1. ASH is a public health charity set up by the Royal College of Physicians in 1971 to advocate for policy measures to reduce the 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, or receive funding from any other commercial organisation.

2. This response was written for ASH by Deborah Arnott, chief executive, who is an honorary fellow of the RCP, member of its Tobacco Advisory Group and contributor to the RCP 2016 report Nicotine without Smoke; expert adviser to NICE and member of NICE working groups developing guidance on tobacco and behaviour change; and was a member of the Commission on Human Medicines ad hoc advisory group to the MHRA on nicotine containing products. I would be happy to give oral evidence to allow the committee to explore the issues covered in this submission further.

Executive Summary and recommendations

3. E-cigarettes are substantially less harmful than smoking and the regulatory system now in place is likely to reduce the risks still further.

4. E-cigarettes are now the most popular aid for smokers trying to stop smoking, and are proving effective in helping many smokers to stop smoking.

5. There is no evidence to date that e-cigarettes are “renormalising” smoking amongst children, nor for that matter among adults.

6. E-cigarettes have the potential to increase the rate of reduction in smoking prevalence, reduce mortality and morbidity, so reducing the burden of smoking on the NHS and increasing productivity. Overall the impact on public finances will be positive.

7. ASH believes it would be beneficial for medicinally licensed e-cigarettes to be available over the counter and on prescription in addition to consumer products to provide additional consumer choice and reassurance.

8. However, the current MHRA licensing process for e-cigarettes has not been effective in encouraging licensed e-cigarettes to be brought to market to date.

9. Regulation of e-cigarettes needs to be considered in the context of the regulation of all nicotine products on the market from combustible tobacco products at one end of the harm continuum to licensed Nicotine Replacement Therapy at the other.

10. Regulation should discourage the use of the most harmful products, smoked tobacco, and incentivise the use of less harmful products as an alternative for smokers, while discouraging their use by never smokers.

11. There are a whole range of regulatory tools which act to motivate behaviour change which can be summarised as:
   - Product regulations
   - Access / availability (including restrictions on locations of permitted use)
   - Packaging and labelling
Advertising, promotion and sponsorship
Product information
Taxation/affordability

12. The UK tends to have stricter regulation of tobacco products than most other EU Member States, but less stringent regulation of e-cigarettes than many others. UK regulation already aligns reasonably well with the continuum of harm, with cigarettes at one end of the spectrum, licensed medicinal nicotine at the other, and non-combustible products and e-cigarettes in between. (see table 1 for a more detailed comparison).

13. Regulation of ‘heat not burn’ tobacco products needs to take account not just of the relative risk of the products but also the role they potentially play in sustaining the profitability of the tobacco industry, which is not necessarily in consumers’ best interest. The evidence to date shows that ‘heat not burn’ products are likely to be more risky than e-cigarettes. They are also proprietary products making them more expensive, for example, than open system e-cigarettes, which use widely available e-liquids which are highly competitive on price.

14. The Secretary of State for Health is required to review the operation and effect of the Tobacco and Related Product Regulations 2016 within five years including e-cigarette regulation. Any revision of the e-cigarette regulations should be evidence-based, involve consultation and fully engage e-cigarette users in the process.

15. ASH suggests that the Select Committee consider the following recommendations.

Recommendations

16. The MHRA should review its licensing process for e-cigarettes in order, as set out in the Tobacco Control Plan for England, to “ensure that the route to medicinal regulation for e-cigarette products is fit for purpose so that a range of safe and effective products can potentially be made available for NHS prescription”.

17. The MHRA should investigate the possibility of licensing e-cigarette liquids including a range of flavourings for prescription and over the counter use without full toxicological and safety data, while requiring the license holder to develop an appropriate ‘risk management plan’ to identify, characterise and quantify any clinically relevant risks associated with flavourings.

On health:

The impact on human health of e-cigarettes—themselves and relative to ‘conventional’ smoking—and any gaps in the science knowledge-base in this area.

18. In 2016 the RCP assessed the evidence available at that time and concluded, in line with the 2015 Public Health England report, that “the hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco” going on to say that, “Technological developments and improved production standards could reduce the long-term hazard of e-cigarettes.”

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The Lords Health Minister committed to parliament that Public Health England would update its evidence report on e-cigarettes annually, and the next report is due to be published shortly.\textsuperscript{3} We commend this to the Committee.

The benefits and risks of e-cigarettes as a ‘stop smoking’ tool, any gaps in the knowledge-base on this

19. ASH has carried out annual representative surveys of adult attitudes and behaviour on tobacco-related issues since 2007. Questions on e-cigarettes have been asked every year since 2012. Our survey provides a rich source of data over time, although as it is cross-sectional it does not demonstrate causality.

