

HEALTH (TOBACCO, NICOTINE ETC. AND CARE) (SCOTLAND) BILL

POLICY MEMORANDUM

INTRODUCTION

1. This document relates to the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill introduced in the Scottish Parliament on 4 June 2015. It has been prepared by the Scottish Government to satisfy Rule 9.3.3 of the Parliament's Standing Orders. The contents are entirely the responsibility of the Scottish Government and have not been endorsed by the Parliament.

2. Explanatory Notes and other accompanying documents are published separately as SP Bill 73-EN.

BACKGROUND AND BILL OVERVIEW

3. The Bill covers three distinct policy areas: controlling non-medicinal nicotine vapour products (NVPs)¹, tobacco control and smoking on NHS hospital grounds; ill-treatment and wilful neglect; and duty of candour. This document sets out the details of consultation, policy objectives, and alternative approaches for each element of the Bill as follows:

- Minimum age of 18 for the sale of NVPs,
- Prohibition of sales of NVPs from vending machines,
- The purchase of NVPs on behalf of an under 18 - 'proxy purchase',
- Mandatory registration for the sale of NVPs,
- Banning certain forms of domestic advertising and promotion of NVPs,
- An age verification policy for sales of tobacco products and NVPs,
- Banning unauthorised sales of tobacco and NVPs by under 18s,
- A smoke-free perimeter around buildings on NHS hospital sites,
- An offence of ill-treatment and wilful neglect, and
- An organisational duty of candour.

¹ References to NVPs throughout this document refer to non-medicinal NVPs, e-liquids and other substances intended to be used in them (including items containing such substances).

4. The Bill also introduces other measures associated with these policies, for example, changes to banning orders and the introduction of a statutory due diligence defence.

5. Alongside the Scottish Government's latest Tobacco Control Strategy, this Bill supports the Scottish Government's objective to support longer healthier lives and to tackle the significant inequalities in Scottish society. It will do this in the main by restricting the accessibility of NVPs to young people; reducing their visibility and appeal to young people and non-smokers; reinforcing the age restriction on tobacco products to further protect young people; and introducing statutory smoke-free perimeters around buildings on NHS hospital sites.

6. The effects of the Bill on equal opportunities, human rights, island communities, local government, sustainable development etc. are summarised in paragraphs at the end of each part.

PART 1: SMOKING, TOBACCO AND NICOTINE VAPOUR PRODUCTS

POLICY OBJECTIVES: BACKGROUND

7. In March 2013, the Scottish Government launched its latest tobacco control strategy, *Creating a Tobacco-Free Generation*². The strategy sets a target to reduce smoking prevalence rates to 5% or less by 2034. The majority of adults who smoke took up smoking before the age of 18³. The ambitious target can only be achieved by focussing heavily on preventing the initiation of tobacco use.

8. The strategy builds on existing legislation. Scotland increased the minimum age of sale for tobacco products from 16 to 18 in 2007. Tobacco sales from self-service vending machines were banned in April 2013, alongside the introduction of a tobacco display ban in large shops, which is the most robust display ban legislation in the UK. April 2015 saw the end of tobacco displays in smaller retail premises. The Scottish Government also continues to invest in NHS cessation services, including free Nicotine Replacement Therapy on prescription, which have helped many smokers break the cycle of addiction. Alongside this, mass media campaigns such as the Scottish Government's recent *Take it Right Outside* campaign continue to improve public awareness and support behaviour change. While adult smoking rates in Scotland have fallen from 31% in 1999 to 23% in 2013, in order to achieve a tobacco-free generation additional legislation and policy measures are necessary. This Bill forms part of the wider tobacco control policy approach while addressing the new and expanding area of NVPs.

9. The Scottish Government is legislating for the first time on NVPs, which pose both potential challenges and opportunities for public health, internationally and within Scotland. NVPs can come in two forms: those which deliver nicotine to the user and those which do not. The Scottish Government's approach to NVPs is in part precautionary, in that it aims to limit the likelihood of potential future negative impacts on the health of individuals, for population health and for tobacco control. This is based on concerns which have been articulated in ongoing

² www.gov.scot/tobaccofreegeneration

³ Office for National Statistics. 2012. General Lifestyle Survey Overview: A report on the 2010 General Lifestyle Survey. Newport: Office for National Statistics
(<http://www.ons.gov.uk/ons/rel/ghs/general-lifestyle-survey/2010/general-lifestyle-survey-overview-report-2010.pdf>)

debates amongst experts internationally. There is also a public interest in preventing and reducing addiction to nicotine in society, to make smoking behaviours (and behaviours which mimic smoking) less appealing and in particular, to protect children from “playing at smoking”. Yet the Scottish Government recognises the potential health benefits which NVPs may have for smokers in reducing smoking rates. This has particularly shaped the proposal on domestic advertising and promotion and informed consideration of other policy options which the Scottish Government has chosen not to adopt at this stage (e.g. creating restrictions on their use in public spaces and standardised packaging). Whilst the Scottish Government recognises that NVPs are likely to be less harmful than conventional cigarettes, they cannot be regarded as risk free⁴. The control of NVPs which can contain nicotine and those which don’t is inextricably linked given their resemblance and operational similarity. There is a need to control both kinds of NVP in the same way to ensure effective enforcement of the measures introduced by the Bill and to help prevent public confusion which could have a consequential health impact.

What are nicotine vapour products?

10. NVPs as defined by the Bill are non-medicinal consumer products which deliver a vapour for inhalation by an individual. NVPs are sometimes referred to as ENDS (electronic nicotine delivery systems) or vapourisers and a variety of types have alternative names either for the whole device or parts of the device (e.g. ‘tanks’, e-shisha, cigalikes, vapes). Cigalike products or “e-cigarettes” were the first to appear on the market and these remain popular. Most disposable NVPs are cigalikes. Rechargeable NVPs with a tank or cartomiser, which is manually filled with e-liquid by the user, are now available in an increasing array of models with a wide variety of liquid capacity and battery power. NVPs normally contain a carrier liquid of propylene glycol and vegetable glycerine, either on their own in combination; nicotine is included in the majority of products (but not all) in different concentrations; and most products contain flavouring.

11. The Bill provides that an NVP is:

- (a) a device which is intended to enable the inhalation of nicotine-containing vapour by an individual,
- (b) a device which is intended to enable the inhalation of other vapour by an individual but is intended to resemble and be operated in a similar way to a device within paragraph (a),
- (c) an item which is intended to form part of a device within paragraph (a) or (b),
- (d) a substance which is intended to be vaporised by a device within paragraph (a) or (b) (and any item containing such a substance).

12. The Bill expressly excludes medical products and devices, and tobacco and smoking related products. The Bill does not cover nicotine in other forms as it is already regulated by the Poisons Act 1972; poisons are not substances intended for human inhalation and nicotine at poisonous levels should not be available in NVPs.

⁴ Pisinger Charlotta, Døssing Martin, A systematic review of health effects of electronic cigarettes, Preventive Medicine (2014), doi:10.1016/j.ypmed.2014.10.009

13. The term NVP is intended to include all devices known as electronic cigarettes. The Bill includes related products, such as refills, liquids, chargers and other components, within the meaning of “nicotine vapour product”. Related products are those which are intended to form part of a device used to inhale vapour or are a substance (either containing nicotine or not) intended to be vaporised by such a device. The Bill’s provisions will cover all non-medicinal NVPs, whether they contain nicotine, could contain nicotine or could never contain nicotine. The Bill will also apply to any substance which is intended to be vaporised by these devices such as e-liquids or e-juice, whether they contain nicotine or not.

14. The decision to include products which do not contain nicotine is on the basis of three main factors. One is that it would be extremely impracticable for enforcement authorities to take action against users and test individual products. This approach provides a clear and consistent framework for all products. It provides for general and simple rules under the Bill which can be easily understood, applied and managed. Without such an approach rules in respect of nicotine containing NVPs might be readily undermined and circumvented. Secondly, products which may or may not contain nicotine are still used in a way which resembles smoking and, so, pose the risk of confusion and a potential risk for the re-normalisation of smoking. Thirdly, many products have refillable tanks: they may be sold and initially used with a liquid which does not contain nicotine but could later be used with nicotine-carrying fluids.⁵

15. In response to the Scottish Government’s consultation *Electronic Cigarettes and Strengthening Tobacco Control in Scotland*, a large majority of respondents (80% of respondents to the question) agreed that the age of sale regulations should apply to NVPs regardless of whether they contain or are capable of containing nicotine. Those who supported the proposal suggested it would be difficult to formulate clear definitions which distinguished between nicotine and non-nicotine NVPs and which would take account of possible future product developments. It was also suggested that the risks of devices and liquids, regardless of whether or not they contain nicotine, are not yet fully understood and that NVPs (with or without nicotine) could possibly re-normalise or model smoking behaviour. This was highlighted with particular reference to devices with a cigarette-like appearance.

Current regulation of nicotine vapour products

16. NVPs are currently subject to general consumer regulations.⁶ The EU Tobacco Products Directive (TPD)⁷ will extend and strengthen this by creating a consistent regulatory regime for nicotine containing NVPs and e-liquids across EU Member States. The TPD has to be transposed into domestic law and implemented by 20 May 2016. The TPD includes a number of provisions regarding NVPs:

- Products containing more than 20 mg/ml of nicotine or which make smoking cessation claims will be prohibited unless they are licensed as medicines.

⁵ E.g. tests have shown that many liquids which claim on their packaging not to contain nicotine actually do and that labelled levels of nicotine are often incorrect. See Goniewicz ML, et al. (2015) Nicotine levels in electronic cigarette refill solutions: A comparative analysis of products from the US, Korea, and Poland. *International Journal of Drug Policy*. 2015. doi: 10.1016/j.drugpo.2015.01.020

⁶ These are described in the draft PAS produced by the British Standards Institute: <http://www.pdf-archive.com/2014/11/07/pas-54115-draft-2-3-for-pr/preview/page/5/>

⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_127_R_0001

- Products which contain less than 20 mg/ml of nicotine and have not opted into medicinal licensing (and therefore cannot make claims relating to smoking cessation), will be subject to the TPD. These will be regulated as consumer products and be subject to the following restrictions:
 - Products must be child and tamper-proof,
 - Health warnings, instructions for use, information on addictiveness and toxicity must appear on the packaging and accompanying information leaflet,
 - There can be no promotional elements on packaging,
 - All ingredients and the nicotine content must be listed,
 - Existing rules for the cross-border marketing of tobacco products will apply to electronic cigarettes, in effect banning any advertising which has a cross-border effect. The TPD leaves it to Member States to decide whether to regulate domestic advertising,
 - Manufacturers must inform Member States before placing a product on the market and must report annually to Member States, and
 - There will be new size limits on products: 10ml for e-liquids for dedicated refill containers and 2ml for electronic cigarette cartridges and tanks.

17. NVPs cannot be sold in the UK as a smoking cessation aid unless licensed as a medicine by the UK Government's Medicine and Healthcare Regulatory Authority (MHRA) and, to date, none have been. The proposals in the Bill apply only to non-medicinal, unlicensed NVPs. The Bill does not regulate medicinal NVPs as they are regulated at the UK level by the MHRA. NVPs which in the future are licensed as medicines will be subject to specific regulatory rules which cover advertising, product presentation, to whom the medicines can be supplied (and whether over-the-counter or on prescription) and other requirements relating to the sale and supply of medicines.

18. Recitals 47, 48 and 53 to 55 of the TPD make clear that the TPD does not harmonise rules on certain matters which it leaves to member states, namely: smoke-free environments, domestic sales arrangements, domestic advertising, flavourings and age restrictions. Nor does it harmonise rules on NVPs which do not contain nicotine.

POLICY OBJECTIVES – SPECIFICS

Introduction

Nicotine vapour products and health

19. NVPs are new products which involve the repeated inhalation of a vapour containing a combination of chemicals. There are a number of public health issues to be examined in considering what action should be taken. NVP policies are required which balance concerns about the risks to children and adult non-smokers with potential benefits for smoking cessation and harm reduction. In short, current evidence indicates that:

- they appear to be considerably safer than conventional smoked tobacco products, but there is a lack of data on the long-term impacts of use,⁸
- the inhalation of chemicals in a vapour (whether or not there is nicotine present) is not risk-free, especially for young people or for those with certain pre-existing conditions.

20. A huge number of different products are on sale, with different chemical components, and scientific understanding of both the short and long-term effects of vaping is only just emerging and so far inconclusive. This uncertainty justifies taking a precautionary public health approach to these products:

- the positive impacts and benefits (e.g. for smoking cessation or tobacco harm reduction) NVPs may offer for individuals and for public health are not fully understood and cannot be quantified,
- the negative impacts and risks (e.g. a possible ‘gateway effect’; and direct and indirect effects on health) NVPs present for individuals using them and for bystanders, are not fully understood and cannot be quantified, although products which mimic smoking clearly contribute to some degree to normalising smoking behaviour, and
- the positive and negative impacts NVPs may have on achieving the outcomes of tobacco control policy are not fully understood.

21. NVPs may prove to be a useful cessation tool for some smokers but there is not the weight of evidence from good quality clinical trials and longitudinal data which would allow the public health community to advocate their use, or to advise on how they can be used, in an attempt to quit.⁹ A Cochrane Review¹⁰ assessed the evidence for their use in cessation and confirmed that there is a shortage of conclusive trials.¹¹ It is unclear what proportion of people who have stopped smoking with an NVP will remain abstinent over the long term and the effectiveness of their use in quit attempts compared to other methods. Policies are needed which do not prevent the public health opportunities from NVPs from being realised. A delicate balance needs to be struck.

⁸ e.g. see: Hajek P, Etter JF, Benowitz N, Eissenberg T, McRobbie H. (2014) Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*. 2014 Jul 31; Nutt, D. et al (2014) Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach *European Addiction Research* 2014;20:218–225; McRobbie, H (2014) *Electronic Cigarettes*. Briefing for the National Centre for Smoking Cessation and Training in association with Public Health England; Cancer Research UK (2014) *Briefing on Electronic Cigarettes*.

⁹ Internationally, there are a number of trials of NVPs effectiveness but it will be some time before there is a sufficient accumulation of evidence for judgements to be made about the benefits versus the risks of NVPs. The expected licensing of NVP devices by the MHRA in 2016 may act as a spur to further research into their potential role in cessation.

¹⁰ Cochrane Reviews are [systematic reviews](#) of primary research in health care and health policy, and internationally recognised as the highest standard in [evidence-based health care](#). They investigate the effects of interventions for prevention, treatment and rehabilitation. They are published online in [The Cochrane Library](#).

