

Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill

Business And Regulatory Impact Assessment

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FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill

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PART 1

TOBACCO, NICOTINE VAPOUR PRODUCTS AND SMOKING PROVISIONS

PURPOSE AND INTENDED EFFECT

1. OBJECTIVES

1.1 The Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill covers three distinct policy areas: controlling non-medicinal nicotine vapour products (NVPs)¹, tobacco control and smoking on NHS hospital grounds; duty of candour; and ill-treatment and wilful neglect. This part of the BRIA deals only with the provisions related to NVPs and tobacco control. Parts 2 and 3 of the BRIA deal with duty of candour and wilful neglect respectively.

1.2 The NVP, tobacco and smoking provisions in the Bill are:

- 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

1.3 These proposals support the commitments in the latest Scottish Government Tobacco Control Strategy, *Creating a Tobacco-Free Generation - A Tobacco Control Strategy for Scotland* (2013).² This sets out the Scottish Government's vision for a tobacco-free Scotland by 2034 (defined as smoking prevalence of less than 5%). This would mean a child born in 2013 would turn 21, and become an adult, in a Scotland largely devoid of tobacco use.

1.4 Smoking is associated with a range of illnesses and is the primary preventable cause of ill health and premature death. Each year, tobacco use is associated with over 13,000 deaths (around a quarter of all deaths in Scotland every year) and 56,000 hospital admissions in Scotland³. Smoking makes a significant contribution to Scotland's health inequalities with smoking rates in our most deprived communities remaining disproportionately high - 39% in the most deprived areas compared to 11% in the least deprived areas in 2013⁴. Annual costs to Scotland's health service associated with tobacco-related illness are estimated to exceed £300m and may be higher than £500m each year.⁵

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

² <http://www.gov.scot/Publications/2013/03/3766>

³ <http://www.scotpho.org.uk/publications/reports-and-papers/868-smoking-ready-reckoner>

⁴ <http://www.gov.scot/Publications/2014/08/7973>

⁵ <http://www.scotpho.org.uk/publications/reports-and-papers/868-smoking-ready-reckoner>

1.5 The proposals in the Bill build on the Scottish Government's existing approach to tobacco control which has aimed to protect public health by de-normalising smoking behaviours and reducing the attractiveness and availability of tobacco products. Helping those who smoke to stop, protecting people from exposure to second-hand smoke, and reducing the number of new people who take up smoking each year are clear public health priorities.

1.6 *Creating a Tobacco-Free Generation* acknowledged the growing market of NVPs. It included a commitment to consider what action should be taken by the Scottish Government to protect children and young people from taking up NVPs and to respond to market developments which may promote or normalise smoking behaviour. This Bill will create a regulatory framework within Scotland for non-medicinal NVPs to complement provision being introduced as a result of the EU Tobacco Products Directive 2014/40/EU.⁶

1.7 The provisions for smoke-free hospital grounds respond to calls for legislation to support compliance with the Scottish Government's existing policy for smoke-free hospital grounds. This recognises that the NHS should be an exemplar in promoting and supporting smoke-free lifestyles.

1.8 The Scottish Government's purpose is to focus Government and public services on creating a more successful country, with opportunities for all of Scotland to flourish, through increasing sustainable economic growth. This is underpinned by five strategic objectives. The NVP and tobacco control provisions in the Bill will contribute positively to the following objectives:

WEALTHIER & FAIRER - Enable businesses and people to increase their wealth and more people to share fairly in that wealth.

1.9 Discouraging young people from becoming addicted to nicotine, from starting to smoke and reducing smoking prevalence rates in Scotland will reduce the burden of nicotine and tobacco use on families and communities, particularly in our most deprived areas, as well as on business and public services. Therefore, contributing to a wealthier and fairer Scotland.

SAFER & STRONGER - Help local communities to flourish, becoming stronger, safer places to live, offering improved opportunities and a better quality of life.