20. The proportion of ex-smokers who regularly vape has risen from 1.1% in 2012 to 9.5% in 2017, with growth slowing since 2013. The top three reasons ex-smokers give for using e-cigarettes are to help them quit (61%) to save money compared to smoking (40%) and to prevent relapse back to smoking (39%).\textsuperscript{4}

21. Survey evidence from the Smoking Toolkit Study shows that e-cigarettes became the most popular aid for smokers trying to stop in Spring 2013 and are helping smokers to quit.\textsuperscript{5,6}

22. A recent US analysis concluded that the substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level.\textsuperscript{7}

23. Data from stop smoking service returns show that smokers using e-cigarettes to quit in conjunction with behavioural support from the services have among the highest success rates in quitting. In 2016/17 7,661 smokers setting a quit date with the services used a licensed medication and unlicensed Nicotine Containing Product (e-cigarette) concurrently, 57% of whom were successful 4 week quitters; 1,915 used licensed and unlicensed products consecutively, 69% of whom were successful; and 2,746 used only unlicensed NCPs with a 59% success rate. This compares to the average success rate of those using pharmacotherapy of 51%.\textsuperscript{8}

Need for product choice to meet the needs of smokers

24. ASH originally supported requiring e-cigarettes to have a medicinal license before they could be marketed. Since the EU Tobacco Products Directive was adopted we have supported e-cigarettes being available as consumer products, but we still believe that it would be beneficial to have medicinally licensed products on the market in addition to consumer products to provide additional consumer choice and reassurance. To quote a vaping advocate, “It is our job to make sure that every smoker has every opportunity if they want it. If the smoker needs the reassurance of an MHRA approved device is it up to us to say they can’t have it?”\textsuperscript{9} The BMA in its recently published position paper on e-
cigarettes also supported having medicinally-licensed products available, as it “may provide an important option for some smokers, and would give health professionals confidence in the safety and efficacy of individual devices”.

25. Recently published research\textsuperscript{11} has identified three groups of vapers, with differing beliefs, motivations for use, identity and political interest. The first two were associated with quitting smoking completely, the third with ‘dual use’. The first group identified ‘vaping as pleasure’, envisaged long-term use and rejected the medical model of vaping. The second group identified ‘vaping as medical treatment’ with vaping seen as a pragmatic choice with the aim of treating nicotine dependence. The last group of ‘ambivalent e-cigarette use’ harboured more negative beliefs about e-cigarettes and continued to smoke as well as vape. This was a qualitative study and so it is not possible to estimate what proportion of vapers might fall into each category.

26. However, our surveys are indicative of the relative size of the first two groups among ex-smokers who vape. Additional analysis of our ASH Smokefree GB survey 2017 shows that 18% of vapers who have stopped smoking say they don’t ever want to stop using e-cigarettes. Another 26% say they think they should stop using e-cigarettes but don’t really want to. So it would not be unreasonable to assume that 18% fall into the first category of those who associate vaping as pleasure, to which one could add another 26% who don’t want to stop vaping, but may be feeling pressured into thinking they should (thus 44% overall). Another 8% don’t know while the remainder definitely want to stop using e-cigarettes to a greater or lesser extent, with 6% planning to in the next few months and 42% not yet having set a date (thus 48% overall). In comparison only 8% of smokers in our survey say they don’t want to ever stop smoking, while over a third 34% think they should but don’t really want to, with 12% wanting to stop without having set a date, and a further 13% having set a date.\textsuperscript{12}

27. In summary therefore around a half (48%) of all e-cigarette users who no longer smoke see vaping as a route to stopping all nicotine use, like medicinal NRT, while nearly another half (44%) don’t want to stop vaping and therefore it would be reasonable to assume they associate vaping with pleasure. It does therefore appear many smokers do see ECs as a quitting aid like NRT, not just a pleasure product, and might therefore benefit from having medicinally licensed ECs. These could provide them with reassurance and could encourage more smokers like them to follow that route. We will be adding questions to our 2018 survey to investigate this further.

28. Medicinal licensing is an ‘authorisation’ process rather than a ‘notification’ process. For nicotine containing products the medicines regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA), has accepted that there is good evidence of the efficacy of nicotine to help smokers quit and therefore only an abridged application is necessary which shows that the product delivers nicotine at least as well as a reference NRT product and that it is safe.

29. Providing pharmacotherapy (NRT, varenicline, bupropion) plus behavioural support to quit is highly cost-effective. In fact NICE has estimated that smoking cessation treatment is not just cost-effective but cost-saving. For every £1 invested, £2·37 will be saved

12 Opinion research from YouGov. Total sample size was 12696 adults. 361 GB e-cigarette users who are no longer smoking; 1864 GB adults who have tried e-cigarettes; 1632 GB current smokers of whom 293 are also currently using e-cigarettes Fieldwork was undertaken between 16th February 2017 and 19th March 2017. The survey was carried out online. The figures have been weighted and are representative of all GB adults (aged 18+).
on treating smoking-related diseases and reduced productivity.\textsuperscript{13} The data from the Stop Smoking Services shows that use of e-cigarettes can enhance quit rates. Furthermore among smokers who have attempted to stop without professional support, those who used e-cigarettes are more likely to report continued abstinence than those who used a licensed NRT product bought over the counter.\textsuperscript{14}

30. However, e-Voke, the only e-cigarette given MHRA authorisation to date in November 2015, has yet to come to market and it seems unlikely it will.\textsuperscript{15} To quote the 2015 PHE report “\textit{The fact that no licensed EC are yet on the market suggests that the licensing route to market is not commercially attractive. The absence of non-tobacco industry products going through the MHRA licensing process suggests that the process is inadvertently favouring larger manufacturers including the tobacco industry, which is likely to inhibit innovation in the prescription market}.”

31. ASH recognises that once the EU TPD came into effect the MHRA had to prioritise the implementation of its notification process for e-cigarettes and that medicinal licensing was not a priority while that was being put in place. However, the notification process was in place by May 2017 as required by the EU TPD and related regulations.