¹¹ McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P (2014) Can electronic cigarettes help people stop smoking or reduce the amount they smoke, and are they safe to use for this purpose? http://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-or-reduce-the-amount-they-smoke-and-are-they-safe-to-use-for-this-purpose

22. The use of NVPs imitates the act of smoking. There is on-going debate internationally, and within Scotland, amongst some public health stakeholders about the potential for confusion, about the extent to which their visibility undermines efforts to de-normalise smoking and whether their use could act as a potential gateway to nicotine addiction and subsequently smoking.

23. The role of tobacco companies raises concern for public health policy. Initially, the industry consisted of small independent companies but in the past couple of years some tobacco companies have acquired NVP businesses. It seems likely that as the market matures there will be consolidation, with many mainstream brands wholly or partly owned by large tobacco companies.¹² There is a legitimate public health concern about the potential for tobacco companies to become involved in discussions about cessation, tobacco harm reduction and public health policies. Article 5.3 of the World Health Organisation Framework Convention on Tobacco Control (FCTC)¹³ arose from a need to prevent the tobacco industry from seeking to influence public health policy, as it had done in the past. Article 5.3 enshrines a principle for public health departments and agencies in countries which are parties to the FCTC: *“In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.”*

24. The precautionary public health grounds for controlling NVPs cannot be ignored. The Scottish Government believes that the protection of public health is of paramount concern. However, it is not only precautionary public health grounds which underpin the justification for the measures to be introduced by the Bill. Nicotine addiction can directly harm health. Nicotine, as a result of NVP use, could potentially act as a gateway to tobacco use and it is also known that nicotine can have negative impacts on the development of the adolescent brain.

Nicotine

25. Nicotine is highly addictive and can be toxic. It is present in most NVPs which are in use. Long-term nicotine addiction is not in the interest of public health in Scotland and the Scottish Government does not believe there is any reason for using NVPs apart from their potential to support an attempt to stop smoking or to prevent or reduce tobacco use.

26. There are hundreds of brands of NVPs and e-liquids which contain nicotine. Many brands may not be independently tested for safety or effectiveness and until the regulatory framework introduced through the TPD is well established there is reason to be concerned about the mislabelling of products, including their nicotine content.

27. Nicotine affects the cardiovascular system and the nervous system. It has particular health implications for certain groups, including young people and children and unborn babies. NRT products which are licensed for medical use, and are available over the counter or on prescription, may be used in pregnancy, although abrupt cessation is the preferred approach for

¹² Quelch, J and Rodriguez, M. (2014) NVPs: Marketing versus Public Health, *Harvard Business Review*, 16 September 2014.

¹³ http://www.who.int/fctc/text_download/en/

pregnant women.¹⁴ The World Health Organisation has expressed concerns about the differential effects for these groups.

28. There are many studies of the health harms of nicotine which distinguish these harms from the harms of tobacco use. In particular, nicotine impacts on brain development which continues into a person's twenties.¹⁵ Exposure to nicotine during adolescence may affect brain activity, producing enhanced vulnerability¹⁶ to nicotine addiction, increased impulsivity, and mood disorders, and it is also likely to adversely affect cognitive function and development with long-term consequences.¹⁷ A report in 2014 by the United States Surgeon General, which reviewed half a century of tobacco control policy and research, included the following conclusions: there is sufficient evidence to infer that at high-enough doses nicotine has acute toxicity, nicotine activates multiple biological pathways through which smoking increases risk for disease, nicotine exposure during foetal development has lasting adverse consequences for brain development and nicotine adversely affects maternal and foetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth.¹⁸ It noted that evidence suggests that nicotine exposure during adolescence may have lasting adverse consequences for brain development.

29. It is also well established that young people are particularly vulnerable to nicotine addiction and more likely to take health risks and discount future consequences of their behaviours. Prevalence data and scientific studies provide a substantial body of evidence showing that the younger a person experiments with tobacco, the more susceptible that person is to nicotine addiction and to habitual tobacco smoking, and the longer the addiction is likely to last, and the higher the levels of their tobacco use in adulthood.¹⁹ Some young people can become addicted to tobacco within a day or two of the first cigarette smoked.²⁰ In the UK, two-thirds of smokers start before the age of 18.²¹ The evidence on this is summarised in a report

¹⁴ Guidance on the use of NRT in pregnancy is provided by NHS Health Scotland: <http://www.healthscotland.com/documents/4661.aspx>.

¹⁵ For example: Johnson, S, Blum, R and Giedd, J (2009) 'Adolescent Maturity and the Brain: The Promise and Pitfalls of Neuroscience Research in Adolescent Health Policy', *Journal of Adolescent Health* 45,3: 216-221 (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892678/>); and Steinberg, L (2010) 'A behavioral scientist looks at the science of adolescent brain development', *Brain and Cognition* 72, 1:160-164. (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2904973/>)

¹⁶ For example, see the work done by the Developmental Cognitive Neuroscience Group at University College London - <https://sites.google.com/site/blakemorelab/research>. Also: <https://www.tes.co.uk/article.aspx?storycode=6430098>

¹⁷ Dwyer, J, McQuown, S and Leslie, F (2009) 'The Dynamic Effects of Nicotine on the Developing Brain', *Pharmacology and Therapeutics* 122(2): 125-139. (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2746456/>).

¹⁸ See Chapter 5 in "The health consequences of smoking – 50 years of progress: a report of the Surgeon General, 2014", published by the U.S. Department of Health and Human Services (<http://www.surgeongeneral.gov/library/reports/50-years-of-progress>). The conclusion can be found on p. 126.

¹⁹ Lydon DM, Wilson SJ, Child A, Geier CF. (2014) 'Adolescent brain maturation and smoking: What we know and where we're headed', *Neuroscience and Biobehavioral Reviews* 45C:323-342. <http://www.ncbi.nlm.nih.gov/pubmed/25025658>
<http://www.sciencedirect.com/science/article/pii/S0149763414001675>

²⁰ Di Franza, et al. (2007). 'Symptoms of tobacco dependence after brief intermittent use: The development and assessment of nicotine dependence in Youth-2 study', *Archives of Pediatrics and Adolescent Medicine* 161(7):704-710.

²¹ ASH (2013) Fact sheet on Smoking Statistics
http://www.ash.org.uk/files/documents/ASH_93.pdf

from 2006 by the Smoking Prevention Working Group²² and a report from 2008 by the Scottish Public Health Observatory²³ (a group led by NHS Health Scotland), documents which are at the heart of the Scottish Government's thinking on efforts to prevent young people experimenting with smoking.

Smoking de-normalisation and modelling behaviours

30. At this stage, there is insufficient evidence to assess the likelihood and magnitude of re-normalising or modelling effects of NVPs, but the Scottish Government considers that this risk should be addressed. There is concern that the widespread use and visibility of NVPs in everyday life could 're-normalise' smoking-like behaviours. This is both relevant for NVPs which do, and those which do not, contain nicotine as they are often identical in resemblance and in the way that they operate. The word "de-normalisation" refers to the effect of shifting the public's perception of smoking as normal and socially acceptable into a less acceptable, or unacceptable, activity.²⁴ ²⁵ Smoking was once normal across much of society. It is now increasingly uncommon and adult smoking rates declined between 1995 and 2013 from 35% to 23%.²⁶

31. The fact that NVPs, both those which contain nicotine and those which do not, can replicate or resemble some of the sensorial, behavioural and social aspects of tobacco smoking is part of their additional appeal for some smokers over other forms of nicotine delivery. The similarity of the hand-to-mouth action contributes to how NVPs may prove to be effective tools for harm reduction and cessation in addicted smokers (the habitual, repeated action has a profound psychological importance for some smokers). This same similarity of NVPs to tobacco cigarettes and of the vaping action to smoking has also prompted concerns that their use could make tobacco smoking more socially acceptable than it has become. Increased exposure to others' use of NVPs could function as a modelling of smoking behaviours for young people and children. Behavioural modelling has an important influence on individuals' choices, attitudes and habits. The potential for confusion between NVPs and conventional tobacco cigarettes, and the increasing visibility of NVPs, may undermine efforts to de-normalise smoking behaviour. It is known from prevalence data that children who are exposed to smoking behaviour in the home and in their social and family networks, as an acceptable habit, are much more likely to become

²² *Towards a future without tobacco: The Report of the Smoking Prevention Working Group* (2006). Published by the Scottish Executive: <http://www.scotland.gov.uk/Publications/2006/11/21155256/0>.

²³ ScotPHO (2008) *Tobacco Smoking in Scotland: an epidemiology briefing*. <http://www.scotpho.org.uk/publications/reports-and-papers/493-tobacco-smoking-in-scotland-an-epidemiology-briefing>

²⁴ De-normalisation strategies seek "to change the broad social norms around using tobacco – to push tobacco use out of the charmed circle of normal, desirable practice to being an abnormal practice": Chapman, S and Freeman, B. (2008) 'Markers of the denormalisation of smoking and the tobacco industry', *Tobacco Control* 2008;17:25-31 (<http://tobaccocontrol.bmj.com/content/17/1/25.long>).

²⁵ See British Medical Association (BMA Board of Science) (2008) *Forever cool: the influence of smoking imagery on young people*. The BMA reviewed the role of modelling in encouraging young people to smoke and highlighted the importance of action to 'de-normalise' and 'de-glamourise' smoking: the more visible it is, the more acceptable it seems to those who smoke and those who do not.

²⁶ Scottish Government (2014) *Scotland's People Annual report: Results from 2013 Scottish Household Survey* (<http://www.gov.scot/Publications/2014/08/7973/9>)

smokers themselves.²⁷ The Scottish Government considers that it is wrong for children to be able to “play at smoking” with NVPs.

The ‘gateway effect’ theory

32. At this time there is insufficient evidence to show whether a “gateway effect” (i.e. people moving from using NVPs into conventional smoking) is being realised in increased rates of tobacco use which appear to be relatively stable. So far use is almost entirely confined to current smokers and recent ex-smokers so any gateway effect would currently be very small. However, this may change over time and will need to be monitored. Given what is known about nicotine addiction, there are concerns that NVP use could, at least potentially, act as a gateway to smoking tobacco for those who do not smoke tobacco (non-smokers, including children, and ex-smokers). This concern is more relevant to those which contain nicotine but may also apply to those which do not as it is known that, although nicotine is the main cause of addiction to cigarette use, there are also environmental and social factors which encourage habituation. The Scottish Government is also mindful that NVPs may serve for some smokers as gateway *out* of combustible tobacco use.

33. The risks of smoking de-normalisation, the effects of modelling behaviours and the gateway effect, cannot be ignored. The Scottish Government advocates a precautionary approach. The need on precautionary grounds to protect against these risks further supports the rationale for controlling NVPs. There is a particularly strong public interest in protecting children from these risks, which forms part of a wider strategy to protect the population of Scotland. The strategy recognises, however, the potential benefits of NVPs to smokers and the need for controls to strike a balance.

Age restriction for nicotine vapour products

34. The Bill includes a prohibition on the sale of NVPs to under-18s and several other proposals primarily designed to support the implementation and enforcement of this policy. There is currently no statutory restriction on the age at which a young person can be sold an NVP in Scotland. The Scottish Government is clear that there is no good reason for persons under the age of 18 to use NVPs and there are particular risks associated with nicotine for young people and children discussed in more detail at paragraphs 23-27. There is industry support for a mandatory age restriction. Many suppliers and retailers of NVPs voluntarily sell NVPs to persons aged 18 or over only. The Electronic Cigarette Industry Trade Association (ECITA) also requires that its members do not sell to minors or target minors in their marketing and has called for the government to legislate to introduce an age restriction.²⁸ Many manufacturers mark their products with warnings that they should not be sold to under-18s and guidance from ECITA states that it is good practice to check proof of age before selling an NVP to someone who appears to be under 25.²⁹

²⁷ E.g. see Royal College of Physicians (2010) *Passive Smoking and Children. A report by the Tobacco Advisory Group of the Royal College of Physicians*

(<https://www.rcplondon.ac.uk/sites/default/files/documents/passive-smoking-and-children.pdf>)

²⁸ http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf

²⁹ http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf

35. The Bill will make it an offence to sell a NVP to a person under the age of 18. It allows fixed penalty notices to be issued by enforcement officers. Local authorities will primarily enforce the measure. This largely replicates the measures already in place restricting the age of sale of tobacco products. It is intended that the same defence be available that currently exist for tobacco in that the person selling believed the young person to be aged 18 or over and obtained proof of their age. The Bill also introduces a statutory due diligence defence. The forms of identification deemed acceptable also remain the same (passport, EU driving licence or other prescribed document³⁰). The person who sells can be the employee or the employer and in either case the enforcement action could count towards an application to the court for a tobacco and NVP banning order.

36. The Bill differs slightly from the measures in place for tobacco and alcohol in that the offence will not apply to an under 18 who attempts to purchase an NVP nor is there any provision to have NVPs confiscated by the police. This difference will avoid the criminalisation of under-18 year olds who attempt to purchase or who purchase a product which is less hazardous, based on the evidence available, than tobacco. It is also possible that in the future, some NVPs could be licensed as medicines and available to young people either by prescription or over the counter. If this were the case, it would not be appropriate to confiscate such NVPs and, in the course of enforcement, it would not be straightforward to distinguish NVPs which had been licensed as medicines from ones which are not.

37. The Bill provides for a due diligence defence against the offence of selling NVPs, to an underage person. That means it is a defence for an accused to prove that the accused (or any employee or agent of that person) took all reasonable precautions and exercised all due diligence to prevent the offence being committed. The Bill also makes this defence available to a person accused of selling tobacco to an underage person, providing consistency between tobacco and NVPs.

38. Most users of NVPs are adults who smoke or used to smoke tobacco. ASH has estimated that around 2.1 million adults in Great Britain use NVPs, up from an estimated 700,000 users in 2012.³¹ UK surveys showed a rise in use by smokers from 2.7% in 2010, to 6.7% in 2012,³² to 11% in 2013, up to 18% in early 2014.³³ So far studies have consistently shown extremely low levels of experimentation in non-smokers (0.1-3.8%).³⁴ ³⁵ In Scotland, the Scottish

³⁰ http://www.legislation.gov.uk/ssi/2010/406/pdfs/ssi_20100406_en.pdf

³¹ ASH (Action on Smoking and Health). 2014 *Use of electronic cigarettes in Great Britain*.

http://www.ash.org.uk/files/documents/ASH_891.pdf

³² Dockrell M, Morrison R, Bauld L, McNeill A. (2013) 'NVPs: prevalence and attitudes in Great Britain', *Nicotine and Tobacco Research* 15(10):1737-44

(<http://www.ncbi.nlm.nih.gov/pubmed/23703732>).