1.10 Discouraging young people from starting to use nicotine, to smoke and reducing smoking prevalence rates in the long term could reduce demand for illicit tobacco and help support the development of more resilient, cohesive and successful communities.

HEALTHIER - Help people to sustain and improve their health, especially in disadvantaged communities, ensuring better, local and faster access to health care.

⁶ http://eur-lex.europa.eu/legal-content/EN/NOT/?uri=OJ:JOL_2014_127_R_0001

1.11 Discouraging young people from starting to use nicotine, to smoke and reducing smoking prevalence rates will contribute to increased physical and mental wellbeing and increased life expectancy amongst Scots, especially in our most disadvantaged communities.

SMARTER - Expand opportunities for people in Scotland to succeed from nurture through to lifelong learning, ensuring higher and more widely shared achievements.

1.12 Supporting young people to make the positive choice to not use nicotine or smoke will help them fulfil their potential without the burden of potential nicotine harm or tobacco-related illness later in life.

1.13 The Strategic Objectives themselves are supported by 15 national outcomes which describe in more detail what the Scottish Government wants to achieve over the next ten years. Policies to tackle smoking behaviours will make a positive contribution to delivering over half of our published national outcomes:

- we live longer and healthier lives
- we have tackled the significant inequalities in Scottish life
- we have strong, resilient and supportive communities where people take responsibility for their own actions and how they affect others
- we live our lives safe from crime, disorder and danger
- we realise our full economic potential with more and better employment opportunities for our people
- our young people are more successful learners, confident individuals, effective contributors and responsible citizens
- we have improved the life chances for children, young people and families at risk
- our children have the best start in life and are ready to succeed.

1.14 The background and rationale for government intervention are discussed in Sections 2 to 5 of Part 1 of this document, as follows:

- Section 2: provisions which apply to the sale of NVPs
- Section 3: powers in relation to domestic advertising and promotion of NVPs
- Section 4: provisions which support the law on under-age sales for both tobacco and NVPs
- Section 5: creation of smoke-free perimeters around hospital buildings

1.15 Consultation activity with stakeholders and the results of the written consultation, *Electronic Cigarettes and Strengthening Tobacco Control in Scotland*, are described in Section 6 of Part 1 of this BRIA.

2. CONTROL OF NVP SALES

2.1 The following Bill provisions apply only to NVP sales and purchase. These provisions already exist for traditional tobacco products.

- A minimum age of sale at 18 years old
- Mandatory registration for the sale of NVPs
- Introducing an offence of proxy purchase of NVPs
- Power to prohibit the sale of NVPs from vending machines.

BACKGROUND

What are Nicotine Vapour Products or Electronic Cigarettes?

2.2 NVPs deliver a vapour for inhalation by an individual. They are sometimes commonly 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 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 or in combination; nicotine is included in the majority of products in different concentrations; and most products contain flavouring.^{7 8}

2.3 NVPs have sometimes been marketed for use in places where smoking is not permitted as they are not lit and do not emit smoke. They have also sometimes been marketed as a cheaper and “healthier” or “less harmful” alternative to tobacco cigarettes. UK-wide rules on how NVPs are marketed, which were introduced in November 2014, prevent the inclusion of health or smoking cessation claims. These rules are discussed in Section 3.

2.4 Most NVPs are manufactured in China. There is a wide variety of devices on the market, produced by a diversity of manufacturers. Worldwide there is estimated to be more than 500 brands, but the contents of very few have been independently analysed. Products have often been poorly or incorrectly labelled and the quality and safety of different devices and liquids inconsistent. The EU Tobacco Products Directive 2014/40/EU⁹ (the TPD) addresses some of these challenges by regulating

⁷ Article 2 of the EU Tobacco Products Directive 2014/40/EU (the TPD) defines an “electronic cigarette” as: “a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.”