32. However, in April 2017 ASH met the MHRA, together with Cancer Research UK, the RCP and a group of interested academics and raised our concerns about the need for the organisation to be more proactive and supportive in seeking medicines license applications and in supporting research into consumer e-cigarettes. The MHRA committed to providing a suite of user friendly communications materials for potential applicants for Marketing Authorisations as they did for the e-cigarette notification process under the EU TPD. Over 7 months has passed since then, and although the MHRA has confirmed these materials will be published imminently, at the time this submission was completed it had not yet happened and all that is available is the current guidance (last updated February 2017).\textsuperscript{16}

33. While such materials will not eliminate the need for companies to ask for more detailed or specific advice our understanding from personal communications from companies which have an interest in pursuing such applications is that they would find it helpful and it would encourage them to believe the MHRA was serious in seeking such applications.

34. The national ambitions in the Tobacco Control Plan for England committed to “Help people to quit smoking by permitting innovative technologies that minimise the risk of harm” and to “Maximise the availability of safer alternatives to smoking” to “ensure that the route to medicinal regulation for e-cigarette products is fit for purpose so that a range of safe and effective products can potentially be made available for NHS prescription”.\textsuperscript{1} To help achieve these ambitions the MHRA committed to “ensure that the route to medicinal regulation for e-cigarette products is fit for purpose so that a range of safe and effective products can potentially be made available for NHS prescription”.\textsuperscript{1}

35. The report on e-cigarettes for Public Health England in 2015 recommended that a review of the MHRA electronic cigarette licensing process be undertaken, with the terms of reference to include a requirement for the MHRA to adapt its processes and costs to enable smaller manufacturers to apply and to speed up the license process.\textsuperscript{17} Such a

\textsuperscript{13} Pokhrel S, Owen L, Coyle K, et al. Costs of disinvesting from stop smoking services: an economic evaluation based on the NICE Tobacco Return on Investment model Lancet Public Health 2016; 388;S95.
\textsuperscript{15} MHRA. Lay summary of Public Assessment Report for e-Voke 10mg and 15mg Electronic Inhaler. 2015.
review has not yet taken place and we would encourage the Select Committee to recommend that it does.

36. It is clearly necessary for the MHRA to review its processes and the terms of reference should be in line with the strategic aim set out in its Corporate Plan refresh 2016 to “Enable safe access to innovative products with prospective risk/benefits monitoring”. 18

37. It should be noted that the MHRA already has a process in place for carrying out such a review. In 2011 it set up an ad-hoc working group on nicotine containing products. The MHRA guidance on licensing e-cigarettes as medicines updated in February 2017 stated that "The findings of the ad-hoc expert working group on nicotine containing products, of the Commission on Human Medicines (CHM), recommended a proportionate assessment of any future marketing authorisation applications (MMA) regarding electronic cigarettes and other nicotine containing products (NCPs)." The author of this submission to the Select Committee was a member of the ad-hoc expert working group and recommended to the MHRA in October 2016 that it be reconstituted to scrutinise whether that has been the case, with no response to date.

38. A key issue which needs to be investigated is that of flavourings in e-cigarettes. The risk that regulation would restrict or prohibit access to flavours has from the outset been a major concern to e-cigarette users, manufacturers and importers. Characterising flavours are an important part of the appeal of e-cigarettes. The ASH Smokefree GB 2017 survey found that only 3% of users reported that the product they use contained no flavour, while a quarter use tobacco flavour, a quarter menthol, 29% some kind of fruit flavour, 15% other and 2% don’t know. It is clear that prohibiting flavours in licensed products, or limiting flavouring to menthol, would be likely to severely limit the appeal of any such product. 19

39. The RCP report concluded that “Although no study so far shows any clear hazards of flavours in e-cigarette vapour, those derived from flavours seem the most likely to pose appreciable health risks in the longer-term.” However, in the short-term there is little evidence of harm in human use of e-cigarettes. To quote the Cochrane review of e-cigarettes, “categorical statements about the toxicity of ECs are not possible because of the large number of devices and fluids available and the frequent addition of new products to the market. However, among those brands of EC that have been tested, levels of toxins have been found to be substantially lower than in cigarettes, and are present at levels that are unlikely to represent a significant risk to health to either the user or to bystanders. Short- to medium-term use of ECs is associated with few adverse events. Long-term effects beyond 12 months are unknown”. 20

40. An analysis of the emissions of e-cigarettes notified to the MHRA has found that all analytes detected in e-cigarettes were at very low levels, in most cases only just above the analytical limit of quantification (this does not include nicotine). All emissions were significantly lower than cigarettes by a factor of between 15 and 200 times and variances in e-liquid composition such as flavours and strengths do not appear to have much impact on emissions. 21 The data were collected over the period September 2015 to September 2016, and the analysis was completed between December 2016 and February 2017.

18 MHRA. Corporate Plan Refresh 2016.
41. There are precedents for adopting a less restrictive approach, in particular in the area of nicotine regulation. Until nicotine replacement therapy was liberalised in 2005, NRT products were licensed for a maximum of 12 weeks. In 2005 this was extended for some products to a year, and in 2009 the MHRA approved a ‘harm reduction’ extension to the license of the nicorette inhalator without a limit to duration of use. This was on the basis that, “it had become widely accepted that there were no circumstances in which it was safer to smoke than to use NRT.” The Commission went on to say that there was a need for further research and data collection to assess long term safety and agreed that the holder of the market authorization “should be asked to provide a robust risk management plan that would satisfactorily address the outstanding issues”.  