³³ Preliminary figures from the Office of National Statistics, based on data collected January-March 2014, showed that, in the UK, 12% of current smokers, 5% of ex-smokers and 0% of non-smokers used NVPs:

<http://www.ons.gov.uk/ons/rel/ghs/opinions-and-lifestyle-survey/adult-smoking-habits-in-great-britain--2013/stb-opn-smoking-2013.html#tab-Use-of-NVPs--and-the-relationship-to-smoking>

³⁴ Prior to 2009 NVP use was negligible but thereafter increased rapidly across Europe and the USA. (Hajek P, Etter JF, Benowitz N, Eissenberg T, McRobbie H. (2014) 'Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit', *Addiction*, 109: 11: 1801-1810 (<http://www.ncbi.nlm.nih.gov/pubmed/25078252>)

³⁵ Data from the Smoking Toolkit Smoking in England Survey is the most up to date and reliable source in the UK for NVP use by adults. It shows that the majority of regular users are either former smokers, many of whom report

Government's annual Scottish Health Survey introduced a question about adult use of NVPs in 2014 which will be reported on in autumn 2015.

39. Survey evidence shows that under-18s are buying or otherwise accessing NVPs, which suggests that NVPs are attractive to some under-18s and that voluntary sales measures are insufficient. Use amongst young people currently appears to be largely limited to those who already smoke tobacco, mirroring adult use. However, it is not known whether this will continue to be the case. Evidence from the USA and across the UK suggests that rates of children and young people trying and using NVPs are continuing to increase.

40. The Scottish Schools Adolescent Lifestyle and Substance Use Survey (SALSUS) collected data on NVP use amongst 13 and 15 year olds in Scotland in 2013.³⁶ Survey findings included:

- Pupils who had tried smoking, used to smoke or are current smokers were more likely to have tried NVPs,
- 6% of regular and 2% of occasional smokers used NVPs weekly,
- 17% of 15 year olds and 7% of 13 year olds reported ever trying or using NVPs,
- 4% who had never smoked had ever used an NVP (3% tried them once; 1% had tried a few times),
- 24% of those who have tried smoking had ever used an NVP,
- 66% of regular smokers and 46% of occasional smokers had used NVPs, however most had only tried them once or a few times (48% of regular and 38% of occasional smokers).

41. It is not just survey data which demonstrate that the industry's voluntary restriction on sale is not working. Test-purchasing in England found that, of 574 visits made by under-18s in March 2014, successful purchases were made by a child on 227 occasions (40%), despite 80% of the products purchased carrying an age-restriction warning.³⁷ Young people were able to buy NVPs most easily from market stalls and car boot sales, specialist NVPs retailers and independent pharmacies; sales were less frequent from national newsagents and large retailers.

42. In response to the Scottish Government's consultation *Electronic Cigarettes and Strengthening Tobacco Control in Scotland*, a large majority of respondents (88% of those who responded to the question) agreed that the minimum age for sale of NVP devices and refills should be set at 18. Those who supported the proposal most commonly suggested that possible health risks and the addictive properties of nicotine provided a rationale for preventing under-18s from accessing NVPs.

that they have used NVP as a tool for quitting, or current smokers who are using them in a pattern of dual use, which is consistent with data from other countries. <http://www.smokinginengland.info/>: The Smoking Toolkit's Smoking in England Survey collects data from a representative sample of households every month.

³⁶ *Scottish Schools Adolescent Lifestyle and Substance Use Survey (SALSUS), Smoking Among 13 and 15 year olds in Scotland 2013.* <http://www.isdscotland.org/Health-Topics/Public-Health/SALSUS/Latest-Report/>

³⁷ MacGregor, J (2014) *Youth Access to E cigarettes and associated products*, Commissioned by Public Health England for the Trading Standards Institute (<http://www.tradingstandards.gov.uk/templates/asset-relay.cfm?frmAssetFileID=75751>)

43. The Institute of Tobacco Control reviewed 123 countries for regulations on NVPs and found that ‘Sixteen countries have minimum ages for NVP purchase that mirror those of traditional cigarettes in their country’. Sales of NVPs are banned in 27 countries and 21 countries have restrictions on the sale of NVPs including restricting/prohibiting the sale or requiring authorisation for products containing nicotine.³⁸

44. In brief, due to the addictive nature of nicotine, the detrimental effects of nicotine on adolescent brain development, the precautionary health grounds noted above and the risk of promoting smoking behaviours to young people (explored in more detail in paragraphs 25-33), the Scottish Government is committed to introducing legislation to prevent the sale of NVPs to children and young people aged under 18.

Prohibition of sales of nicotine vapour products from vending machines

45. The Tobacco and Primary Medical Services (Scotland) Act 2010 banned the sale of tobacco from vending machines. This was because the sale of tobacco to a person under the age of 18 is prohibited and self-service vending machines cannot satisfactorily include a process for the vendor to verify age. It is not generally accepted for age-restricted goods to be sold through vending machines. The simple and workable solution was a complete ban for tobacco sales from vending machines. Responses to the Scottish Government consultation did not identify any instances where NVPs are currently being sold from vending machines in Scotland. However, it is possible that such businesses may appear in future if no action is taken to prevent the opportunity.

46. In response to the Scottish Government’s consultation *Electronic Cigarettes and Strengthening Tobacco Control in Scotland*, a large majority of respondents (79% of those who responded to the question) agreed that the sales of NVPs and refills (e-liquids) from self-service vending machines should be banned. Those who supported the proposal most commonly referred to difficulties in ensuring robust age verification for such sales.

47. The Bill contains a power to also prohibit the sale of NVPs from vending machines. As with tobacco, this will support the prohibition of sales of NVPs to those under 18 years of age. It also forms part of a wider strategy to reduce smoking behaviours (and mimicking behaviours) across the population. A majority of respondents to the written consultation agreed that the sale of NVP devices and liquids from self-service vending machines should be banned. Similar to the ban on tobacco vending machines, those who supported a ban on NVP vending machines most commonly referred to difficulties in ensuring robust age verification for vending machine sales.

Proxy purchase of nicotine vapour products

48. To support the prohibition of sales of NVPs to those under 18 years of age, the Bill will prohibit ‘proxy purchase’. This is where someone aged 18 or over purchases NVPs for, or on behalf of, a person under 18. These measures will bring the sale of NVPs into line with other age-restricted products, such as tobacco and alcohol. In response to the Scottish Government’s consultation *Electronic Cigarettes and Strengthening Tobacco Control in Scotland*, a majority of

³⁸ globaltobaccocontrol.org: Country Laws Regulating E-cigarettes: A Policy Scan: May 2015

respondents (78% of respondents to the question) agreed that the Scottish Government should legislate to make it an offence to proxy purchase NVPs.

Mandatory registration for nicotine vapour products

49. There is currently no system for identifying the many businesses which sell NVPs. The Tobacco and Primary Medical Services (Scotland) Act 2010 means that all retailers of tobacco products must register their business on the Scottish Tobacco Retailers Register. The Register is not a licensing scheme but allows legitimate businesses to be easily identified. The Register is a valuable tool, which enables local authority officers to provide advice and support to aid responsible retailing and also take enforcement action where necessary.

50. While many retailers who sell tobacco will also sell NVPs, there are many retailers – including specialist shops, pharmacies and pop-up kiosks – which sell NVPs but not tobacco. If measures are introduced to regulate NVP sales, it will be necessary for local authority officers to identify these retailers in order to assist with advice and enforcement functions in relation to the NVP related offences. This will mean that retailers who are already registered to sell tobacco products would be required to update their registration, if they also sell NVPs. Other NVP retailers would be required to register their premises for the first time.

51. There are various offences attached to the existing Register, including selling tobacco without a registration and not notifying changes of details. The Bill will attach these offences in relation to NVP retailer registration. As a result, if a retailer commits three or more tobacco or NVP related offences (such as selling these products to persons under 18) within a 2 year period, a local authority can apply to the Sheriff for a retail banning order (now called a “tobacco and nicotine vapour product banning order”). The order prevents a retailer from selling both NVPs and tobacco for up to 2 years and results in the retailer being removed from the Register. Retailers will also be required to declare whether they sell tobacco, NVPs or both.

52. A majority of respondents (65% of those who responded to the question) to the consultation on these measures were in favour of introducing a requirement that all retailers of NVPs should be registered and with making it an offence to sell such products without registration. A majority also agreed that the offences and penalties for selling NVPs without registration should mirror existing ones for the Register and tobacco sales. Views were mixed amongst individual respondents, NVP industry and tobacco sector representatives were both split, and most pharmacy respondents were opposed to registration.

Domestic advertising and promotion of nicotine vapour products

53. There are a range of existing legislative measures designed to protect children and young people, and the wider public, from exposure to tobacco advertising and promotion. Tobacco advertising was largely banned by the Tobacco Advertising and Promotion Act 2002 (TAPA); the Tobacco and Primary Medical Services (Scotland) Act 2010 banned retail displays of tobacco, and the Standardised Packaging of Tobacco Products Regulations 2015 ban any brand markings on cigarette and hand-rolling tobacco. These measures were based on a well-established evidence base on the role of advertising, promotion and displays in the take-up of tobacco use and normalisation of smoking and the difficulty of creating marketing which would only be accessed by, and attractive to, adults who smoke.

54. Marketing of NVPs is extensive and uses a wide variety of channels³⁹. The TPD⁴⁰, which will be implemented by May 2016, requires EU member states to implement a ban on cross-border advertising and promotion of nicotine containing e-cigarettes to protect primarily young people, citing concerns that these products could re-normalise smoking behaviour. The forms of advertising and promotion which will be banned by the TPD include:

- Television broadcasting;
- Radio broadcasting;
- Information society services;
- Most publications (e.g. newspapers);
- Sponsorship with a cross-border effect (e.g. televised sporting events).

55. The TPD does not cover domestic advertising, although it encourages member states to consider regulation within their own jurisdiction (see recital 48 of the TPD). Point-of-sale, billboards, posters, brand-stretching, nominal pricing and free distribution are powerful marketing tools which are not covered by the TPD. To date, no action has been taken in other parts of the UK to regulate domestic advertising and promotion of NVPs.

56. The Institute of Tobacco Control reviewed 123 countries for regulations on NVPs and found that of the 47 countries that have bans or restrictions on sale of NVPs, 33 prohibit or restrict the advertising, promotion or sponsorship of NVPs in their policies.⁴¹

57. In November 2014, the UK Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP) published a new statutory code to ensure that NVPs are promoted responsibly.⁴² The CAP/BCAP explained that they “consider that electronic cigarettes’ particular characteristics, their potential for harm, for addiction and their relationship with tobacco, carry a reasonable expectation of specific regulatory protection in relation to how they may be advertised”. The rules are enforced by the Advertising Standards Authority (ASA). The CAP/BCAP rules require that adverts should not target children, but experience with tobacco and other products (e.g. alcohol and junk food) show that it is not possible to create a regime where children are not exposed to advertising aimed at adults and it is very difficult to design and deliver marketing in such a way that it only reaches a small targeted subset of the population. It is extremely difficult to ensure that marketing is designed in such a way that will only reach and appeal to a defined age group or very specific target audience. Spillover is inevitable and it is known that adolescents and children look to their elders as role models and are influenced by, and aspire to the socio-cultural context and habits of older age groups. In

³⁹ de Andrade, M., Hastings, G and Angus, K (2013). *The Marketing of NVPs. A report for Cancer Research UK.*–
http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/cr_115991.pdf

⁴⁰ [Tobacco Products Directive \(2014/40/EU\)](#)

⁴¹ globaltobaccocontrol.org: Country Laws Regulating E-cigarettes: A Policy Scan: May 2015

⁴² <http://www.cap.org.uk/News-reports/Mediacentre/2014/~media/Files/CAP/Consultations/ecig%20consultation/Regulatory%20Statement.ashx>

addition, the rules set by the CAP/BCAP codes require interpretation in some circumstances as to what might or might not target or appeal to young people.⁴³

58. The Scottish Government welcomes the current CAP/BCAP rules but does not believe that these rules are sufficient; there is no statutory offence attached to them and they are too open to interpretation. The Scottish Government believes a stronger legislative footing is necessary which is similar (but not necessarily identical) to the restrictions on tobacco advertising and promotion contained in TAPA. As the TPD will ban cross-border advertising it is reasonable to assume that companies will respond by diverting resources into domestic advertising in response to this. It is also worth noting that the TPD will not ban advertising of NVPs which do not contain nicotine. The Scottish Government believes that a comprehensive ban on all NVP domestic advertising and promotion is required to complement the TPD, but allowances should be made for advertising at point of sale where NVPs are sold. A display of NVPs, the purpose or effect of which is not to promote a NVP, should not be regarded as an advert or promotion, and therefore should not be prohibited. The Scottish Government considers that allowing advertising at the point of sale and certain displays balances the need to protect non-smokers, especially children and young people, whilst recognising the harm reduction potential of NVPs for smokers who might benefit from being made aware of NVP availability. The Scottish Government will monitor compliance with a ban and commit to reviewing the policy.

59. The Bill contains powers which will enable the Scottish Ministers to make regulations prohibiting or restricting domestic advertising and promotion in Scotland, principally:

- Published advertising, including adverts on billboards, bus stops, vehicles, posters, leaflets, banners and certain published material (e.g. brochures and booklets), product displays whose purpose or effect is to promote NVPs and certain audio-visual media (e.g. publically exhibited moving-picture advertisements),
- Free distribution and in support of that, nominal pricing,
- Domestic sponsorship of an activity, event or person, and
- Brand-stretching in products and services (whereby NVP branding is used in relation to unrelated products or services, and vice versa).

60. The powers can make contravening a prohibition or restriction on domestic advertising or promotion an offence and make related provision. In particular, the powers can be used to make exceptions such as for point of sale advertising, which, as mentioned, the Scottish Ministers intend to permit as this offers a legitimate means for smokers to be informed about, and to find out information about NVPs. However, the intention is that this exception would not include displays visible from outside shops that have the same effect as non-point of sale advertising (e.g. posters taking up entire shop windows are little different to billboard advertising).

61. The purpose of the powers in the Bill in respect of published advertising, sponsorship and brand-stretching is to enable regulations to reduce the visibility and attraction of NVPs, to children and young people under 18 and adult non-smokers. This is not about controlling misleading advertisements (i.e. adverts which mislead consumers by misinforming them or

⁴³<http://cap.org.uk/News-reports/Media-Centre/2014/~media/Files/CAP/Consultations/ecig%20consultation/Regulatory%20Statement.ashx>

otherwise impair a fair choice to purchase) or comparative advertising (advertising explicitly or by implication which makes reference to a competitor or competing goods or services). The issue is the promotion of NVPs in general. The Bill will make NVPs age-restricted products and it follows that controls are needed to protect how they are advertised and promoted, in particular, to protect children. Similar to the objective of tobacco advertising and display bans, the aim of measures to reduce NVP advertising and promotion is to prevent the take up of these products amongst children and young people under 18 and adult non-smokers. The public health and public interest reasons which underpin this are set out above. The balance to be struck in weighing the health benefits against the health harms of controlling NVPs forms part of a wider tobacco and NVP control strategy across the population, yet recognises that NVPs are distinct products from tobacco products.