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

⁸ ASH (2014) *ASH briefing: E-cigarettes*; this includes an accessible description of the main types of device on the market. Available at: http://www.ash.org.uk/files/documents/ASH_715.pdf

⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_127_R_0001 The Trading

Standards Institute and ASH have produced a summary of the TPD provisions:

http://www.ash.org.uk/files/documents/ASH_937.pdf

content and quality and creating a reporting regime for manufacturers in respect of nicotine-containing products.

Definition in the Bill

2.5 The Bill defines a nicotine vapour product as:

- (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).

2.6 Because of the similarity in appearance and use, the possibility of using interchangeable parts being used to construct an NVP (e.g. tanks), and the use of liquids which can be mixed by the user, mean the proposals in the Bill cover devices and liquids which do not contain nicotine as well as those which do. The Bill's proposals do not include medical products or devices, nor nicotine when regulated as a poison.

Current regulation of NVPs

2.7 NVPs are currently subject to general consumer regulations.¹⁰ The TPD will extend and strengthen this by creating a consistent regulatory regime for e-cigarettes and e-liquids which contain nicotine across EU Member States. The TPD has to be transposed into domestic law by 20 May 2016. It will be implemented UK-wide by the UK Government. The EU is taking action on areas which need a European-wide response in order to:

- Ensure that Member States apply consistent high standards for health and safety.
- Overcome Member States' obstacles in bringing their national legislations in line with new market, scientific and international development in already harmonised areas.
- Allow economic operators to manufacture for one market (the EU) rather than having to adapt products to several different national laws.

¹⁰ These are described in the PAS produced by the British Standards Institute:
<http://shop.bsigroup.com/ProductDetail/?pid=000000000030303130>

2.8 The EU TPD includes a number of requirements regarding nicotine containing e-cigarettes. These include:

- Products containing more than 20 mg/ml of nicotine or which make smoking cessation claims will be prohibited unless they are licensed as medicines. In the UK, such products would require authorisation by the Medicines and Healthcare Products Regulatory Agency (MHRA).
- 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 substances contained in the product and information on the product's nicotine content must be listed.
 - Restrictions on cross-border advertising and promotion which in effect bans any advertising with a cross-border effect.
 - Manufacturers must inform Member States before placing a product on the market and must report annually to Member States.
 - There will be new size limits on products: 10ml for e-liquids with dedicated refill containers and 2ml for NVP cartridges and tanks.

2.9 The TPD does not regulate e-cigarettes in relation to flavours, their use in specific environments, domestic sales arrangements or domestic advertising. Nor does it introduce an age limit for the sale of e-cigarettes.

2.10 NVPs cannot be sold as smoking cessation aids unless licensed as a medicine by the Medicine and Healthcare Regulatory Authority (MHRA). To date no NVPs have been granted such a licence. The proposals in the Scottish Government's Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill apply only to non-medicinal NVPs. NVPs which in the future are licensed as medicines will be subject to separate regulatory rules which cover medicines 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.

Use of NVPs

2.11 Data on the profile of NVP users in the UK is discussed in more detail in the Policy Memorandum accompanying the Bill.¹¹ ASH has estimated that around 2.1 million adults in Great Britain currently use NVPs, up from an estimated 700,000

¹¹ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

users in 2012.¹² UK surveys showed a rise in use by smokers from 2.7% in 2010, to 6.7% in 2012,¹³ to 11% in 2013, up to 18% in early 2014.¹⁴ So far studies have consistently shown extremely low levels of experimentation in non-smokers (0.1-3.8%).¹⁵

2.12 In Scotland, the Scottish Government's Scottish Health Survey introduced a question about adult use of NVPs in 2014 which will be reported on in autumn 2015. ASH Scotland surveyed a representative sample of the Scottish population aged 18 and over in March 2014 with similar results as the UK as a whole.¹⁶ The results are summarised in Table 1.