42. This is standard practice for pharmacovigilance as set out in European Medicines Agency guidelines, which are adhered to by the UK. These state that, “A medicinal product is authorised on the basis that in the specified indication(s), at the time of authorisation, the risk-benefit balance is judged to be positive for the target population. Generally, a medicinal product will be associated with adverse reactions and these will vary in terms of severity, likelihood of occurrence, effect on individual patients and public health impact. However, not all adverse reactions and risks will have been identified at the time when an initial marketing authorisation is granted and some will only be discovered and characterised in the post-authorisation phase.”

43. Yet while the first novel nicotine delivery device licensed by the MHRA Voke, was licensed with menthol flavour, that was not the case for the only e-cigarette to be licensed, e-Voke. The e-liquid licensed for use in e-Voke only includes nicotine and glycerol, with no flavourings. The lack of clarity about the MHRA’s approach to flavourings is one of the issues that we understand is deterring potential applicants for a market authorisation for e-cigarettes.

44. In the e-cigarette licensing guidance the MHRA states that, “Other ingredients should meet European Pharmacopoeia monograph requirements where they exist; if flavouring components do not have such monographs, then they should meet EU food safety legislation requirements. Excipients should be approved for inhalation use or have appropriate toxicological data to support such use.” If this standard is met it could potentially be prohibitively expensive and time consuming and might effectively prohibit all flavours, or at best limit flavours to menthol, the only flavour to meet European Pharmacopoeia requirements.

45. If the MHRA made clear that it would be willing to license a range of flavourings for prescription and over the counter use without full toxicological and safety data, perhaps in the first instance for a limited time period for cessation, say 12 weeks or perhaps a year, this is likely to encourage applications. Successful applicants could then be required to develop an appropriate ‘risk management plan’ to identify, characterise and quantify any clinically relevant risks associated with flavourings. We would encourage the Select Committee to recommend that this approach be investigated by the MHRA.

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Gaps in the knowledge base

22 Commission on Human Medicines (CHM). Extract from Minutes. accessed 5th December 2017
24 MHRA. Lay summary of Public Assessment Report for Voke/Nicotine 0.45mg Inhalers PL39589/0001-2. 2014.
25 MHRA. Lay summary of Public Assessment Report for e-Voke 10mg and 15mg Electronic Inhaler. 2015.
46. While survey data and the Cochrane review of a small number of randomised controlled trials\textsuperscript{26} (RCTs) supports the hypothesis that e-cigarettes are useful in quitting, further research is needed, both on safety and on effectiveness as a cessation aid.

47. The sort of question that could be answered by further research includes the often raised concern about whether so-called “dual use” risks undermining quitting.

48. There is evidence from randomised controlled trials which have shown that “dual use” of NRT to cut down, even amongst smokers not interested in quitting but only in cutting down\textsuperscript{27}, is effective in supporting quitting which is why it is licensed by the MHRA for this purpose.\textsuperscript{28,29} The pharmaceutical industry funded these RCTs in order to get a license for this indication, and had the expertise and research investment capacity to do so. While this suggests that it may well be the case that e-cigarettes would have the same effect, it is only indicative not conclusive. As an analysis of ASH 2016 data indicated that dual use might be a transient phase of heightened motivation to stop smoking: current dual users were more likely to be motivated to stop smoking in the next three months (after adjusting for socio-demographics and dependence), than past EC users whose motivation was similar to never vapers.\textsuperscript{30}

49. Clearly more research is needed on this important issue. Yet there is no incentive to most consumer e-cigarette companies to carry out such research as they are not seeking medicines licenses for their products. Consumer e-cigarette companies are neither expert in commissioning such research, nor do they have the large research budgets that would be required.

50. Cancer Research UK in collaboration with Public Health England is supporting such research through its UK Electronic Cigarette Research Forum and the provision of e-cigarette specific research funding, with more than 40 studies funded to date. This has been invaluable, but the budgets available are not large in comparison to the costs of clinical research.

51. Initially after the Tobacco Products Directive came into force on 20th May 2016 the MHRA designated e-cigarettes as ‘Investigational Medical Products (IMP)’ subject to Directive 2001/20/EC meaning Clinical Trial Authorisation (CTA) was required. The MHRA subsequently risk assessed e-cigarettes as a type B or C study meaning any CTA would require close collaboration with a manufacturer. ASH heard from researchers that this was making e-cigarette research in the UK largely impossible. This conclusion was supported by the Cochrane review of e-cigarettes, cited above, which found only two randomized controlled trials of e-cigarettes, with no new RCTs having been published since the previous review in December 2014, although more are now underway.

52. Following a challenge by ASH supported by CRUK and the UKCTAS the MHRA commissioned legal advice and concluded in April 2017 that “An e-cigarette which is a consumer product regulated by the Tobacco Products Directive 2014/40/EU (TPD) is not a medicinal product and this product would not be considered an investigational

\textsuperscript{27} Fagerström KO. Can reduced smoking be a way for smokers not interested in quitting to actually quit? Respiration 2005;72:216–20.
medicinal product (IMP) in health/clinical research.”  

For research comparing e-cigarettes to an NRT, being used in accordance with its licence, the MHRA has confirmed that all that would be necessary would be a clinical trials notification (CTIMP A) which does not attract a fee or require collaboration with a manufacturer and enables the trial to proceed 14 days after notification. This should facilitate the commissioning of timely and more cost-effective research into e-cigarettes which will bear fruit in the years to come.

Whether any approaches are needed to tackle e-cigarette addiction.