62. In relation to the powers in the Bill to prohibit or restrict free distribution, the purpose is slightly different from the powers in respect of published advertising, sponsorship and brand-stretching. It is not so much about reducing visibility and attraction. It is about protecting children and young people under 18 and adult non-smokers from being encouraged to try NVPs for free. Similarly, in so far as NVPs which do not contain nicotine are concerned, and are not in themselves addictive, the power aims to protect children and young people under 18 and adult non-smokers from being encouraged to try them for free and then potentially go on to try products which do contain nicotine or the conventional tobacco products which they mimic. A prohibition or restriction on nominal pricing is desirable to support a prohibition or restriction on free distribution, to ensure it is not easily circumvented by selling at prices reduced so low that it is tantamount to giving NVPs away for free. Free distribution and nominal pricing are promotions which by their nature have the same effect: encouraging people to try NVPs.

63. Young adults are heavily exposed to NVP marketing, particularly through the internet, which is one of the primary channels for their promotion and where it is estimated around half of all NVPs are bought.⁴⁴ A survey of 2,000 secondary pupils in Scotland was undertaken in October-December 2014, before and just after the introduction of the new CAP/BCAP code which came into effect on 10 November. The survey asked the pupils several questions about their exposure to the use of and the marketing of NVPs. The results of the survey demonstrated that, in the previous week, pupils had been exposed to NVP adverts in a wide range of cross-border and domestic marketing contexts (radio and TV, in print, outdoor billboards and posters, in retail outlets, on social media, use by celebrities, and events sponsorship).⁴⁵

64. While the industry has a voluntary age of sale restriction in place, and has welcomed the UK Government's intention to bring in regulation for an age restriction in England, the same consideration of age is not always reflected in the industry's approach to marketing. Formal analyses of the content of websites, adverts and promotional materials in the UK and the USA have shown that some NVP marketing appears to have been aimed at a younger demographic and that some of it could appeal to adolescents and children. In the UK analysis was undertaken for Cancer Research UK which systematically audited all forms of NVP marketing, and related PR and editorial comments in tobacco industry and the retail press trade.⁴⁶ Findings from that

⁴⁴ Scottish Government survey data which will be reported on in summer 2015 showed that secondary school pupils were exposed to NVP promotions through a diversity of channels.

⁴⁵ SG Health Analytical Services Division will publish a summary analysis of the survey results in the summer.

⁴⁶ de Andrade, M., Hastings, G and Angus, K (2013). *The Marketing of NVPs. A report for Cancer Research UK.*

study concluded that: NVPs were being promoted as lifestyle accessories with a possible appeal for young people; some NVP marketing could still suggest or inadvertently promote the act of tobacco smoking or could be mistaken for banned tobacco promotion.⁴⁷

Tobacco advertising: lessons and common issues

65. As noted in paragraph 53, a well-established evidence base underpinned legislation to protect young people and non-smokers from exposure to tobacco advertising. Children and young people are particularly susceptible to marketing as they have fewer life skills and less knowledge to make informed consumer, lifestyle and health choices. While combustible tobacco products and NVPs are clearly distinct products, there are sufficient similarities between their recreational use, the method of use and their addictive potential to justify drawing a comparison between how the two products have been promoted. It seems reasonable to assume that many of the same factors at play in tobacco and its marketing are also at work with NVPs given the many elements they have in common. Such assumptions underpin the extension to nicotine containing e-cigarettes of cross-border tobacco advertising regulations in the TPD. The independent review of standardised packaging evidence by Sir Cyril Chantler⁴⁸ observed that there is very strong evidence that exposure to tobacco marketing increases the likelihood of children taking up smoking. This is relevant because the use of NVPs can resemble aspects of smoking behaviour and imagery in NVP marketing could lead to confusion with tobacco products and smoking.

66. There is no good reason why NVPs should be marketed to non-smokers or to children and young people but there is also no practical way to ensure that permitted mass advertising only targets adult smokers, so a partial restriction is not an option in that respect. Extending the restrictions which the TPD will introduce to cover domestic advertising in Scotland of all NVPs would be in line with developments in other countries.⁴⁹ In contrast to the situation with tobacco, where the public health ambition is to eradicate all use, the public health aim for NVPs is not to prevent all use of NVPs for the foreseeable future, but to restrict their use to those who might benefit (i.e. adult smokers). It is not the intention of the Scottish Government's policy to prevent those who might benefit from having access to factual material or to be made aware of where NVPs are being sold. Point of sale seems, on balance, to be the best channel for the provision of information about NVPs, where the buyer can ask questions and be shown how to

http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/cr_115991.pdf

de Andrade, M., Hastings, G and Angus, K (2013). Promotion of electronic cigarettes: Tobacco marketing reinvented? *British Medical Journal*, 347: f7473. doi:[10.1136/bmj.f7473](https://doi.org/10.1136/bmj.f7473).

<http://www.bmj.com/content/347/bmj.f7473?variant=full-text.pdf%2Bhtml&hwoasp=authn%3A1407329954%3A4130224%3A1354951930%3A0%3A0%3AT4OwOOq2YsSyibamPDnuYg%3D%3D>

Bauld, L., Angus, K, and de Andrade, Marisa (2014) *NVPs uptake and marketing. A report commissioned by Public Health England.*

[https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311491/Ecigarette uptake and marketing.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311491/Ecigarette_uptake_and_marketing.pdf)

⁴⁷ The study pre-dated the introduction of the CAP/BCAP rules and at the time of writing no independent analyses had yet replicated the CRUK study to assess the impacts the new rules are having on industry practice.

⁴⁸ Chantler, Cyril (2014). *Standardised Packaging of Tobacco. Report of the independent review undertaken by Sir Cyril Chantler.* (<http://www.kcl.ac.uk/health/packaging-review.aspx>)

⁴⁹ The World Health Organisation undertook a study in 2014 that showed that comprehensive advertising, promotion and sponsorship bans on NVPs were in place in 39 countries (in which 31% of the world's population live): http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1

use a device and therefore should be exempt from any outright ban (such an exemption would, however, be for the regulations made under the Bill to set out).

67. A majority of respondents (66% of those who responded to the question) to the consultation on these measures believed that further regulation of the domestic advertising and promotion of NVPs, in addition to the cross-border restrictions to be introduced by the TPD, is required. However, both NVP and tobacco industry respondents were against additional regulation. Respondents were asked whether regulation was needed in relation to specific domestic advertising channels or media. Of the 106 who answered this question, a clear majority thought that all forms of domestic advertising and promotion should be regulated and for each specific form more than 90% of those who responded to the question agreed that it should be regulated, with the exception of point of sale, where 80% were in favour of regulation. The consultation paper asked whether any exemptions should be allowed. One-third of respondents thought there should be no exemptions and the most frequent reason for any exemptions was the need to balance restricting young people's exposure to the marketing against the potential contribution NVPs could make to harm reduction or as a cessation tool which means that smokers would need to know about the products.

Supporting the age restriction for the purchase of both tobacco and nicotine vapour products

68. Two measures in the Bill apply to both NVPs and tobacco products, and are primarily intended to support the enforcement of the minimum age of 18 for legally buying these products. The World Health Organisation considers tobacco to be one of the biggest public health threats the world has ever faced, killing nearly six million people a year worldwide⁵⁰. Each year in Scotland, tobacco use is associated with over 13,000 deaths (around a quarter of all deaths in Scotland each year) and 56,000 hospital admissions.⁵¹ The annual costs to Scotland's health service associated with tobacco-related illnesses are estimated to exceed £300m and may be higher than £500m each year⁵². Smoking makes a significant contribution to Scotland's health inequalities, with smoking prevalence rates at 39% in Scotland's most deprived areas, compared to 11% in the least deprived areas⁵³. Helping people who smoke to stop, and creating an environment that supports non-smokers to choose not to smoke, are therefore clear public health priorities.

69. Scotland is a recognised world-leader in tobacco control. Scotland's ban on smoking in public places led the way in the UK and is widely regarded as the most significant piece of public health legislation for a generation. The primary aim of the smoking ban was to tackle second-hand smoke and evaluation has shown measurable improvements in health since its introduction in March 2006.⁵⁴

70. The Scottish Government was amongst the first countries in the world to set a timescale for creating a tobacco-free nation. Its latest five-year Tobacco Control Strategy included a

⁵⁰ <http://www.who.int/mediacentre/factsheets/fs339/en/>

⁵¹ <http://www.scotpho.org.uk/publications/reports-and-papers/868-smoking-ready-reckoner>

⁵² <http://www.scotpho.org.uk/publications/reports-and-papers/868-smoking-ready-reckoner>

⁵³ <http://www.gov.scot/Publications/2014/08/7973/9>

⁵⁴ <http://www.healthscotland.com/scotlands-health/evidence/smokefreelegislation/publications.aspx>

commitment to reduce smoking prevalence to less than 5% by 2034. This means that a child born in 2013 would turn 21 in a country largely free of tobacco use. The Strategy sets out a range of measures to drive progress towards achieving this target. This includes a commitment to consider the need for measures to protect public health from any risks posed by new smoking related products and a specific commitment to consider the need for further advice on NVPs.

71. It is illegal to sell tobacco to a person under the age of 18. It can be difficult to judge age by appearance. This can potentially result in tobacco products being sold illegally if the retailer has not asked for proof of age. Schemes have been developed, now commonly known as “Challenge 25” or “Think 25”, which prompt retailers to ask customers who appear to be under 25 years of age for proof that they are 18 years or older before making a sale of age restricted product, the best known statutory example being alcohol. These schemes have been welcomed and very widely applied by many retailers as they encourage responsible practice.⁵⁵ They also encourage people to carry identification. Acceptable forms of proof of age are listed in the regulations associated with the age of sale restrictions for tobacco and for alcohol.⁵⁶

72. Improved trade practice, including age verification (Challenge 25), and enforcement mechanisms, including test purchasing, have been partly credited with a reduction in sales of alcohol to those under 18 years of age.⁵⁷

73. Enforcement data shows that there are retailers who make illegal sales of tobacco products to persons under 18⁵⁸ despite legislation setting an age restriction being in place since 2007.⁵⁹ There is also evidence that NVPs are being sold to persons under 18 despite a voluntary ban by retailers being in place.⁶⁰

74. Currently there is no age restriction on the age of the person selling tobacco or NVPs. Retail staff who are aged under 18 may feel less confident in challenging the age of a customer and refusing to make a sale to a customer on the grounds of age. The customer could be a friend or peer or may appear to be much older than them. This could be exacerbated if the proposals in the Bill are introduced which will require retailers selling to have an age verification policy in place (Challenge 25). Best practice suggests that either under 18s should not make sales of age restricted products at all or that each sale should be supervised by someone over the age of 18: the Tobacco Retailers Alliance advise retailers that “under-18s are supervised, as refusing sales

⁵⁵ ScotCen Social Research/NHS Health Scotland (2013) *Final report: Licensing Act (Scotland) 2005*, pp. 62-63. This report was part of the programme for Monitoring and Evaluating Scotland’s Alcohol Strategy (MESAS) (<http://www.healthscotland.com/scotlands-health/evaluation/planning/MESAS/MESASstudyportfolio.aspx>)

⁵⁶ SSI 2013/202 - The Sale of Tobacco (Prescribed Documents) (Scotland) Regulations 2013: <http://www.legislation.gov.uk/ssi/2013/202/contents/made>
SSI 2013/199 - The Sale of Alcohol to Children and Young Persons (Scotland) Amendment Regulations 2013: http://www.legislation.gov.uk/ssi/2013/199/pdfs/ssi_20130199_en.pdf

⁵⁷ E.g., ScotCen Social Research/NHS Health Scotland (2013) *Final report: Licensing Act (Scotland) 2005*, p 68. <http://www.healthscotland.com/scotlands-health/evaluation/planning/MESAS/MESASstudyportfolio.aspx>.

⁵⁸ <http://www.scotss.org.uk/reference/etsep2014.pdf>

⁵⁹ SSI 2007/431 increased the age restriction from 16 to 18 years old.

⁶⁰ MacGregor, J (2014) *Youth Access to E cigarettes and associated products*, Commissioned by Public Health England for the Trading Standards Institute.

to people in the same age range can be extremely difficult and young people are often more easily intimidated.”⁶¹.

Age verification policy for tobacco and nicotine vapour products

75. SALSUS 2013 found that of 13 year olds who smoked regularly, 15% purchased cigarettes themselves and 31% of 15 year olds who smoked regularly also purchased cigarettes themselves.⁶²

76. The Alcohol etc. (Scotland) Act 2010 introduced a licensing requirement for all premises selling alcohol to operate an Age Verification Policy, whereby retailers must ask for proof-of-age from any customers they believe to be under 25 (or a higher age which the policy may determine). The policy helps reduce the scope for ambiguity and should prevent illegal sales being made in borderline cases where it is not clear whether or not the customer is over 18. It supports compliance with the prohibition on underage sales.

77. The age verification policy has been welcomed by alcohol retailers as it supports them to ask for identification without confrontation.⁶³ It also encourages young people to habitually carry identification. Many tobacco retailers (primarily those who also sell alcohol) already implement an age verification policy for sales of tobacco products. *Creating a Tobacco-free Generation* welcomed this approach and encouraged all tobacco retailers to do the same.

78. The Bill will introduce a similar mandatory age verification policy for retailers of NVPs and tobacco products (but excluding premises from which only distance sales are made - e.g. internet sales). However, as these products are not subject to a licensing scheme, this requirement will not operate in the same way as for alcohol. Rather than being a licensing requirement, the Bill will make it an offence for a retailer to not operate an Age Verification Policy. An Age Verification Policy lays down the steps to be taken by a person selling (e.g. to ask for proof-of-age identification) to a customer seeking to purchase NVPs or tobacco where the person selling thinks or suspects that the customer is aged under 25 (or an older age set in the policy). The Scottish Ministers can amend the minimum age of 25 years old by regulations; there are equivalent powers in alcohol licensing legislation. The Scottish Government will consult with key stakeholders in the development of guidance relating to the policy. The guidance will set out what an age verification policy should include. Retailers should have regard to the guidance in operating a policy, which may cover matters such as training, awareness raising and appropriate identification. It is not the intention of this policy to prevent legal sales from taking place (e.g. where the customer is over age 18), rather it is intended to ensure that steps are taken to reduce the likelihood of illegal sales taking place. It is also intended to help encourage employers to give staff proper training and support on age verification.

79. A majority of respondents (75% of those responding to the question) to the consultation who commented on this proposal agreed with the introduction of Challenge 25 for sales of NVPs

⁶¹www.tobaccoretailersalliance.org.uk/index.php?option=com_content&view=article&id=23&Itemid=19

⁶²http://www.isdscotland.org/Health-Topics/Public-Health/Publications/2014-11-25/SALSUS_2013_Smoking_Report.pdf

⁶³<http://www.healthscotland.com/documents/5989.aspx>

and tobacco. A majority also agreed that penalties should be the same as for selling tobacco or NVPs to someone aged under 18.

