus (a product which, when switched to completely, is recognised as reduced-risk compared to cigarettes), and were similar to the levels measured in NRT. The chemical profiling measured 22 toxicants, whereby 20 toxicants were found to be below the level of detection for tobacco-free oral nicotine pouches, in comparison to 18 out of 22 for NRT products (see Azzopardi, Liu & Murphy (2021): Chemical characterization of tobacco-free "modern" oral nicotine pouches and their position on the toxicant and risk continuums, Drug and Chemical Toxicology, DOI: 10.1080/01480545.2021.1925691).

⁷ See e.g. List of scientific and public health organizations that have concluded that nicotine vaping is safer than smoking, available <u>here</u>.

⁸ For example, in its 2018 report, Public Health England concluded that "[t]he available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes." and that "[c]ompared with cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds (HPHC). The extent of the reduction found varies between studies." McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 2018.* A report commissioned by Public Health England. London: Public Health England, 2018. See also: https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway

if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved."⁹

Sweanor et al. (2007) summarised the global public health implications of tobacco harm reduction, stating: "*The relative safety of smokeless tobacco and other smokefree systems for delivering nicotine demolishes the claim that abstinence-only approaches to tobacco are rational public health campaigns... Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century."¹⁰*

In October 2021, a distinguished international group of 100 specialists in nicotine science, policy, and practice wrote a letter urging the World Health Organization to make "tobacco harm reduction a component of the global strategy to meet the Sustainable Development Goals for health."¹¹ They wrote:

"Over the last decade, innovation in the tobacco and nicotine marketplace has meant there are now many nicotine products available that do not involve combustion of tobacco leaf and inhalation of smoke. These smoke-free products include vaping products, novel oral nicotine pouches, heated tobacco products, and low-nitrosamine smokeless tobacco, such as snus. Cigarettes and other smoked tobacco products are responsible for the vast majority of the deaths caused by tobacco use globally. Smoke-free nicotine products offer a promising route to reducing the harms arising from smoking. There is compelling evidence that smoke-free products are much less harmful than cigarettes and that they can displace smoking for individuals and at the population level."

<u>The evidence suggests that RRPs have contributed to reduced smoking prevalence in countries</u> with a more flexible regulatory landscape

Experience from markets where other smokeless alternatives have been available for some time also supports the concept that smokers can transition to alternative nicotine delivery systems, with associated decreases in smoking prevalence.

For example, in the February 2021 Eurobarometer survey on Europeans' attitudes to tobacco and electronic cigarettes¹², Sweden reported that the number of current smokers was 7%, the lowest national level in Europe; the number of daily smokers across the EU is 23%. This low smoking rate has been contributed to by the availability of snus in Sweden. As one study reports: "*snus has*

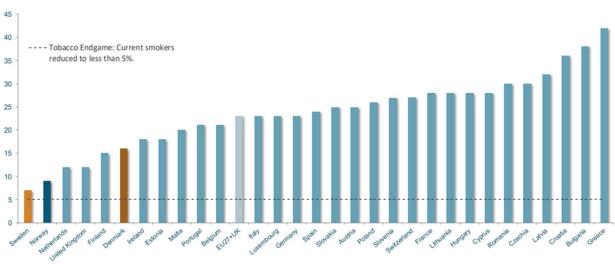
⁹Royal College of Physicians. *Harm reduction in nicotine addiction: helping people who can't quit.* A report by the Tobacco Advisory Group of the Royal College of Physicians. London, United Kingdom; 2007.

¹⁰Sweanor D, Alcabes P, Drucker E. Tobacco harm reduction: how rational public policy could transform a pandemic. Int J Drug Pol. 2007;18:70–74 at p74. doi: 10.1016/j.drugpo.2006.11.013.

¹¹ https://clivebates.com/documents/WHOCOP9LetterOct2021-EN.pdf.

¹² Special Eurobarometer 506, issued February 2021. Available at: https://europa.eu/eurobarometer/surveys/detail/2240

both contributed to decreasing initiation of smoking and, when used subsequent to smoking, appears to facilitate smoking cessation. All these effects suggest that the availability and use of snus has been a major factor behind Sweden's record-low prevalence of smoking and the lowest level of tobacco-related mortality among men in Europe."¹³



Base: All respondents, EU27 + UK + Norway + Switzerland (%)

Source: Eurobarometer 506, February 2021. Central Bureau of Statistics Norway, chart 05307, 2019. The Federal Office of Public Health Switzerland, 2017.