53. There are a number of varying definitions of addiction, that provided by NHS choices is clear and simple “not having control over doing, taking or using something to the point where it could be harmful to you”. As the RCP concluded in its 2016 report “nicotine use, of itself, presents relatively little risk to users or wider society and that most of the harm that arises from nicotine use is due to the mode of delivery”. It is not clear that e-cigarettes are addictive in the same way that nicotine when delivered through tobacco products, particularly cigarettes, is addictive.

54. For e-cigarette users who want to quit vaping and are unable to succeed on their own, the stop smoking services have the tools to help them, in just the same way as they have helped those concerned about their long-term NRT use to quit. However, if users want to continue to vape, or use NRT, they should not be made to feel that this is a bad choice. The priority is to avoid relapse to smoking, and e-cigarettes may assist in this regard.

The uptake of e-cigarettes among young people and evidence on whether e-cigarettes play a role in ‘re-normalising’ smoking.

55. Concerns that use of e-cigarettes by young people could be leading to smoking are so far not borne out by analysis of five large-scale surveys conducted in the UK during 2015-17 which involved over 60,000 11-16 year-olds. ASH draws the Committee’s attention to these data as it represents the largest analysis undertaken and therefore the conclusions are more robust than possible with smaller scale one-off studies.

56. The findings show a consistent pattern: most e-cigarette experimentation among young people does not lead to regular use, and levels of regular e-cigarette use in young people who have never smoked remain very low. Regular (at least weekly) use of e-cigarettes amongst all young people surveyed was 3% or less. This was highly concentrated in those who also smoked tobacco. Among young people who have never smoked, regular use of e-cigarettes was negligible – between 0.1% and 0.5% across the five surveys.

57. Furthermore the ASH Smokefree GB survey has found that every year since we started asking in 2012 fewer than 0.5% of adult never smokers are current vapers.

58. Both the youth and adult data show smoking prevalence has continued to decline as e-cigarette use has grown, and smoking rates are currently at their lowest recorded levels (15.5% for adults in England down from 19.9% in 2010 before e-cigarette use really
began to take off, and 7% for regular smoking among 15 year olds in England, compared to 12% in 2010\(^{35}\).

59. In conclusion there is no evidence to date that e-cigarettes are “renormalising” smoking amongst children, nor for that matter among adults.

On regulation:

Has Government policy kept up with the full range of ‘smoking’ and novel tobacco products (such as ‘heat not burn’) that are becoming available to the public, and does it take account of their likely impact on human health.

60. E-cigarettes are just one nicotine product, albeit a very significant one in the UK market. In examining the regulatory framework, therefore, it is important to put their regulation in context of the nicotine market as a whole. This market ranges from medicinal nicotine products (NRT) at one end of the harm continuum to the most harmful combustible tobacco products at the other.

61. The continuum of harm related to the use of nicotine products is a widely recognised concept. At the current time we have the best evidence about the risks of the most and least risky nicotine products. To quote the RCP report, “NRT products have an excellent safety profile and present negligible risks to users” (5.5).\(^2\)

62. On the other end of the spectrum are combustible tobacco products, which remain the most widely used nicotine product in the UK. Combustible tobacco products kill at least half all long-term users prematurely primarily through cancer, cardiovascular and respiratory disease which reduces life expectancy by on average 10 years.\(^{36}\)

63. There is much less evidence about the more recent products on the market such as electronic cigarettes or ‘heat not burn’ products. However, electronic cigarettes are estimated to be very significantly less harmful than smoking. ‘Heat not burn’ tobacco products recently placed on the UK market are considered likely to be more harmful than e-cigarettes but again much less harmful than smoking.\(^{37}\) The evidence so far is short-term and can tell us what toxins and carcinogens are delivered by products, but not what their impact on longer-term health will be. But there is clearly a continuum of harm with combustible products on one end of the spectrum and NRT on the other.

64. Regulation should be designed to discourage the use of the most harmful products, smoked tobacco, and incentivise the use of less harmful products as an alternative for smokers, while discouraging their use by never smokers.

65. Regulatory incentives or disincentives act to motivate consumer behaviour either to act in a certain way or not to act. They do not just include financial incentives but also, for example, the provision of accurate information about relative risks. Set out below is a list of the range of regulatory tools currently in place for nicotine products.

- Product regulations
- Access / availability (including restrictions on locations of permitted use)

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• Packaging and labelling
• Advertising, promotion and sponsorship
• Product information
• Taxation/affordability

66. See table 1 for a detailed summary of the current regulatory position in the UK. Almost by definition regulatory policy is likely to lag behind product innovation and it may take some time for the evidence to emerge about how best to regulate relatively new products like e-cigarettes and ‘heat not burn’. However, UK regulation already aligns reasonably well with the continuum of harm, with cigarettes at one end of the spectrum, licensed medicinal nicotine at the other, and non-combustible products and e-cigarettes in between.

67. Cigarettes are allowed on the market despite the fact they can’t comply with the generally accepted minimum safety requirement for consumer products that they don’t kill their users. However, marketing is heavily regulated, no advertising is allowed and they are highly taxed. The only branding allowed is the product name and 65% of the pack is given over to large picture and text warnings. Smoking in enclosed public places and workplaces including public transport and private cars including children under 18 is prohibited. All characterising flavours are banned including, from May 2020, menthol. Sale is restricted to adults aged 18 and over.

68. At the other end of the spectrum medicinal nicotine products have to meet high standards of product safety and quality in order to be authorised for sale on the UK market but their marketing is much less heavily regulated, advertising is allowed, they are available on prescription and sold over the counter have preferentially low taxation (5% VAT instead of the standard 20%). NRT is available on prescription and over the counter to anyone aged 12 and over.