Unauthorised sales of tobacco and nicotine vapour products by under-18s

80. It is legal for persons under 18 to sell both tobacco and NVPs, however it may be more difficult for young people to challenge the age of or refuse sales to their peers or customers who are older than them. This would be especially true with the introduction of the age verification policy, which would result in under 18s having to challenge the age of customers who may be significantly older than them. Without the appropriate support and training, young people may be at risk of making illegal sales of these products.

81. If under 18s were prohibited from selling NVPs and tobacco altogether, or were required to have each individual sale authorised in person by someone over the age of 18, there might be a disproportionate effect on some smaller businesses. For example, where a business does not have the staffing capacity to have an over 18 present on site at all times. The Scottish Government does not wish to place undue burden on these retailers or to discourage retailers from employing under 18s.

82. This Bill will prohibit unauthorised sales of tobacco and NVPs by under 18s. This supports compliance with the prohibition on underage sales. It is also intended to protect persons under 18 who make sales and to encourage employers to give them proper supervision, training and support. The “responsible person” commits an offence if the prohibition is breached on their premise. The registered person will be the responsible person; only in cases where a person is unregistered will it be someone else. The registered person can authorise a person under 18 to allow that person to sell tobacco and NVPs without an adult member of staff being present or they can authorise transactions on a case by case basis. This means that sales by the person under 18 are not unauthorised and the registered person does not commit the offence of allowing unauthorised sales.

83. All premises should be registered if they are selling tobacco or NVPs. In cases where a premises is not registered, and a person under 18 is found to be selling tobacco or NVPs unauthorised, the offence is committed by the employer and / or the person who has management and control of the premises (this is in addition to the offence of carrying on a tobacco or NVP business unregistered). Again, this measure brings the sales of tobacco and NVPs further into line with alcohol legislation. The due diligence defence mentioned at paragraph 34 is also made available in respect of this offence by the Bill.

84. Records of authorisations must be kept on the premises to aid enforcement and, if they cannot be produced, they are presumed to not exist. The Scottish Ministers are given a power by the Bill to make regulations setting out the form and content of such authorisations.

85. A large majority of respondents (87% who responded to the question) to the written consultation agreed that people under the age of 18 should be prohibited from selling tobacco and non-medicinal NVPs and refills unless authorised by an adult.

Smoke-free hospital grounds

Background

86. Section 2 of the Smoking, Health and Social Care (Scotland) Act 2005⁶⁴ makes it an offence to smoke in wholly or substantially enclosed public spaces.⁶⁵ This had the effect of making it an offence to smoke inside a NHS hospital building but there are currently no legal restrictions on smoking outside on NHS hospital grounds.

87. *Creating a Tobacco-free Generation* included an action for all NHS Health Boards to implement smoke-free policies across all NHS grounds by April 2015. This built on existing Scottish Government guidance to Health Boards on the development and implementation of smoke-free policies and the creation of health-promoting hospitals.⁶⁶ ⁶⁷ To support Health Boards to take a consistent approach across Scotland and to raise public awareness, NHS Health Scotland developed implementation guidance for Health Boards and launched a national information campaign in March 2015.⁶⁸ While early signs suggest this is having a positive impact, there remain concerns about compliance. The Scottish Government does not have comprehensive and reliable empirical data from across Health Boards on how many people smoke on NHS hospital grounds, where people smoke on the grounds, and the levels of second-hand smoke (“SHS”) in and around NHS hospital building entrances and windows.

88. Health Boards have reported difficulties in enforcing the ban as there is no sanction that can be applied if someone refuses to comply with the policy, other than asking the person to leave the grounds. However, this may not be desirable should a person be a patient. It is also difficult to enforce on large hospital grounds where a person could easily re-enter undetected. The Bill introduces a framework for smoke-free areas around NHS hospital buildings.

89. The Scottish Government has considered introducing measures to make it an offence to smoke anywhere within all NHS hospital grounds (with and without exempted zones where smoking would be permissible) but does not believe that this is a proportionate response to the current situation. The Bill will therefore make it an offence for a person to smoke within a designated area outside of buildings on hospital sites. The area will be bounded by a perimeter of a specified distance from hospital buildings (unless a building is exempted) but the perimeter cannot extend beyond the hospital grounds. The detail is to be set out in regulations under powers in the Bill. This approach will effectively extend the indoor smoking ban under the Smoking, Health and Social Care (Scotland) Act 2005 to include an outside area. This is important given the size of some grounds. Setting a perimeter around buildings focusses on the areas where there is the highest level of traffic of people on foot leaving and entering the hospital and where there is a risk of smoke entering hospital buildings as a result of people smoking close to the building, in particular at entrances. It is also easier to enforce a prohibition backed by the criminal law near buildings given that some hospital grounds are vast in size. For areas beyond

⁶⁴ 2005 asp 13. Schedule 1 to the Prohibition of Smoking in Certain Premises (Scotland) Regulations 2006 (SSI 2006/90) includes “Hospitals, hospices, psychiatric hospitals, psychiatric units and health care premises” within the meaning of “no-smoking premises”

⁶⁵ Section 4 of the 2005 Act defines “no-smoking premises”.

⁶⁶ http://www.sehd.scot.nhs.uk/mels/CEL2012_01.pdf

⁶⁷ <http://www.scotland.gov.uk/Publications/2005/12/21153341/33417>

⁶⁸ <http://www.smokefreegrounds.org/>

the perimeter, Health Boards will continue to operate smoke-free policies, as required by *Creating a Tobacco-free Generation*, in ways which best meet local needs. This is supported by an existing national campaign and investment in cessation support.

90. Fixed penalty notices can be issued to those who smoke within the defined perimeter in the same terms as those already issued under the 2005 Act. The outside smoking ban will likewise be enforced primarily by local authorities. Warning signs will be mandatory at entrances to NHS hospital grounds and hospital buildings. It will be an offence for a person having management and control of a hospital building to fail to put up signs. The Scottish Ministers have powers to specify the form and content of signage. A duty will be placed on the relevant NHS Health Board to display signage at every entrance to NHS hospital grounds. The Bill contains powers to make various exemptions in relation to the outside smoking ban, including exempting certain hospitals (e.g. the state hospital and psychiatric hospitals), exempting certain hospital buildings (e.g. where long term residential care is delivered such as adult hospices) on hospital grounds which are otherwise subject to the outside smoking ban and exempting areas of land from being a part of hospital grounds (e.g. residential areas otherwise associated with the hospital, like staff accommodation) or a part of the no-smoking area (e.g. to prevent the perimeter of a neighbouring building preventing smoking near an exempt building). The Bill also provides powers to include land within hospital grounds (e.g. where it might be unclear if land forms part of hospital grounds and it is desirable to ensure it is included) and to modify signage requirements as a consequence of the inclusion of land and the exemptions. The Bill provides a framework within which regulations can be made setting out the detail.

91. The proposal reflects the NHS's direct but compassionate message: it appreciates that smoking is a difficult habit to break but advises people to seek support to quit. The policy supports people who visit hospital for smoking cessation treatment, who have given up or who have reduced their smoking, and who might find it difficult to pass through areas close to entrances where people have congregated to smoke. The proposal will help people who have been advised to stop or reduce their smoking for periods of medical treatment. Social acceptability has a strong bearing on health behaviours and evidence shows that quitting is made more difficult if a smoker's social environment is filled with smokers⁶⁹. It is well established that one of the factors which influence whether a quit attempt will be successful is the extent to which a smoker is exposed to 'cues'.⁷⁰ This has partly motivated policies in Scotland such as the display ban and, although the enclosed public spaces smoking-ban in the 2005 Act was motivated by the desire to cut exposure to SHS, it may also have played an important part in de-normalising smoking. Support for the smoking ban increased significantly between 2006 and 2007 amongst smokers and non-smokers; and there has been a high level of compliance.⁷¹ The ban on smoking in hospital grounds is an important contribution to the progressive de-normalisation of smoking.

⁶⁹ Scollo, MM and Winstanley, MH (2008) *Tobacco in Australia: Facts and Issues. A comprehensive online resource*, 4th edn (Cancer Council Victoria):

[\(http://www.tobaccoinaustralia.org.au/downloadchapters/\)](http://www.tobaccoinaustralia.org.au/downloadchapters/)

⁷⁰ Scollo, MM and Winstanley, MH (2008) *Tobacco in Australia: Facts and Issues. A comprehensive online resource*, 4th edn (Cancer Council Victoria): Section 7.7.2: 37-38.

<http://www.tobaccoinaustralia.org.au/downloadchapters/>

⁷¹ Hyland, A, et al (2009) 'The impact of smoke-free legislation in Scotland: results from the Scottish ITC Scotland/UK longitudinal surveys', *European Journal of Public Health*, 19(2) pp. 198–205.

92. Another aim of the proposal is to prevent or reduce public, patients and staff from being exposed to SHS around entrances and near windows and vents through which smoke could drift into hospital buildings. The health harms from SHS are well understood and the World Health Organisation advises that there is no safe level of exposure to the small particles in cigarette smoke.

93. It is difficult to measure SHS out of doors as the chemical markers in the air may come from a range of other sources (for example, vehicle emissions). There is some evidence from studies of outdoor environments (primarily hospitality settings) which shows that it is possible, under certain conditions, to record levels of chemicals or particulates that could be attributable to SHS which approach those which are found in indoor areas where smoking is permitted. Smoke-drift from outside can lead to SHS levels inside building entrances and windows which may be high enough to warrant concern for those exposed to it over a prolonged period (for example, NHS staff working near vents)⁷². This evidence largely relates to SHS outside entrances to hospitality venues but it does serve as a useful comparator.

94. In Scotland, there is public support for smoke-free hospital grounds. A recent ASH/YouGov survey indicated that 73% of a representative sample (n=1,064) of the Scottish population would be in favour of a complete ban on smoking in hospital grounds.⁷³ The survey asked, “How strongly, if at all, do you agree or disagree with the following statement? Smoking should be banned in hospital grounds.”

	All Adults	Smokers
Base	1064	144
Strongly agree	56%	10%
Agree	17%	21%
Neither agree nor disagree	10%	16%
Disagree	11%	28%
Strongly disagree	4%	21%
Don't know	2%	5%
Net: Agree	73%	32%
Net: Disagree	15%	48%

95. Public opinion in Scotland is consistent with that in many other high-income countries with well-developed tobacco control laws, where outdoor smoke-free areas are increasingly being considered and introduced.

96. A majority of respondents to the written consultation (67% of those who responded to the question) were in favour of national legislation including all but one of the 18 Health Boards and health partnerships which responded to a question on this. Respondents had diverse views about where and how such a policy should be enforced. A majority of those who responded to a question on where such a ban should apply thought that it should apply to all NHS grounds (including offices, dentists and GP practices); almost none chose only hospital grounds; and about one tenth chose only within a designated perimeter around NHS buildings. The Scottish

⁷² Sureda, X., Fernández, E., López, MJ. And Nebot, M. (2013) Secondhand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Systematic Review, *Environmental Health Perspectives*. Vol. 121 Issue 7, p. 766-773.

⁷³ YG-Archive-140314-ASH-Scotland

Government believes that legislation on smoking on hospital grounds should be applied and enforced in a consistent and proportionate manner across Scotland. The rules should be as simple and as easy to comply with, and enforce, as possible. The size of NHS hospital grounds varies considerably across Scotland, from small to large and complex hospital sites. Many people who use these facilities as patients will have temporary or permanent impeded mobility due to an illness or disability and it would not be safe for some patients to go far from the hospital building with or without someone accompanying them. The existing policy approach allows NHS Boards to make decisions about how they choose to implement and enforce local smoke-free policies. This includes raising public awareness, providing alternatives to tobacco and asking those who visit NHS sites to respect the policy. People who do not comply, including those with impeded mobility and serious illness, do not face a criminal penalty. In considering the option of legislation, which would introduce criminal penalties issued to those who do not comply, the impact of such action needs to be balanced with the commitment to treat all users of hospitals, particularly those who are most vulnerable, with dignity and respect.

97. The primary aim of these provisions in the Bill is to support the de-normalisation of smoking in NHS hospital grounds in order to help reduce the use of tobacco across the population, in particular to reinforce that the NHS should be seen as an exemplar of health promotion within society and to support people in their efforts to reduce or stop smoking. The secondary aim is to help prevent or reduce exposure to second-hand smoke by people in NHS hospital grounds, at entrances and near windows/vents to buildings. These aims seek to improve and protect public health, and also as a matter of public policy, to ensure the NHS in Scotland is an exemplar in the health field. The need to achieve these aims is not in any doubt. People smoke at entrances and near buildings on hospital grounds. The evidence of harm from smoking behaviour and second-hand smoke is well established and the NHS should clearly be at the forefront of reducing these harms. Yet the provisions strike a balance, by not going as far as allowing a prohibition to apply in a blanket fashion to entire hospital grounds and enabling regulations to make exceptions, which is practical from an enforcement perspective and compassionate.

Consultation

Public written consultation

98. A public consultation paper, *Electronic Cigarettes and Strengthening Tobacco Control in Scotland*, was published on 10th October 2014 and closed for submissions on 2nd January 2015.⁷⁴ It contained 49 questions and covered all of the tobacco and NVP policies in the Bill as well as other topics which are not included in the Bill. By the closing date, 172 written responses had been received. These were analysed by an external contractor and a summary report of this analysis was published on the Scottish Government website.⁷⁵ There were 78 responses from individual members of the public and 94 responses from organisations. Organisational respondents were assigned to a specific category to allow for respondent group or sectorial analysis.

⁷⁴ <http://www.gov.scot/Publications/2014/10/5471>

⁷⁵ <http://www.gov.scot/Publications/2015/05/7711>

Respondent Type	Total
Academic Group	4
NVP Industry or Tobacco Industry	11
General Retail or Pharmacy	9
Health Body or Partnership	19
Local Authority	16
Other Public Body	4
Third Sector or Professional Body	25
Other	6
<i>Groups (Total)</i>	<i>(94)</i>
Individual	78
TOTAL	172

99. There was a mix of 49 closed and open questions. Many respondents did not respond to every question and many provided text which did not refer to a single question but discussed an issue more generally. To assess where the weight of opinion lay, quantitative analysis was undertaken of responses to closed questions and qualitative analysis was undertaken of free text responses to open questions and of additional text.

100. It is important to remember that the respondents to formal consultations are self-selecting and tend to be individuals and organisations with a particular interest or stake in the consultation topic. The results of consultation exercises are not reflective of wider public opinion.