Norway has experienced similar results with its more recent growth in snus consumption being associated with significant reductions in smoking prevalence. Notably, Statistics Norway reports that the prevalence of daily smoking reduced from 19% in 2010 to 8% in 2021, while daily snus use increased from 7% to 15% in the same period.¹⁴

Lund *et al.* (2014)¹⁵ studied how the availability of snus influenced overall tobacco consumption, smoking initiation and smoking cessation in Norway. They found that the increased use of snus has not led to an increase in overall tobacco consumption, as sales of cigarettes have decreased in Norway. The study concludes that snus has contributed to a decrease in cigarette consumption through three mechanisms:

- as a method of smoking cessation;
- as an alternative product for new generations of tobacco-prone consumers who otherwise would take up smoking; and
- as an alternative to cigarettes for smokers who are unwilling to quit tobacco altogether or find it difficult to do so through traditional cessation techniques.

¹³ Ramström L., (2016) Patterns of Smoking and Snus Use in Sweden: Implications for Public Health Int. J. Environ. Res. Public Health 2016, 13(11), 1110

¹⁴ Available at: https://www.ssb.no/en/helse/helseforhold-og-levevaner/statistikk/royk-alkohol-og-andre-rusmidler

¹⁵ Lund *et al* (2014), *How Has the Availability of Snus Influenced Cigarette Smoking in Norway*? Int. J. Environ. Res. Public Health 2014, 11, 11705-11717.

Given that nicotine pouches do not contain tobacco, they are expected to present substantially less risk than combustible tobacco products and even less risk than snus, which the scientific shows is far less harmful than combustible tobacco. Accordingly, they offer the potential for even greater public health gains than those seen with snus.

The evidence also shows that e-cigarettes have contributed to reduced smoking prevalence in some jurisdictions. For example, in the UK, where there is reasonable means of product distribution and communication coupled with the support of the Government and public health authorities, there has been a significant decline in smoking prevalence following the introduction of e-cigarettes. For example:

- West et al. (2014)¹⁶ estimated that the availability of e-cigarettes resulted in between 16,000 and 22,000 long-term quitters in England during 2014;
- Similarly, Beard et al. (2016)¹⁷ estimated that e-cigarettes may have contributed about 18,000 additional long-term ex-smokers in the England in 2015;
- Referring to these studies, the 2018 Public Health England Report concluded that: "*While caution is needed with these figures, the evidence suggests that e-cigarettes have contributed tens of thousands of additional quitters in England*".¹⁸

A recent factsheet by UK Action on Smoking and Health ("**ASH**")¹⁹ on the use of vaping products among adults in Great Britain found that in 2021, the proportion of the adult population using e-cigarettes was 7.1%, amounting to 3.6 million people' and:

- "Nearly two thirds of current vapers are ex-smokers (64.6%), and the proportion continues to grow, while the proportion who also smoke (known as dual users) has fallen to 30.5% in 2021";
- "As in previous years the main reason given by ex-smokers for vaping is to help them quit (36%) then to prevent relapse (20%)".

The report also noted: "*The Annual Population Survey found that smoking prevalence among adults aged 18 and over in England declined by 5.9 percentage points from 2011 to 2019. In 2011, 19.8% of adults smoked, falling to 13.9% in 2019; equivalent to a drop from 7.7 million smokers in 2011 to 5.7 million in 2019.*"²⁰

Public Health England's 2021 evidence update for e-cigarettes²¹, found:

¹⁶ West R, Shahab L, Brown J. Estimating the population impact of e-cigarettes on smoking cessation in England. Addiction. 2016;111(6):1118-9.

¹⁷ Beard E, West R, Michie S, Brown J. Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends. BMJ Brit Med J. 2016;354:i4645-i.

¹⁸ Public Health England (2018), Public Health Matters (Blog) - Turning the tide on tobacco: Smoking in England hits a new low. Available at: <u>https://publichealthmatters.blog.gov.uk/2018/07/03/turning-the-tide-on-tobacco-smoking-in-england-hits-a-new-low/</u>.

¹⁹ ASH (2021), <u>Use of e-cigarettes (vapes) among adults in Great Britain</u>

²⁰ ASH (2020), <u>Use of e-cigarettes (vapes) among adults in Great Britain</u>.

²¹ McNeill, A., Brose, L.S., Calder, R., Simonavicius, E. and Robson, D. (2021). <u>Vaping in England: An evidence update including</u> vaping for smoking cessation, February 2021: a report commissioned by Public Health England. London: Public Health England.

- Studies show that tens of thousands of smokers stopped as a result of vaping in 2017, similar to estimates in previous years.
- Compared to the 2018 review, there is stronger evidence in this year's report that nicotine vaping products are effective for smoking cessation and reduction.
- As suggested in previous evidence reviews, combining vaping products (the most popular source of support used by people making a quit attempt in the general population), with stop smoking service support (the most effective type of support), should be an option available to all people who want to quit smoking.