69. Novel tobacco products known as ‘heat not burn’ are new to the market. They are regulated as tobacco products but less strictly than combustible tobacco. For example while they come under the comprehensive advertising ban and cannot be displayed in shops plain packaging is not required and there is only a 30% text warning which states “This product damages your health and is addictive” rather than the 65% picture and text warnings required for combustible products. HMT consulted on the tax treatment of ‘heat not burn’ recently, but excise duty on these products is currently significantly lower than for cigarettes (manufactured and hand rolled).

70. Current regulation of e-cigarettes under the EU TPD has been criticised. However, the product standards require only notification not authorisation to the competent authority the MHRA and are significantly less stringent than medicinal NRT e-cigarettes. And on the other hand the marketing regulations are much less draconian than for tobacco products, including ‘heat not burn’. They are taxed at only the standard rate of VAT, characterising flavours are allowed, they are not included in smokefree laws, although many employers and premises operators have implemented their own rules prohibiting e-cigarette use.

The effectiveness of regulation on the advertising and marketing of e-cigarettes.

71. While e-cigarette advertising on TV, radio, print and online is prohibited as it crosses borders, localised advertising such as point of sale, cinema, poster advertising, leaflets and direct mail in hard copy are all allowed. This is significantly less stringent than the rules for tobacco products, including ‘heat not burn’, for which all advertising is prohibited
in the UK. Furthermore while products have to be authorised as medicines in order to be able to make medicinal claims about their effectiveness as quitting aids, a consultation has only recently been completed by the advertising authorities (CAP) which would allow health claims to be made by manufacturers and importers if there is sufficient supporting evidence for their products.

The impact to date of the Tobacco and Related Products Regulations on the vaping industry and on the prevalence of e-cigarettes.

72. The product standards in the EU TPD have been criticised in particular for setting a maximum nicotine concentration of 20 mg/ml, maximum tank sizes of 2 ml and refills of 10 ml. ASH did not support the introduction of these standards but, while they are not ideal, we accepted their adoption at UK level as part of a comprehensive package of regulations in the EU TPD, largely governing tobacco products. The ASH YouGov survey carried out prior to implementation of the TPD showed that 6% of vapers used more than 20 mg/ml, that 1% of daily vapers report using more than 10ml of e-liquid a day and 20% more than 4ml a day.  

73. The notification procedure itself seems to be working efficiently. Under the EU Tobacco Products Directive the notifying manufacturer or importer bears full responsibility for the quality and safety of the product, but notification is a much less burdensome process than medicines authorisation. By the end of September 2017, over 32,000 e-cigarette and refill container products had been notified to MHRA by over 400 companies. The notification fee is £150, with a £60 annual fee and £80 fee for any substantial modification. The MHRA has given a commitment to review the level of fees in the light of the number of notifications received in the first year and this may lead to a reduction in fees.

74. The Smoking Toolkit Survey shows growth in the e-cigarette market stalled in the UK between 2013 and September this year. This started before the EU TPD was finalised and long before it came into force (May 2016 for the advertising restrictions, May 2017 for the product regulations) therefore it is clear the TPD is highly unlikely to have had a significant impact.

75. While it is not possible to show causation as it is a cross-sectional survey, surveys for ASH show that this happened over a time when the perceptions of harm from e-cigarettes were growing. In 2013 only 9% of smokers thought e-cigarettes were more or equally harmful than e-cigarettes, by 2017 this had grown to 22%. Over the same time period a declining proportion of smokers accurately believe that e-cigarettes are a lot less harmful than smoking, down from 29% in 2013 to 20% in 2017.

76. Good regulation should reassure consumers about the risks of vaping versus smoking but, given the current levels of misunderstanding about relative risk, this has to be reinforced by appropriate messaging from authoritative health bodies and government.

The safety of e-cigarette devices, and any safety regulation requirements.

77. Consumers and healthcare professionals can report side effects and safety concerns with e-cigarettes or refill containers to the MHRA through the Yellow Card reporting system. Since 20 May 2016, MHRA has received 33 Yellow Card ADR reports. From

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39 See the MHRA website at https://yellowcard.mhra.gov.uk/
these reports no new safety concerns have been identified. The MHRA also receives reports of potential safety concerns and work with local Trading Standards teams to investigate as needed.

78. A review is needed of the measures included in the EU TPD for safety reasons and whether these are necessary (for example nicotine strength, tank size and refill container size).

**Whether there is any regulatory variation between the EU and UK, and across UK nations, and the implications of Brexit on regulation in this area.**

79. Nicotine products are regulated under a number of EU Directives, relating to tobacco and medicines. But many regulations are not EU-wide but regulated by each member state separately. For this reason there are variations across the EU.

80. In general the UK tends to have stricter regulation of tobacco products than many other EU Member States. For example, we ban all tobacco advertising, promotion and sponsorship, whereas the EU Directive only requires prohibition of that which crosses borders such as TV, press and internet. We also prohibit the display of tobacco products and require cigarettes to be put in plain, standardised packaging, neither of which is required by EU regulation. When it comes to taxation we have amongst the highest tobacco taxes in the EU. Laws about where tobacco can be smoked are not governed by the EU either and we have amongst the most stringent in Europe, prohibiting smoking in all enclosed public places and public transport, including psychiatric premises and private vehicles carrying children under 18. Our regulations on tobacco are amongst the strictest in Europe and we have seen the most rapid decline in smoking prevalence and uptake in recent years.