Electronic cigarette use	Tried but no longer use	Current use
Current smokers	28%	17%
Ex-smokers	4%	3%
Never smoked	0%	1%

Table 1: Adult use of electronic cigarettes in Scotland, March 2014 (ASH Scotland)

2.13 England has some of the most current data on adult smoking behaviours (including quit attempts), gathered through the monthly Smoking Toolkit Smoking in England Survey which reports quarterly.¹⁷ The survey has included questions about e-cigarettes since 2011. The majority of regular e-cigarette users in England are either former smokers, many of whom report that they have used NVPs as a tool for quitting, or current smokers who are using them in a pattern of dual use with tobacco. Throughout 2014, 28-33% of quit attempts by survey participants involved NVPs as a cessation aid, which is consistent with data from other countries.¹⁸ A UK-wide survey undertaken for ASH in the UK in March 2014 found that for 56% of current users of NVPs who were ex-smokers, the principle reason for their use was

¹² ASH (Action on Smoking and Health). 2014 *Use of electronic cigarettes in Great Britain*.

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

¹³ Dockrell M, Morrison R, Bauld L, McNeill A. (2013) 'E-cigarettes: prevalence and attitudes in Great Britain', *Nicotine and Tobacco Research* 15(10):1737-44

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

¹⁴ 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-e-cigarettes--and-the-relationship-to-smoking>

¹⁵ 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>)

¹⁶ ASH Scotland (May 2014) Briefing paper on 'Electronic cigarettes/E-cigarettes':

<http://www.ashscotland.org.uk/media/6093/E-cigarettesbriefing.pdf>

Data tables available at:

http://d25d2506sfb94s.cloudfront.net/cumulus_uploads/document/acw2ey8jk1/YG-Archive-140314-ASH-Scotland.pdf

¹⁷ <http://www.smokinginengland.info/>: The Smoking Toolkit's Smoking in England Survey collects data from a representative sample of households every month.

¹⁸ The website includes a quarterly update on "Electronic cigarettes in England - latest trends" - <http://www.smokinginengland.info/latest-statistics/> In the first quarter of 2015, 35.1% of reported quit attempts by survey respondents had involved an NVP.

“to help me stop smoking entirely”.¹⁹ This was also the most popular reason amongst current smokers who were using NVPs (32%).

2.14 Use amongst young people appears to be largely limited to those who already smoke tobacco which mirrors adult use, although it is not known whether this will continue to be the case. Evidence from countries like the USA and other parts of the UK suggests that rates of children and young people trying and using NVPs are continuing to increase, but more research is needed to understand who is most likely to use or experiment with NVPs and why.

2.15 The Scottish Schools Adolescent Lifestyle and Substance Use Survey (SALSUS) collected data on electronic cigarettes use amongst 13 and 15 year olds in Scotland in 2013.²⁰ The survey found that:

- Pupils who had tried smoking, used to smoke or are current smokers were more likely to have tried an e-cigarette;
- 6% of regular and 2% of occasional smokers used e-cigarettes weekly.
- 11% of regular and 6% of occasional smokers used e-cigarettes at least monthly.
- 17% of 15 year olds and 7% of 13 year olds had ever tried or used an e-cigarette.
- 4% who had never smoked had ever used electronic cigarettes.
- 24% of those who have tried smoking had ever used electronic cigarettes.
- 39% of former smokers had used them (19% once, 14% a few times, 3% used to use them and 2% were using them once a month or more).
- 66% of regular smokers and 46% of occasional smokers had used e-cigarettes, however most had only tried them once or a few times (48% of regular and 38% of occasional smokers).²¹

2.16 It will be important to continue to compare levels and patterns of NVP use with smoking prevalence and to monitor the effects which NVP use may have on the denormalisation or renormalisation of smoking behaviours. Data suggest that NVPs may be a gateway out of tobacco smoking for some smokers, but there is concern that they might also be a gateway into tobacco use. Smoking rates in the UK continue to fall but there is insufficient evidence to demonstrate the nature of the impact which the use of NVPs may be having on this sustained trend.