In Japan, THPs have also emerged as a potentially strong tool for reducing smoking prevalence. A Berenberg analysts' report estimated that, during 2017, the total tobacco "*stick*" market (including cigarettes and tobacco sticks for THPs) declined by just over 2%, but within that the cigarette market declined by 12.5%, with the balance being the growth of the THP segment.²² Analysis by Cummings *et al.* (2020)²³ also found that there was a five-fold increase in the annual percentage decline in cigarette sales in Japan following the introduction of THPs in late 2015. The authors stated: "*between 2011 and 2015, cigarette sales in Japan were declining at a slow but steady pace. However, the pace of decline in cigarette sales accelerated beginning in 2016, corresponding to the introduction of* THPs into the marketplace."

New Norwegian approval regulation and nicotine pouches

On 1 July 2021, the Government repealed Regulation No 1044 which prohibited new forms of tobacco and nicotine products in Norway by a *Stortinget*, and replaced it with Regulation No 2131 of 17 June 2021 which provides an authorization scheme for novel tobacco and nicotine products. In its Resolution 164/2021, the Parliament had requested the Government to urgently, in line with the Parliament's resolution on the approval scheme based on the EU Tobacco Directive, allow the sale of e-cigarettes with nicotine and tobacco-free nicotine snus. . To our knowledge, even though several applications have been processed, the Directorate of Health has not rejected all applications for new forms of tobacco and nicotine products to date (13 April 2022).

Despite the new approval scheme, the Norwegian Directorate of Health states in its input to the new public health report that the Directorate believes that there should still be a high threshold for introducing new tobacco and nicotine products to the market. In the proposal, the Ministry states that «... the requirements in the approval scheme should... take care of general tobacco policy considerations». In the consultation note on changes in the tobacco regulations, it was further stated:

"In addition, the ministry believes that special consideration must be given to the protection of children and young people and whether the product will be able to attract them. The conditions for approval should also take into account tobacco policy considerations, including whether the product can contribute to recruitment and

²² Berenberg analysts' report on Tobacco sector, issued 10 January 2018.

²³ K. Michael Cummings, Georges J Nahhas and David T Sweanor., "What Is Accounting for the Rapid Decline in Cigarette Sales in Japan?" Int. J. Environ. Res. Public Health 2020, 17(10), 3570.

normalization of tobacco use. There should be a factor in the degree to which the product is addictive. "

A specific product category that was not approved is tobacco-free nicotine pouches. The Norwegian Directorate of Health accepted that tobacco-free nicotine pouches could provide a health benefit if today's snus users and smokers switched to this type of product. Nevertheless, the Norwegian Directorate of Health rejected the approval applications due to the claimed uncertainty associated with the product's potential appeal to young people. This is despite the existing comprehensive restrictions on the marketing of these products that would apply under the Tobacco Damages Act. The Norwegian Directorate of Health's practice under the new Regulation 2131 in effect maintains the general ban under the repealed Regulation 1044 and renders the authorization scheme under the Regulation purposeless.

It is therefore timely to question whether the approval scheme entails any reality, and furthermore exactly how the Norwegian Directorate of Health's stated threshold, which effectively requires proof of the complete absence of any risk for the Norwegian market, can be met for any new products.

Maximum 20 pcs in a cigarette pack

Today, Norway has banned the sales of cigarette packs containing less than 20 pieces of cigarettes. We believe that Norway could also consider banning cigarette packs containing more than 20 cigarettes – the so-called **big packs** - for the simple reason that the segment by and large can only attract economy priced cigarettes and thereby create an incentive for younger cost conscious smokers.

Taxation and pricing as an instrument for reducing consumption

There is a well-known correlation between prices and consumption on most consumer products in this world. Tobacco products are no exemption. But prices and taxation cannot be seen in isolation. As known Norway has imposed some of the highest taxes on tobacco products for decades. The new government even increased the 2022 tobacco excises by 6%.

In the input to the next Public Health Report a reference is made to the WHO recommendation that puts excise taxes high on the list of effective tools to reduce tobacco consumption.

We believe that Norway, like most of the world, through the Coronavirus pandemic has experienced two years of extraordinary circumstances, where the closing of borders have illuminated the true picture of domestic consumption of consumer goods like tobacco.

According to our industry studies the consumption of non-Norwegian cigarette packs constituted approximately 45% of the Norwegian market up to 2019. During the Coronavirus pandemic this figure dropped to approximately 23%. Now that Norwegians and foreigners can travel freely in

and out of Norway, indications show that the cross-border trade will revert and reach former levels rapidly.

If new excise increases or other sanctions push the cross-border trade beyond 50% then the Norwegian health and excise policy on tobacco will no longer impact the majority of tobacco consumption in Norway.