Youth Commission on Smoking Prevention

101. The Scottish Government's Tobacco Control Strategy: *Creating A Tobacco-Free Generation*⁷⁶ included an action to establish a Youth Commission on Smoking Prevention. The Commission was established by the Scottish Government, its members are young people aged 12-22, from a range of backgrounds. It undertook its own research to provide the Scottish Government and local delivery partners with a series of recommendations and solutions aimed at supporting young people to choose not to use tobacco.

102. The Commission published its final report⁷⁷ on 14 October 2014. The report contained a number of recommendations, including:

- implementation of a 50m smoking ban around public places including schools and hospitals,
- a call on the Scottish Government to support the proposed Member's Bill around a ban on smoking in cars,

⁷⁶ <http://www.gov.scot/resource/0041/00417331.pdf>

⁷⁷ <http://www.youngscot.net/wp-content/uploads/2015/02/Youth-Comission-on-Smoking-Prevention.pdf>

- an increase in the age limit for those wishing to purchase tobacco products to 21 years old, and
- a ban on the sale of all e-cigarettes in shops and retail outlets – the product must be regulated and distributed as a medicinal product only.

Alternative approaches

103. The Business and Regulatory Impact Assessment and the Equality Impact Assessment which will accompany the Bill will outline in further detail the reasoning involved when considering policy options in terms of their likely impacts.

Minimum age for sales of non-medicinal nicotine vapour products

104. The following options to prevent NVPs being sold to under 18s were considered:

- Option 1 – do nothing,
- Option 2 – create an offence for a person under 18 to purchase or attempt to purchase an NVP as well as the offence for a retailer to sell an NVP to an under 18,
- Option 3 – create an offence for a retailer to sell an NVP to an under 18. This is the chosen option.

105. Option 1 would offer no safeguards to prevent young people from accessing NVPs. Although there is a widespread voluntary approach in place across manufacturing and retail elements of the sector, test purchasing exercises and survey data show that under 18s are able to access NVPs despite these voluntary measures. This option was ruled out.

106. Option 2 would support the aim of protecting young people and create greater consistency for retailers by aligning NVPs with other age restricted products, such as tobacco and alcohol, where it is also an offence for a young person to purchase or attempt to purchase these products. However, it would lead to the criminalisation of under-18 year olds who attempt to purchase or purchase a product which appears to be less hazardous than tobacco. For this reason, Option 2 was discounted and Option 3 was chosen.

Proxy purchase of non-medicinal nicotine vapour products

107. The following options were considered to prevent adults buying NVPs on behalf of children:

- Option 1 – do nothing,
- Option 2 – create an offence for an adult to purchase NVPs for a child or young person aged under 18 (this is the chosen option).

108. Option 1 would mean that while young people aged under 18 could not be sold NVPs, adults could purchase and legally supply them to a young person. Adults who have legitimate concerns for a young person who smokes and wish to purchase an NVP for them as a means of harm reduction would be permitted to do so. However, this would not prevent an adult who does

not know the young person or does not have a harm reduction motivation to purchase an NVP for them. Since Option 1 offers no protection for young people, this was discounted and Option 2 was chosen.

109. By creating an offence of purchasing NVPs or related products on behalf of a person under 18, Option 2 sends a clear and consistent message that NVPs are not suitable for young people. It supports the ban on underage sale. Since young people over the age of 12 can be prescribed Nicotine Replacement Therapy, which is available free on prescription, an adult concerned about a young person using tobacco would still be able to seek medical advice on treatment options.⁷⁸

Ban on sales of nicotine vapour products from vending machines

110. The options considered were:

- Option 1 – do nothing,
- Option 2 – introduce a ban on the sale of NVPs from vending machines. This is the chosen option.

111. Option 1 would allow NVPs to be purchased from vending machines. This would mean that the age of customers could not be verified at all, or not verified in a way that is necessarily secure nor conducive to general and simple rules capable of being easily applied and enforced, and under 18s could likely access NVPs if they became available on sale from vending machines. Similar to the rationale for banning the sale of tobacco from vending machines, Option 1 was therefore rejected and Option 2 was chosen. Option 2 supports the ban on underage sale and it forms part of a wider NVP control strategy across the population.

Mandatory registration to retail nicotine vapour products

112. There is currently no requirement to register as a retailer of NVPs. Three policy options were considered:

- Option 1 - do nothing,
- Option 2 - create an entirely separate register for retailers of NVPs,
- Option 3 - create a combined register of tobacco and NVP retailers, based on the existing Tobacco Retailers Register, where businesses will be required to identify the type of business they are carrying on and whether they are selling tobacco, NVPs or both. It follows that the banning order also applies to both the sale of tobacco and NVPs. This is the chosen option.

113. Option 1 would be the least burdensome option for retailers. However, Trading Standards would have difficulty in enforcing the new statutory measures to regulate NVPs (in this Bill and under the EU TPD) if they were not able to easily identify NVP retailers. This may lead to irresponsible retailers being able to operate unnoticed and illegal sales being made and so Option 1 was rejected.

⁷⁸ In the future, the MHRA may also license NVPs which could be prescribed for children as NRT.

114. Option 2 would create a new register of NVP retailers entirely separate from the Scottish Tobacco Retailers Register. This option would recognise the differences between the two product groups. However, it would involve an additional administrative burden for the many retailers who sell both NVPs and tobacco, who would be subject to two separate registration schemes, and there would be a small additional cost to the Scottish Government for the creation of a new register, so this was rejected.

115. The chosen policy, Option 3 would create a combined register of NVP and tobacco retailers by expanding the existing Register. It supports the ban on underage sale. Many businesses which sell NVPs also sell tobacco. They would not need to register anew on a separate NVPs system but would just need to update their entry to reflect that they sell both. It was considered that this option does not wholly address concerns that NVPs could be conflated or confused with tobacco if treated in a single register. However, businesses will identify whether they sell NVPs, tobacco or both. If a person is not responsibly selling one product then they may not be responsibly selling the other, so in that respect, it makes sense for a banning order (if granted by a sheriff) to apply to retailing both tobacco and NVPs rather than just one or the other; this also keeps the legislation on banning orders and the register simpler and easier to work in practice – a single register lends itself to a single banning order. The Scottish Government recognises that tobacco and NVPs are distinct products and are regulating them differently, but believe that Option 3 offers a proportionate and efficient administrative approach.

Domestic advertising and promotion of nicotine vapour products

116. Three options for regulating the domestic advertising and promotion of NVPs were considered:

- Option 1 – do nothing,
- Option 2 – introduce powers capable of banning or restricting on all forms of domestic advertising and promotion of NVPs,
- Option 3 – introduce powers capable of banning or restricting all forms of domestic advertising with exceptions which can be made, for example, for in-store point of sale marketing. This is the chosen option.

117. Option 1 would benefit retailers and manufacturers of NVPs, as they would be able to market their products to attract new customers and expand their businesses. Domestic advertising and promotion would still be subject to the CAP and BCAP codes and the ASA could require the removal of any advertising which breaches these codes. However, the codes are not as robust or as extensive as statutory controls backed by the criminal law; and there could continue to be examples of marketing which might be attractive to under-18s and non-smokers who would be exposed to such marketing before it was retroactively removed by the ASA in the event of a breach. It is also reasonable to expect that, following the implementation of the TPD, there would be an increase in domestic advertising to offset not being able to use cross-border forms. It is for these reasons that Option 1 was rejected.

118. Option 2 would allow for a ban or restriction (without the possibility of exceptions being made) on all forms of domestic advertising and promotion of NVPs. However, such a ban or

restriction would make it difficult for current smokers, who might benefit from substituting tobacco with NVPs, to learn about non-medicinal NVPs and their use. Option 2 was therefore rejected.

119. Option 3 provides for powers which are intended to be used to ban or restrict most forms of advertising and promotion of non-medicinal NVPs, apart from in-store point of sale advertising. This would allow for a channel of information for current smokers to be told about (e.g. when they are asking for NRT or tobacco products) and to find out about NVPs and to make a more informed decision about whether or not to switch to NVPs. This was chosen as a proportionate approach to achieving the aim of limiting NVP marketing to forms that would be almost solely aimed at smokers. However, it is important to note that the Bill establishes the powers and the detail of a ban or restriction, and the exceptions, would be for regulations.

Age verification policy for tobacco and nicotine vapour product sales (Challenge 25)

120. The options considered were:

- Option 1 – do nothing,
- Option 2 – require retailers to have in place a “Challenge 25” policy for the sale of tobacco and NVPs. This is the chosen option.

121. Option 1 would mean no additional burdens for retailers and allow retailers who voluntarily implement a Challenge 25 policy to continue doing so. There would be no additional legislative safeguards to prevent sales of these products to young people in borderline cases where it is not clear whether the customer is over 18. It would also mean continued inconsistency between the approaches taken by different retailers. Option 1 would not support or strengthen the age of sale restriction so it was rejected.

122. Option 2 would support the age of sale restriction for tobacco and NVPs purchases, aiding enforcement, empowering retailers to ask for proof of age, sending a clear message to customers that they may need to prove their age, and it would be in line with the law on alcohol.

Unauthorised sales of tobacco and nicotine vapour products by under 18s

123. A number of options were considered:

- Option 1 – do nothing,
- Option 2 – require a responsible person to specifically authorise and be present for each sale of tobacco or NVPs by an under 18,
- Option 3 – require a responsible person to authorise an employee under 18 to sell tobacco or NVPs. This is the chosen option.

124. Option 1 would mean that all under 18s continue to be legally allowed to sell tobacco and NVPs and there would be no additional support or safeguards in place for them to challenge their peers or those older than them for identification should the sale of sale restriction and the mandatory age-verification policy be introduced. Since Option 1 does nothing to offer additional protection and support for young people to make legitimate sales, it was discounted.

125. Option 2 would mean that under 18s would be supported in asking for identification when selling NVPs and tobacco as they would have a responsible adult authorise each sale in person. This would decrease the risk of illegal sales being made. This option would mean that under 18s would not be able to make sales while alone or unsupervised on the premises. Businesses which do not have the capacity to have more than one staff member on duty at all times may therefore be less likely to employ an under 18. Small to medium enterprises and family businesses would be especially impacted. For this reason, this Option 2 was rejected.

126. Option 3 takes into account the impacts on these businesses. It means that the responsible person should take responsibility for deciding whether they need to authorise each sale by the under 18 of tobacco or NVPs (Option 2) or provide a young person who has been appropriately trained with general authorisation to make sales when an adult is not present. In this case the employer must make a judgement that the young employee is responsible and skilled enough to comply with the law without an over-18 being present. By having to give prior authorisation, it encourages retailers to support young employees they authorise. Authorisation encourages responsible sales and thereby supports the ban on underage sales.

Smoke-free hospital grounds

127. Three approaches to support smoke-free hospital grounds policies were considered:

- Option 1 – do nothing,
- Option 2 – to ban smoking everywhere in the grounds of NHS hospitals with or without the option of making exceptions by regulations,
- Option 3 – to ban smoking within a designated area around buildings on NHS hospital grounds but allowing exceptions to be made in regulations. This is the chosen option.

128. Option 1 would not introduce measures to strengthen and enhance the smoke-free grounds-wide policies which NHS Health Boards were asked to implement by the Scottish Government by 1 April 2015. This would mean that no action would be taken to mitigate the concerns raised by NHS Chief Executives that there are no statutory requirements to support compliance with their policies. Option 1 was therefore rejected.

129. Option 2 would send a clear and consistent message that NHS Scotland is a health-promoting health service and that smoking on hospital grounds is not socially acceptable. It would help to reduce second-hand smoke exposure. This option would underpin the current smoke-free grounds policy. However, in terms of applying penalties, rather than allowing flexibility for NHS Health Boards to decide on locally appropriate and proportionate action to support compliance, with or without making complicated exceptions for certain areas on the grounds it would disproportionately and indiscriminately impact on addicted smokers who struggle with mobility, such as the elderly, disabled and seriously ill, and who may already feel stigmatised. This is especially the case on large hospital grounds where the exit to grounds could potentially be miles from a hospital building. On large hospital grounds enforcement of the entire site becomes impractical and the issues of second-hand smoke and social acceptance are primarily a concern at the entrances to, and near windows/vents of, buildings. Option 2 was therefore rejected.

130. Option 3 was chosen because a smoke-free perimeter around buildings protects in law, the area where there is the highest volume of foot traffic and the greatest risk of exposure to second-hand smoke and smoke-drift into buildings. People tend to smoke near buildings, which means that the visibility of smoking behaviour is most pronounced in these areas; countering this visibility further reduces the social acceptability of smoking. It complements existing smoke-free policies while taking a balanced, more realistic and more compassionate and safe approach while still supporting the Scottish Government's ambition for the health service. This option would allow NHS Boards to continue to have the flexibility to make decisions about how they choose to implement and enforce smoke-free policies on their estate beyond the statutory smoke-free area.

EFFECTS ON EQUAL OPPORTUNITIES, HUMAN RIGHTS, ISLAND COMMUNITIES, LOCAL GOVERNMENT, SUSTAINABLE DEVELOPMENT, ETC.

Equal opportunities

131. The Bill's provisions on NVPs and tobacco products are not discriminatory on the basis of gender, race, disability, sexual orientation, LGBTI status or pregnancy/maternity status. Several of the Bill's provisions are deliberately and justifiably discriminatory on the basis of age in order to protect the health of young people. The provision for smoking-free perimeter zones around hospital buildings is not directly discriminatory on the basis of age, gender, race, disability, sexual orientation, LGBTI status or pregnancy/maternity status. It may be indirectly discriminatory towards people who have limited mobility because of their age, a disability or pregnancy, but this has been carefully considered in the development of the policy.

Human rights

132. In relation to the provisions on nicotine vapour products, on tobacco, and on smoking in hospital grounds, the Scottish Government has assessed and is satisfied that these provisions in the Bill are compatible with the European Convention on Human Rights. In the assessment of the Scottish Government the rights which could arguably be considered relevant to the Bill are Article 8 (right to respect for private and family life), Article 10 (right to freedom of expression) and Article 1 Protocol 1 (right to peaceful enjoyment of property). Should there be any interference in these rights the Scottish Government has assessed that the provisions in the Bill fall within a state's margin of appreciation and are justified. As described in this Policy Memorandum, the measures pursue legitimate aims (public health and public interests), they are necessary and they are a proportionate response to that need.

Island communities

133. The provisions of the Bill will apply equally to all communities in Scotland and there are no particular implications for island communities.

Local government

134. The implementation of measures in the Bill will undoubtedly have implications for local government given their lead role in the enforcement and monitoring of tobacco and NVP provisions. COSLA and individual local authorities had the opportunity to contribute to the

formal written consultation and the Scottish Government will continue its on-going engagement with COSLA. The Scottish Government will engage with the new Scottish Local Government Partnership. COSLA have been consulted in the process for developing the Business and Regulatory Impact Assessment which will be finalised and published shortly after the Bill's introduction.