81. On the other hand we have been less strict than many other EU Member States in our regulation of non-tobacco nicotine products. With respect to e-cigarettes the MHRA has been widely recognised as having tried to make the notification process as transparent and easy to fulfil as possible. The Westminster government has clarified that it will not go further than the TPD in areas where we have discretion, unlike some other Member States. For example the UK has committed not to levy excise tax on e-cigarettes, nor will we include e-cigarettes in our smokefree laws, nor prohibit characterising flavours. Among the devolved nations Wales considered including e-cigarettes in its smokefree laws but did not proceed, and Scotland has introduced a register for retailers selling e-cigarettes as had previously been introduced for tobacco retailers. In addition Scotland has powers to introduce further restrictions on e-cigarette advertising, although to date regulations to do so have not been introduced.

82. However, due to a variation in the translation of the EU TPD from English, the negotiating language, into French, France has felt able to interpret the Directive to only limit the tank size of e-cigarettes to 2ml where these are disposable or single use cartridges. (see article 20.3(a)). The UK has transposed the requirement of the English language version into UK law which requires all tanks to be limited to no more than 2ml.

83. Licensed medicinal NRT is taxed at lower rates of VAT in the UK (5%) than in other member states and is more widely available. In the UK all medicinal NRT products are licensed for general sale including not just patches and gum but inhalators and nasal sprays. Medicinal NRT can be sold in any retail outlet whereas in many other member

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40 The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016
states, which limit where medicines can be sold, they can only be sold in pharmacies. This is the case, for example, in France where licensed medicines have to be sold through pharmacies.

Implications of Brexit

84. The current regulatory framework for e-cigarettes could be improved and potentially Brexit provides opportunities for this. Any revision of the regulations should be evidence-based, involve consultation and fully engage vapers in the process.

85. The date for Brexit is 29th March 2019, but it seems unlikely there will be an immediate opportunity for revision. The Tobacco and Related Product Regulations 2016 require the Secretary of State to review the operation and effect of the regulations within five years (ie by 20 May 2021) and assess if the objectives could be achieved using “less onerous regulatory provision”. This is a requirement taken from the Tobacco Products Directive.

86. At that point the UK can vary our product regulations but we need to be cognisant of the fact that potentially this could limit the market for UK products as if they do not meet EU standards they are unlikely to be able to be sold in other EU MS.

On finance:

The economic impact of the UK’s e-cigarette industry.

87. The tobacco industry is an oligopoly dominated by 4 companies globally who between them control 70% of global production and consumption (excluding China where the state owned manufacturer is the dominant company).41 In the UK two firms, Imperial and JTI control nearly 80% of the cigarette market with the other two, Philip Morris and British American Tobacco making up the vast majority of the remainder.42 Selling an addictive product in an oligopolistic market gives the companies unparalleled pricing power and profitability. Profit margins for the tobacco industry on cigarettes in the UK have been estimated at up to 68% in the UK, compared to only 15-20% in most consumer staple industries.43

88. Initially e-cigarettes were produced by small manufacturers and importers who were in the most part vapers themselves who moved into the market because of their personal interest in the products. However, when e-cigarettes began to take off both in the UK and internationally the tobacco industry began to move in.

89. The tobacco manufacturers want to tie consumers in to using their proprietary products and therefore sells rechargeable e-cigarettes with pre-filled cartridges. The desire to have proprietary products is also demonstrated with the new novel ‘heat not burn’ tobacco products.

90. IQOS is the most advanced on the UK market. Produced by Philip Morris it is designed to replicate the smoking experience both for the user and the company. The product is a proprietary design and can only be used with PMI ‘heet sticks’, unlike the most widely

used tank system e-cigarettes which can be refilled with any e-liquid. Each pack of ‘heet sticks’ contains twenty sticks.

91. The online IQOS catalogue lists a starter kit – with IQOS holder, charger and ten packs of HEETS - at £121.50 (standard price for the kit is £99 plus £70 for ten packs of HEETS). The IQOS holder and pocket charger are guaranteed for one year, or 7,300 cycles (equivalent to 20 a day for 365 days), and the cost of a replacement IQOS holder is £49. A single pack of HEETS costs £8, the equivalent of 40 pence per stick, or £7 for 10 packs. Anecdotal evidence from a case study of a single smoker known to ASH who started off switching to IQOS is informative. As a heavy smoker who used handrolled tobacco he found that using heets was more expensive, costing him £10 a day. After some weeks he went to a vape shop and was encouraged to switch to a mid-range refillable e-cigarette which cost him under £30 to buy. His daily costs are now £1 for the e-liquid plus an additional 20 pence a day to regularly replace the coil in his e-cigarette.

92. According to the ASH survey in 2014 47% of vapers said they used an e-cigarette which was rechargeable with replaceable pre-filled cartridges, while 41% said they used a rechargeable electronic cigarette with a tank or reservoir which you fill with liquids. From then onwards the use of pre-filled cartridges declined rapidly and by 2017 only 22% of current e-cigarette users said they used pre-filled cartridges compared to 69% who used open systems which enabled them to use whatever e-liquid they want. The refills for open systems are commoditised rather than proprietary and the market is therefore much more competitive to the benefit of consumers.

93. ASH supports smokers having a variety of choices to help them quit smoking, however, tobacco industry options, whether they are e-cigarettes or the new ‘heat not burn’ technology, are not necessarily the healthiest or the most cost-effective option. With respect to ‘heat not burn’ products they are likely to be more harmful than vaping from the evidence to date and more expensive.