RRP products will have an overall positive effect on public health in Norway

We urge the Directorate to support the tobacco harm reduction potential of RRPs and incorporate them into their public health strategy. Well-regulated RRPs can and should be considered as a valuable tool to help prevent disease and save the lives of adult consumers who would otherwise continue to smoke or use tobacco snus.

In 2014 a group of tobacco researchers examined 12 different tobacco and nicotine products using 14 different harm criteria. The result placed non-tobacco nicotine products, including e-cigarettes, oral nicotine delivery products (including NRT products), nasal sprays, and patches as the least harmful products in a model comparative risk continuum.²⁴

McNeill and Munafò (2013)²⁵ state: "we believe that switching to alternative products could be significantly increased if harm reduction was explicitly adopted by regulators. This will require a clear statement from government that the production of clean nicotine products is to be encouraged and public information campaigns implemented which highlight the importance of stopping combustible nicotine products incorporating clear messages on the relative risks of nicotine, e-cigarettes and other new products compared with smoking."

According to the Norwegian Directorate of Health, tobacco policy should be construed in a way that causes as many smokers as possible to quit or switch entirely to less harmful products. According to the Directorate, "The dilemma is that products that can make it easier for the remaining smokers to quit may also attract young people."

However, RRPs are expected to be used by persons who currently use traditional tobacco and nicotine products, including snus, as is the case with e-cigarettes in accordance with the studies previously carried out by SIRUS (now part of Folkehelseinstituttet) - i.e. the evidence does not establish that the use of RRPs cause a "gateway-effect" into smoking. To the contrary, as discussed above, the evidence suggests that they have provided a gateway out of smoking for millions of smokers.

In the Swedish report from *Snuskommissionen* about the health aspects of snus from 2020, *Snusets Helsoeffekter*, the authors elaborate on the snus usage vs smoking in Sweden.

²⁴ Nutt D, J, Phillips L, D, Balfour D, Curran H, V, Dockrell M, Foulds J, Fagerstrom K, Letlape K, Milton A, Polosa R, Ramsey J, Sweanor D: Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur Addict Res 2014;20:218-225. doi: 10.1159/000360220

²⁵ McNeill A, Munafò MR (2013). Reducing harm from tobacco use. *Journal of Psychopharmacology*,27(1), 13–18. https://doi.org/10.1177/0269881112458731

On p. 19 it says:

"In the Swedish political debate, this marked one of many posts in an infected discussion about the possible role of snus as a harm minimizer. The idea is that snus is so much less harmful to health than cigarettes that it would save many lives if more smokers switched to snus instead. It may also be the case that snus becomes an alternative to other types of tobacco for young people, which means that they never go into other uses than just snus. Organizations such as Tobacco Facts object to this reasoning. They claim, on the one hand, that the harm minimization argument rather contributes to increased tobacco use, as certain consumers would otherwise have stopped altogether. On the one hand, they believe that snus contributes to a larger number of tobacco users through the very existence of snus - if snus had not existed, many would have been tobacco-free. Today's all tobacco users had hardly become smokers. However, we object to this - even if more people would use tobacco overall through the existence of snus, this must be put in proportion to the reduced bad health among people that leads to more people using snus instead of some other form of tobacco. Both of these claims from Tobacco Facts also come without reference to studies. Let us instead take a closer look at what evidence actually exists!"

Final remarks to the consultation

BAT believes that the new Regulation on the approval scheme for new tobacco and nicotine products gives the authorities a practical and effective "toolbox" to set terms for approving novel RRP products, including ongoing reporting and market data requirements. The Directorate may require the manufacturer or importer to carry out further tests or provide further information, and may also set conditions for an approval in accordance with the purpose of the Regulation. The regulation also makes it possible for the Directorate to order the withdrawal of products from the market if placing a specific type of product on the market results in a gateway effect.

Also, the fact that Norway is a completely "dark market" with a total advertising ban, point of sales display ban, etc., the likelihood of creating any gateway effects for adolescents and current non-smokers marginal to non-existent. The same goes for users of ordinary tobacco snus.

The danger of excessive regulation was recognised by the UK Royal College of Physicians in its 2016 Report, in which it stated:

"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, <u>if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or progression of the second second</u>

*inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking.*²⁶

Accordingly, rather than continuing its existing practice of banning all new RRPs, the Directorate should focus on developing a balanced approach under the existing authorization regime that appropriately supports the RRP market - so that adult smokers have awareness of, and access to, a wide range of reduced risk alternatives to combustible tobacco and snus products - while protecting against youth usage.

We strongly urge the Government to consider our comments. We would also welcome the opportunity to work with the Government in establishing an appropriate framework for the regulation of RRPs. We are also able to make our research and development scientists available for any further questions or comments regarding smoke and tobacco free alternatives.

²⁶ Royal College of Physicians (2016), Nicotine without smoke – Tobacco Harm Reduction (emphasis added).