Sustainable development

135. The Bill will have no impact on sustainable development.

PART 2: DUTY OF CANDOUR

Background

136. The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry⁷⁹, chaired by Robert Francis, QC included recommendations in support of an essential aim to ensure openness, transparency and candour throughout the health system about matters of concern. It was recommended that every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh that duty to be honest, open and truthful. The Inquiry recommended that where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or any lawfully entitled personal representative or other authorised person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information.

137. The Berwick Report⁸⁰ 'A Promise to learn – a commitment to act' emphasised the importance of the requirement that patient or carers affected by serious incidents should be notified and supported. It recommended that where an incident qualifying as a serious incident occurs the patient or carers affected by the incident should be notified and supported. The report cautioned against an automatic 'duty of candour' where patients are told about every error or near miss, highlighting that this will lead to defensive documentation and large bureaucratic overhead that distracts from patient care. The importance of providing patients with all the information they ask for was emphasised.

138. The Dalton Williams Review⁸¹ clearly outlined the expectations that all those involved in caring roles have a responsibility to be open and honest to those in their care. They noted that the evidence they heard reaffirmed what was already known: that when things do go wrong, patients and their families expect three things: to be told honestly what happened, what can be done to deal with any harm caused, and to know what will be done to prevent a recurrence to someone else. Health and care organisations have a responsibility to ensure that all of these are reliably undertaken.

⁷⁹ <http://www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf>

⁸⁰ Department of Health (2013). A promise to learn – a commitment to act: improving the safety of patients in England. Available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

⁸¹ <https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf> (Accessed 25th September 2014)

139. It is internationally recognised that between 10-25% of episodes of healthcare (in general hospital, community hospital and general practice) are associated with an adverse event.⁸² However, it has been recognised that as few as 30 per cent of incidents resulting in harm are disclosed to people who have been affected. Denial and dismissal of mistakes often results in distress and people spending several years seeking the truth, accountability and an apology.⁸³

140. Adult social care providers already work within a well-developed framework for incident reporting. This involves a range of statutory reporting and practice arrangements that support engagement with an external reporting regime. This has driven a culture of candour in adult social care for some time. Adult social care providers are commonly already candid with people using their services when things go wrong. The less episodic nature of adult social care means that people are supported by social care providers for longer periods of time. The resulting establishment of longer term relationships tends to promote candour in practice, as something that is accepted as the ‘right thing to do’.

141. There are a range of factors that have been consistently shown to facilitate disclosure of harm and some that impede disclosure. Known barriers to disclosure include fear, a culture of secrecy and/or blame, lack of confidence in communication skills, fears that people will be upset and doubt that disclosure is effective in improving culture.⁸⁴ Factors that facilitate disclosure are an emphasis on accountability, honesty, restitution, trust and reduced risks of claims.⁸⁵ Disclosure is inhibited by professional or institutional repercussions, legal liability, blame, lack of accountability and negative family reactions.⁸⁶

142. Improvements in arrangements to support the disclosure of harm, is a key element supporting a continuously improving culture of safety.⁸⁷ There are several healthcare systems and organisations worldwide that have introduced initiatives or arrangements to support open disclosure of harm. For example, The Australian Open Disclosure Framework is a national initiative of the Australian National, state and territory governments, in conjunction with private health services, through the Australian Commission on Safety and Quality in Health Care. It is intended to contribute to improving the safety and quality of health care.⁸⁸

143. Ethically and morally, health and care professionals are already required to tell people about instances of harm. However of the eight UK wide professional regulatory bodies, only the General Medical Council (GMC) and Nursing and Midwifery Council’s (NMC) standards explicitly require their registrants to be candid with people harmed by their practice. The General Pharmaceutical Council has a standard that requires their registrants to respond ‘appropriately’

⁸² The Health Foundation (2011). Evidence scan: Levels of Harm. Available at: <http://www.health.org.uk/publications/levels-of-harm/> (Accessed 21st September 2014),

⁸³ Halligan, A. W. F. (2014). Implications for medical leaders of the proposed Duty of Candour. *Clinical Risk*, 20(1-2), 29-31.

⁸⁴ Iedema, R., Allen, S., Sorensen, R., & Gallagher, T. H. (2011). What prevents incident disclosure, and what can be done to promote it? *Joint Commission journal on quality and patient safety*, 37(9), 409-417.

⁸⁵ Kaldjian, L. C., Jones, E. W., & Rosenthal, G. (2006). Facilitating and impeding factors for physicians’ error disclosure: a structured literature review. *Joint Commission Journal on Quality and Patient Safety*, 32(4), 188-198.

⁸⁶ Kaldjian, L. C., Jones, E. W., & Rosenthal, G. (2006). Facilitating and impeding factors for physicians’ error disclosure: a structured literature review. *Joint Commission Journal on Quality and Patient Safety*, 32(4), 188-198.

⁸⁷ Etchegaray, JM., Gallagher, TH., Bell, SK et al. (2012). Error disclosure: a new domain for safety culture assessment. *BMJ Quality and Safety*, 21, 594-599.

⁸⁸ <http://www.safetyandquality.gov.au/publications/australian-open-disclosure-framework/>

when care goes wrong however, it does not specify that this involves being candid with the patient. The Professional Standards Authority has been overseeing the work of the professional regulatory bodies to reflect a common position on candour.

144. The General Medical Council and Nursing and Midwifery Council have recently consulted on a professional duty of candour.⁸⁹ The new Code issued by the Nursing and Midwifery Council includes new content emphasising the professional duty of candour for nursing and midwifery registrants. Further guidance will be issued by the General Medical Council in summer 2015.

145. NHS Boards are required to implement the requirements outlined in ‘Learning from adverse events through reporting and review: A national framework for NHSScotland’^{90 91} and also the ‘Can I Help You?’ guidance in respect of feedback, comments, concerns and complaints received⁹². This includes a requirement to submit Annual Reports on Comments, Concerns, Feedback and Complaints to the Scottish Government and the Scottish Health Council. The Scottish Health Council have published two reports following reviews of NHS Boards Annual Reports.^{93 94}

146. ‘*Learning from Adverse Events, through reporting and review: A National Framework for Scotland*’ (the National Framework) a document published by Healthcare Improvement Scotland is intended to provide an overarching approach, developed from best practice to support health and care providers to effectively manage adverse events.

147. The aims of the National Framework are to:

- learn locally and nationally to make service improvements that enhance the safety of our care system for everyone,
- support adverse event management in a timely and effective manner,
- provide a consistent national approach to the identification, reporting and review of adverse events, and allow best practice to be actively promoted across Scotland,
- present an approach that allows reflective review of events which can be adapted to different settings, and
- provide national resources to develop the skills, culture and systems required to effectively learn from adverse events to improve services across Scotland.

⁸⁹ Nursing and Midwifery Council and General Medical Council (2014). ‘Openness and honesty when things go wrong: the professional duty of candour. A draft for consultation’

http://offlinehbpl.hbpl.co.uk/NewsAttachments/PGH/Openness_and_honesty_draft.pdf

⁹⁰<http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=3b248733-5f86-4379-9a28-35beae432004&version=-1>

⁹¹<http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=3e877507-c77e-4bef-9566-852329abe425&version=-1>

⁹²<http://www.gov.scot/Publications/2012/03/6414>

⁹³http://www.scottishhealthcouncil.org/publications/research/listening_and_learning.aspx#.VUASwxdFAhs

⁹⁴http://www.scottishhealthcouncil.org/publications/research/complaints_and_feedback_report.aspx#.VUAS1BdFAhs

148. The National Framework seeks to ensure that no matter where an adverse event occurs in Scotland:

- the affected person receives the same high quality response,
- any staff involved are treated in a consistent manner,
- the event is reviewed in a similar way, and
- learning is shared and implemented across the organisation and more widely, to improve the quality of services.

149. All care homes, care at home, childminders, daycare of children, adoption and fostering, housing support, secure care, school accommodation, nurse agencies, and offender accommodation are required to notify the Care Inspectorate of the death of a service user and the circumstances of the death under The Regulation of Care (Requirements as to Care Services) (Scotland) Regulations 2002. Additional requirements are placed on providers of care home services to notify the Care Inspectorate of any serious injury of a service user, accident or any allegation of misconduct by the provider or any person who is employed by the care service.

150. For care services registered on or after 1 April 2011, additional notification requirements are in place. These are not specified in legislation but are determined by the Care Inspectorate and include accidents, incidents or injuries to a person using a service. The Care Inspectorate regards accidents requiring notification as unforeseen events resulting in harm or injury to a person using the service which results in a GP visit or a visit or referral to hospital. An incident is defined as a serious, unplanned event that had the potential to cause harm or loss, physical, financial or material. The Care Inspectorate also requires notification of allegations of abuse in relation to a person using a service. These additional notification requirements relate to all services regulated by the Care Inspectorate except childminders.

151. Healthcare Improvement Scotland requires that independent healthcare providers notify them of serious injury or unintended death of a service user as part of their notification requirements.

Policy objectives

152. The overarching purpose of the duty of candour provisions of this Bill are to support the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm, that is not related to the course of the condition for which the person is receiving care.

153. The Scottish Government believes that openness and transparency in relation to adverse events is increasingly recognised as an important element to establish a culture of continuous improvement in health and social care settings. The inclusion of the duty of candour procedure in this Bill reflects on the Scottish Government's commitment to putting people at the heart of health and social care services in Scotland, while also recognising and respecting the need of staff to feel supported when contributing to system review and learning.

154. The duty of candour procedure (which will be set out in regulations to be made using powers in the Bill) will emphasise learning, change and improvement - three important elements that will make a significant and positive contribution to quality and safety in health and social care settings.

155. The new duty of candour on organisations will create a legal requirement for health and social care organisations to inform people (or their families/carers acting on their behalf) when they have been harmed (physically or psychologically) as a result of the care or treatment they have received. This will act as a powerful signal that when harm occurs, the focus will be on personal contact with those affected, support and a process of review and action that is informed by learning and improvement. These proposals will have a positive effect on professional practice, patient and service user safety and public confidence. There will be a requirement for organisational emphasis on staff support and training to ensure effective implementation of the organisational duty. Staff must feel they have the necessary skill and confidence if they are to be meaningfully involved in the delivery of duty of candour procedures.

156. The duty of candour reporting requirements will provide a way for organisations to outline the approaches that they adopt in responding to reports of unintended or unexpected events, resulting in harm. Public reporting will help people's understanding of the health and social care environment and empower them by providing information for those seeking care and treatment. It will also encourage organisations to involve people.

157. The introduction of the statutory duty of candour must not become a 'box-ticking' or 'form-filling' exercise. The concerns about the introduction of an unnecessary administrative burden will be addressed through clear guidance that supports integration with existing processes for responses to complaints, adverse event and incident reporting – emphasising the requirements for support, training and identification of learning and improvement actions.

158. Actions must be focused on review of systems and processes, delivered within a supportive and learning-focused culture, not one that is focused on individual fear and blame. Guidance based on the work of the National Patient Safety Agency Incident Decision Tree⁹⁵ will inform implementation guidance to ensure that all elements of a 'just culture' inform organisational decision-making after incidents involving death or harm.

Alternative approaches

159. Health and care professionals in Scotland already have a professional duty of candour. There is also guidance across organisations in relation to reporting unexpected events that result in death or harm, and established procedures in support of public protection that includes similar reporting requirements. An alternative approach would therefore be to continue to rely upon professional duties and existing guidance.

160. However, there is currently variation in implementation of existing guidance and it does not consistently include the need for training, support and emphasis on publication of learning.

⁹⁵ <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/advances-in-patient-safety/vol4/Meadows.pdf>

Research that has highlighted the multiple organisational factors that influence optimal conditions for disclosure and learning from harm all suggest a need for alternative approaches to improve the current position across health and social care organisations in Scotland.

161. Healthcare Improvement Scotland has visited all Health Boards in Scotland as part of the national programme supporting learning following adverse events. This confirmed that there is variation across the country in respect of the rigour and standard of open disclosure and support for families and staff when harm occurs.

162. The following extracts from the review reports illustrate the variation that currently exists across the NHS in Scotland:

- “The three significant cases showed evidence of a consistent, robust approach to the involvement of patients and families throughout the process”,
- “...there was no consistent approach for involving patients, families and carers in the incident investigation, or a systematic process for documenting these events”,
- “Of the four cases we reviewed, only two documented some level of engagement with the family or relatives”,
- “We were unable to identify from the policy how NHS Board X actually involves patients, families or carers in investigations of adverse events”,
- “However the level of support provided to staff was sometimes variable”,
- “The level of engagement with the patient or family varied across the six cases”
“Most policies lacked guidance on how to involve stakeholders and there were significant inconsistencies in practice”.⁹⁶

163. The observations made by Healthcare Improvement Scotland are consistent with observations from work that has shown that ethical and policy guidance has largely failed on its own to improve rates of disclosure.⁹⁷

164. In relation to health care, the Professional Standards Authority has published a summary of research that outlines that the existence of a professional duty might not always be sufficient to ensure that this is consistently delivered within organisations. Their review of research identified that there are factors that in some circumstances mean that staff might not always feel able to discharge their professional duty of candour – these relate to matters such as to diffusion of responsibility, divided loyalties, profession-specific cultures and concerns about career progression.⁹⁸

165. The Professional Standards Authority document makes a compelling case in support of the need to move beyond the current reliance on standards and guidance. They have outlined the

⁹⁶http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/adverse_events_review_reports.aspx

⁹⁷ O’Connor, E., Coates, H. M., Yardley, I. E., & Wu, A. W. (2010). Disclosure of patient safety incidents: a comprehensive review. *International Journal for Quality in Health Care.*, 22(5), 371-379.

⁹⁸ Professional Standards Authority (2013). ‘Candour, disclosure and openness’.
<https://www.rcseng.ac.uk/policy/documents/duty-of-candour-psa-research-paper>

marked mismatch that has been noted between people's attitudes and actual behaviours in relation to disclosure of harm and emphasised that disclosure in principle does not regularly translate into action. They outline the impact on health and social care professionals to exposure to stressful situations and heavy workloads, often linked with a requirement to process complicated information and focus on specific goals and targets. This 'stimulus overload' is cited as a potential contributor to unreliable implementation of best practice regarding a duty of candour. Normalisation of abnormal events as a way of coping with high risk situations has been noted and, in some circumstances, suboptimal situations become viewed as normal features of care. This can result in passive tolerance that leads to inaction following an unexpected event resulting in harm. Inter-professional tensions may also contribute to different approaches to disclosure of harm and a hierarchical approach to decisions about which profession is obligated to lead on disclosure.

Consultation

166. The Scottish Government consulted on proposals for the introduction of a statutory organisational duty of candour⁹⁹ from 14 October 2014 to 15 January 2015. The responses to the consultation have been published on the Scottish Government's website.¹⁰⁰ The analysis of consultation responses also has been published.