94. ASH is concerned to ensure that the market for reduced risk products remains as competitive as possible and that any regulatory changes are assessed with this as one of the criteria by which they are judged.

**The public finances implications of e-cigarettes, including how the rise in e-cigarette consumption could affect NHS costs.**

95. E-cigarettes have the potential to increase the rate of reduction in smoking prevalence, to meet the Government’s targets as set out in the Tobacco Control Plan for England and reduce mortality. The Tobacco Control Plan for England 2017 estimates that smoking costs our economy in excess of £11 billion a year, including £2.5 billion to the NHS, £5.3 billion to employers (because of lost output due to sickness and smoking breaks), £4.1 billion to the wider society due to lost output. There are further costs including around £760 million from increased social care costs to local councils.

96. Researchers have recently modelled the population impact in the future if more smokers switched to e-cigarettes in the USA, where the products are legally available as in the UK. They estimated that: “compared with the Status Quo, replacement of cigarette by e-cigarette use over a 10-year period yields 6.6 million fewer premature deaths with 86.7 million fewer life years lost in the Optimistic Scenario. Under the Pessimistic Scenario, 1.6 million premature deaths are averted with 20.8 million fewer life years lost.

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44 IQOS. IQOS Catalogue. [accessed 30 November 2017].
The largest gains are among younger cohorts, with a 0.5 gain in average life expectancy projected for the age 15 years cohort in 2016. Similar estimates are not available yet for the UK, but these projections suggest that replacing cigarette use with e-cigarette use would clearly lead to reductions in the burden of smoking.

December 2017

**Table 1: Regulatory framework for nicotine in the UK**

<table>
<thead>
<tr>
<th>Product regulation</th>
<th>Licensed medicinal nicotine products</th>
<th>TPD regulated consumer e-cigarettes</th>
<th>‘Heat not Burn’ novel tobacco products</th>
<th>Cigarettes (manufactured and handrolled tobacco)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age of sale</strong></td>
<td>Age of sale 12 (18 for licensed e-cigarettes). Can be sold anywhere. No legislation limiting use.</td>
<td>Age of sale 18. Can be sold anywhere. Not covered by smokefree laws but voluntary restrictions are widespread (e.g. on public transport, and in most workplaces.)</td>
<td>Age of sale 18. Vending machine sales banned and tobacco not available in pharmacies. Not covered by smokefree laws, but voluntary restrictions likely to apply although usage not yet sufficiently widespread for this to have become an issu.</td>
<td>Age of sale 18. Vending machine sales banned and tobacco not available in pharmacies. Legislation prohibits smoking tobacco in enclosed public places, public transport and private cars carrying children under 18.</td>
</tr>
<tr>
<td><strong>Packaging and Labelling</strong></td>
<td>No health warning on pack</td>
<td>Health warning = 30% of the pack text ‘This product contains nicotine which is a highly addictive substance.’</td>
<td>Health warning = 30% of pack as for smokeless tobacco text ‘This tobacco product damages your health and is addictive’</td>
<td>Health warning = 65% of pack; picture and text warnings Plain packaging = only branding allowed is product name in 8 point Helvetica.</td>
</tr>
<tr>
<td><strong>Advertising promotion and sponsorship</strong></td>
<td>Advertising allowed for OTC medicines on all media.</td>
<td>No cross border advertising, promotion or sponsorship. Domestic</td>
<td>No advertising, promotion or sponsorship.</td>
<td>No advertising, promotion or sponsorship.</td>
</tr>
<tr>
<td></td>
<td>advertising allowed e.g. at point of sale, public transport, billboards.</td>
<td>Only product name, price and size allowed.</td>
<td>Only product name, price and size allowed.</td>
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</tr>
<tr>
<td><strong>Product information</strong></td>
<td>Can make health and quitting claims. Packs must include a patient information leaflet (PIL), providing information on using the medicine safely.</td>
<td>Ability to make health claims under consultation – can’t make quitting claims. Packs must contain consumer information leaflet on using product safely</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tax and affordability</strong></td>
<td>Lower rate VAT = 5%</td>
<td>Standard VAT = 20%</td>
<td>Under consultation by HMT. Currently std VAT + excise tax = ‘other smoking tobacco and chewing tobacco’ £119.13/kg Std VAT + excise tax roll your own £221.18/kg MET for cigarettes £280.15 per 1,000 [£5.60 per 20 pack] Minimum pack size mandated 20 cigarettes and 30g HRT.</td>
<td></td>
</tr>
</tbody>
</table>

NB We have not included smokeless tobacco products in the table. This is because smokeless tobacco historically and currently has a limited market in the UK. Oral snuff, known as snus, is banned throughout the EU apart from in Sweden although this is currently being challenged in the European Court of Justice. Chewing tobacco, while legal, is not widely used, except in some south Asian communities.

**Sources:**
Tobacco Advertising and Promotion Act 2002
The Health Act 2006
The Children and Young Persons (Sale of Tobacco etc.) Order 2007
The Protection from Tobacco (Sales from Vending Machines) (England) Regulations 2010
The Tobacco Advertising and Promotion (Display and Specialist Tobacconists) (England) (Amendment) Regulations 2011
The Standardised Packaging of Tobacco Products Regulations 2015
The Tobacco and Related Products Regulations 2016
MHRA. Advertise your medicines. Last updated 15 September 2017.