167. Respondents regarded the development of a culture of openness and honesty as key to ensuring safe, high-quality health and social care services in Scotland. It was this openness and honesty which would support organisational learning and service improvement. Some respondents believed that the proposed legislation was helpful in promoting and supporting such a culture, while others saw it as potentially counterproductive. The general consensus amongst those broadly supportive of the introduction of the new duty was that it could not, on its own, be an effective lever for change. Respondents suggested that change would require a clear message from management at all levels that openness and honesty were valued and encouraged.

168. Respondents generally supported the introduction of the new duty – seeing it as complementary to existing arrangements – but were clear about the need for a primary focus on learning and the requirement for alignment of the new procedures wherever possible to support a consistency of approach.

169. Respondents thought the duty and its implementation had to take full account of the entire health and social care landscape, particularly in the light of moves towards service integration. They highlighted the need for the duty to be consistent with existing processes and procedures operating in health and social care services; the primary and secondary care sectors; large and small organisations; and a full range of professions and specialisms.

170. Respondents largely agreed that being candid with patients/service users when something went wrong, should be inherent to a person-centred approach to service provision. It should reflect a positive relationship based on open communication between professionals and service users at all stages of care and treatment (e.g. in explaining care options and treatment risks).

⁹⁹ <http://www.gov.scot/Publications/2014/10/9897/downloads>

¹⁰⁰ <http://www.gov.scot/Publications/2015/02/6913/downloads>

171. It was stressed that it would be important for the public to be aware of the duty and what it entailed, that the disclosable events should be meaningful to non-professionals, that those harmed were actively involved and supported at all points in the disclosure process, and that public reporting took account of the needs of a wide audience. The duty of candour, thus, had to be developed to meet the needs of patients and services users (and should not result in worrying people unnecessarily about minor incidents.)

172. The importance of taking account of the needs of different equality groups was raised by respondents in relation to a range of questions. The groups referred to most often were children and young people, those with communication difficulties and those who lacked mental capacity. It was argued that written information (e.g. summaries of disclosable events, information on sources of advice and guidance, public reports) should be provided in suitable formats for different groups, and that support should be provided by appropriately trained staff. It was further suggested that the provisions to inform ‘relevant persons’ should allow for carers, parents / guardians or ‘named’ persons to accompany or represent a harmed person . This would ensure that all groups understood and had the opportunity to be fully involved in proceedings.

173. Respondents emphasised the importance of clarification in relation to specific aspects of the proposed new duty, its requirements and its implementation. In particular, respondents called for clarity about the definitions of harm that would be used and of terms such as ‘relevant person’ and ‘reasonable support’.

174. Respondents emphasised the importance of the development of resources to support the implementation of the duty, such as guidance with examples and case studies and the development of national training courses and support materials.

175. Concern was expressed both by those in favour and those opposed to the proposed new duty about possible unintended consequences. These included the impact on professional practice and organisational culture; on compensation claims and litigation; and on public confidence in services. There was concern the new duty might lead to risk-averse decision-making in care and treatment, a tendency to classify events in ways which avoided the need for disclosure and the encouragement of a ‘blame’ culture with attention focused on the individuals involved in disclosable events. There was also concern that the definition of disclosable events might move attention away from the learning opportunities presented by less serious incidents and ‘near misses’.

176. In terms of claims and litigation, there was concern that any increase could impact on resources for services and in turn could impact on professional practice and organisational culture. Those concerned about undermining public confidence highlighted the need for careful handling of the public reporting requirements.

177. Frontline staffing and staff training were seen as the key resource issues, although respondents also highlighted the resource implications of administrative, communication and system support, management input, and the provision of support services. In general, respondents argued that the resource implications would be significant and on-going and could impact disproportionately on smaller organisations. It was also argued by some that a poorly resourced duty would ‘do more harm than good’. There was a general plea that minimising the

burden on organisations should be a key objective in developing the proposed requirements further, for example, by making use of existing procedures and systems for recording events and in setting the frequency of reporting.

178. There were calls for further work with stakeholder groups – particularly in relation to the definitions and supporting guidance for implementation.

EFFECTS ON EQUAL OPPORTUNITIES, HUMAN RIGHTS, ISLAND COMMUNITIES, LOCAL GOVERNMENT, SUSTAINABLE DEVELOPMENT, ETC.

Equal opportunities

179. The Scottish Government has considered potential equalities impacts and does not consider that the Bill's provisions on duty of candour are discriminatory on the basis of age, gender, race, disability, marital status, religion or sexual orientation. The provisions of the Bill are not intended to eliminate any specific form of discrimination or promote equality of opportunity. A full Equalities Impact Assessment (EQIA) has been undertaken, and the Scottish Government will continue to monitor and examine any potential equalities impacts which emerge as the policy is implemented.

Human rights

180. The Scottish Government has assessed and is satisfied that these provisions are compatible with the European Convention on Human Rights (ECHR). In disclosing information regarding instances of harm, to the individuals concerned and for the purposes of reporting, it is important that the Article 8(1) right to private life for all parties involved is respected. The provisions for the disclosure of personal information ensure Article 8 rights are protected.

Island and rural communities

181. The Scottish Government is satisfied that the Bill has no significant differential impact on island and rural communities. In some instances staff involved in application of the duty of candour procedure may not have access to training in geographical locations, though this will be addressed through the provision of a national training resource and online support materials.

Local government

182. The provisions will have costs implications for local government in respect of: provision of support for people affected by unexpected incidents or events that result in harm; and for training and implementation of the duty. Detailed costs are set out in the accompanying Financial Memorandum.

Sustainable development

183. The Bill will have no impact on sustainable development.

PART 3: ILL-TREATMENT AND WILFUL NEGLECT

Background

184. As part of its response to the Francis Report into the breakdown of care at Mid-Staffordshire hospitals, the UK Government commissioned Professor Don Berwick to carry out a review of patient safety in England. One of the recommendations in his report was to create an offence to place wilful neglect or ill-treatment of all NHS patients on a par with the offence that currently applies only to mental health patients in England and Wales. An equivalent criminal offence of wilful neglect or ill-treatment of mental health patients exists in Scotland in section 315 of the Mental Health (Care and Treatment) (Scotland) Act 2003 (“the 2003 Act”).

185. In November 2013, the First Minister announced in Parliament, the Scottish Government’s intention to examine the best way to legislate for a similar offence in Scotland.

186. Existing legislative and regulatory provisions that may apply in some cases of wilful neglect or ill-treatment (including the 2003 Act) are not considered sufficient to cover all situations of neglect or ill-treatment that may arise.

187. The intention of the provisions on wilful neglect/ill-treatment is to ensure that the worst cases of ill-treatment or deliberate neglect, which may be uncommon, can be dealt with effectively by the criminal justice system.

188. The provisions on wilful neglect/ill-treatment will establish a new criminal offence which will apply to individual care workers, managers and supervisors, either employed, or volunteering on behalf of a voluntary organisation, who provide care or treatment and to directors or similar officers.

189. The offence will also apply to organisations. The Bill provides courts with additional penalty options in respect of organisations who are convicted of wilful neglect or ill-treatment.

Policy objectives

General

190. The provisions on wilful neglect/ill-treatment are intended to create an offence which will allow the courts to deal with instances of ill-treatment or neglect across a range of health and social care settings. This will improve accountability for care that falls well below the accepted standard.

191. The Bill creates two separate offences: a care worker offence and a care provider offence.

Scope of the offences

192. The consultation document described a number of settings where the offences would apply, and respondents indicated strong support for its application right across health and social

care. The range of services to be covered by the Bill is consistent with the views provided in the responses to the consultation.

193. The offences described in the Bill only relate to health or social care provided to adults. The consultation asked for views on applying this offence to social care for children, and did not ask about health care situations. A number of the responses received indicated the need for further discussion about implementation, and how these offences would work alongside other legislation that impacts children and young people. There were further queries about extending it to health care situations for children. Further detailed consultation will take place about extending the provisions to children in both health and social care situations and whether this should be done at Stage 2 in the parliamentary process.

194. In line with proposals set out in the consultation and the responses received, the offence will not apply to unpaid carers but it will apply to volunteers who are volunteering on behalf of a voluntary organisation. In respect of volunteers, voluntary organisations often provide services on a commissioned basis and it is right that such contractual arrangements, and the role that voluntary organisations play in the provision of health and social care services, should be recognised by these provisions.

195. The existing offences of wilful neglect/ill-treatment of mental health patients and adults with incapacity do not require any set level of harm. The new offence is consistent in this way and will not specify a required level of harm in order to trigger the offence. The consultation responses strongly supported this and the Scottish Government feels that this is the right approach given that there may be some situations where a person could perpetrate neglect or ill-treatment but is discovered before any actual physical or psychological harm occurred.

196. The organisational offence will apply to care providers (which can be self-employed individuals who have others working for them, partnerships, companies, or unincorporated associations) who provide or arrange for the provision of adult health or social care. Neglect or ill-treatment in some circumstances may be symptomatic of failings within the wider organisation and some organisational policies and practices may contribute to a culture of poor care. Therefore it is important that these issues, where identified, can be addressed by the justice system.

197. Recognising the challenges associated with establishing an offence that will be effective for organisations, the offence is described with regard to the way that an organisation's activities are managed or organised. Several replies to the consultation referenced the Corporate Manslaughter and Corporate Homicide Act 2007 as a possible model for determining an organisation's culpability and this has been drawn on in developing the policy in this area.

Penalties

198. For the care worker offence, the Bill sets out a penalty of five years maximum imprisonment on indictment (as well as, or instead of, a fine). A number of responses to the consultation called for tougher penalties for those convicted of wilful neglect or ill-treatment, therefore the maximum penalty on indictment is now five years imprisonment as opposed to the two year maximum set out in the consultation document. For consistency, the Bill will also amend the penalty for the offence of wilful neglect/ill-treatment in section 315 the Mental Health

(Care and Treatment) (Scotland) Act 2003 to a maximum of five years imprisonment on indictment.

199. A majority of those responding to the consultation agreed that the courts should have additional penalty options in respect of organisations. While the imposition of a fine will often be appropriate, it may not always be a means of bringing about a positive change in organisational policies, standards, or culture. In the consultation responses, reference was made to publicity orders and remedial orders. Provision for publicity orders can be found in the Regulatory Reform (Scotland) Act 2014 and both publicity and remedial orders in the Corporate Manslaughter and Corporate Homicide Act 2007. The Bill gives the courts the power to make a publicity order, or a remedial order (or both) in respect of organisations convicted of wilful neglect or ill-treatment.

200. A remedial order is an order which will require the convicted organisation to take particular steps to remedy the breach of the duty of care owed to the person neglected or ill-treated. The order can also require the organisation to take any other steps to address other issues or deficiencies in the organisation's policies or practices which are relevant to the breach.

201. A publicity order is an order which will require the organisation to publicise details of its conviction and any penalties imposed (including the terms of any remedial order).

Alternative approaches

202. There is no alternative approach to primary legislation that would achieve the Bill's policy objectives of creating a new offence of wilful neglect or ill-treatment.

203. It would be possible to take no action but this would leave the situation whereby people in similar care settings could be wilfully neglected or ill-treated in the same way but charges could only be brought in respect of those neglected or ill-treated falling within the provisions of the 2003 Act.

Consultation

204. The consultation paper *Proposals for an Offence of Wilful Neglect or Ill-treatment in Health and Social Care Settings* launched on 10 October 2014 for a period of 12 weeks. The consultation responses were analysed by an external contractor and a summary report of this analysis was published on the Scottish Government website www.gov.scot/Publications/2015/05/9655.

205. The consultation received 103 responses in total: 95 from organisations and 8 from individuals. Organisational respondents included: NHS organisations; local authorities; third sector organisations; professional bodies and trade unions; scrutiny and regulatory agencies; adult/child protection bodies; and partnership bodies.

206. Although the consultation did not specifically ask whether the proposed offence should be created, respondents nevertheless offered views on this issue. In general, respondents were supportive of the introduction of the offence and saw the legislation as helpful in offering a

consistent level of protection to all individuals receiving health and social care, and in holding to account those who have intentionally harmed or neglected these individuals. There were also high levels of agreement with the specific proposals set out in the consultation document, although respondents often also expressed a range of caveats or concerns.

207. Nearly one-fifth of all organisational respondents questioned the need for, or expressed serious reservations about, the creation of a new offence, arguing that existing legislation and professional regulation already provided adequate protection; that the intended beneficiaries did not require special protection; that the creation of a new offence was a disproportionate response to a relatively small number of recent incidents; and that there was no evidence that a criminal sanction would act as a deterrent.

208. These respondents were also concerned about unintended consequences relating to costs, the potential for undermining existing regulatory frameworks, and the possible negative impacts on organisational culture and quality of care. These comments were also frequently reflected in the caveats and concerns expressed by other respondents.

EFFECTS ON EQUAL OPPORTUNITIES, HUMAN RIGHTS, ISLAND COMMUNITIES, LOCAL GOVERNMENT, SUSTAINABLE DEVELOPMENT, ETC.

Equal opportunities

209. The Scottish Government has considered potential equalities impacts and does not consider that the Bill's provisions on ill-treatment and wilful neglect are discriminatory on the basis of age, gender, race, disability, marital status, religion or sexual orientation. The provisions of the Bill are not intended to eliminate any specific form of discrimination or promote equality of opportunity. A full Equalities Impact Assessment (EQIA) has been undertaken, and the Scottish Government will continue to monitor and examine any potential equalities impacts which emerge as the policy is implemented.

210. Consultation respondents were largely positive about the equality implications of the proposed new offence. Older people and disabled people were seen as particularly likely to benefit from the legislation; it was also suggested that those from minority ethnic groups may be less likely to benefit from the protection offered as they were more likely to be cared for by family at home. Responses highlighted the need to facilitate access to justice for vulnerable groups.

Human rights

211. The Scottish Government has assessed and is satisfied that these provisions are compatible with the European Convention on Human Rights (ECHR). The Scottish Government has assessed that each offence is set out with enough clarity and certainty so as to allow a person to regulate their behaviour and to allow the authorities to effectively inform a person suspected of committing one of these offences of the reasons for their arrest, detention, and any subsequent charge in relation to that offence. Those prosecuted in Scotland are guaranteed to receive a fair trial. These provisions are proportionate to the aims described in the Policy Memorandum and are in the public interest.

Island communities

212. The Scottish Government is satisfied that the provisions have no significant differential impact on island and rural communities.

Local government

213. The provisions will have an impact on Local Government insofar as the offences will cover care or treatment provided by a local authority or its employees.

Sustainable development

214. The Bill will have no impact on sustainable development.

This document relates to the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (SP Bill 73) as introduced in the Scottish Parliament on 4 June 2015

HEALTH (TOBACCO, NICOTINE ETC. AND CARE) (SCOTLAND) BILL

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