¹⁹ This was undertaken by ASH with a representative sample of the population: ASH (Action on Smoking and Health). 2014 *Use of electronic cigarettes in Great Britain*. http://www.ash.org.uk/files/documents/ASH_891.pdf.

²⁰ *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/>

²¹ SALSUS figures are broadly comparable with data that ASH gathered from 11-18 year olds in 2014: see ASH (Action on Smoking and Health). 2014 *Use of electronic cigarettes in Great Britain*. http://www.ash.org.uk/files/documents/ASH_891.pdf

NVPs and health

2.17 The Policy Memorandum which accompanies the Bill discusses in more detail a range of public health considerations for NVPs.²² In brief, these include:

- Nicotine is a highly addictive substance, which is toxic at high doses, and can be harmful for some users.
- Public health policy should concern itself with limiting forms of chemical dependency in the population. Long-term nicotine addiction is not in the interest of public health in Scotland.
- NVPs may prove to be a useful cessation tool for some smokers but there is not currently the same weight of evidence from good quality clinical trials as exist for other cessation methods and aids.²³ A Cochrane Review²⁴ assessed the evidence for their use in cessation and confirmed that there is a shortage of conclusive trials.²⁵
- There is currently an absence of evidence about the effects of long-term use of NVPs but this will improve with time.
- It is unclear what proportion of people who have stopped smoking with an NVP will remain abstinent over the long term. There is currently insufficient evidence to identify who amongst current smokers would benefit most.
- There is on-going debate amongst the public health community internationally, and within Scotland, about whether NVPs could act as a potential gateway to tobacco smoking.
- The use of NVPs imitates the act of smoking. There is on-going debate amongst the public health community internationally, and within Scotland, about the potential for confusion and whether their visibility undermines efforts to de-normalise smoking.
- The role of tobacco companies raises concern for public health policy. It seems likely that as the market matures, many mainstream brands will be wholly or partly owned by large tobacco companies.²⁶ There is a legitimate concern about the potential for tobacco companies to become

²² <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

²³ Internationally, there are a number of trials of NVP effectiveness but it will be some time before there is a sufficient evidence for solid judgements to be made about their benefits versus risks.

²⁴ 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 are published in *The Cochrane Library*.

²⁵ 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

²⁶ Quelch, J and Rodriguez, M. (2014) E-cigarettes: Marketing versus Public Health, *Harvard Business Review*, 16 September 2014.

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)²⁷ arose from a need to prevent the tobacco industry from seeking to influence public health policy, as it had done in the past.

2.18 NVP policies are therefore required which balance concerns about the risks to children, young people and adult non-smokers/ non-nicotine users with potential benefits for smoking cessation and tobacco harm reduction. The Scottish Government does not believe that there is any legitimate health reason for using NVPs apart from their potential to support an attempt to stop smoking or to reduce tobacco use.

2.19 There are therefore a number of reasons to merit a precautionary public health approach to these products:

- The positive impacts (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 (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 contribute to some degree to normalising smoking behaviour and products which contain nicotine can harm young users.
- The positive and negative impacts which NVPs may have on achieving the outcomes of tobacco control policy are not fully understood.

RATIONALE FOR GOVERNMENT INTERVENTION

2.20 There are a number of significant areas where the TPD does not regulate but instead encourages Member States to develop domestic regulations. This includes restrictions on the sale of the products (which includes an age limit for purchase or sale) and domestic advertising, where intervention is required.

2.21 The World Health Organisation (WHO) recommends that regulators should collaborate to determine the most effective means of regulating (or possibly banning) the use of NVPs in order to protect public health. In its most recent report,²⁸ citing nicotine addiction as the underpinning reason, WHO recommends that: "Retailers should be prohibited from selling ENDS (Electronic Nicotine Delivery Systems) products to minors, and vending machines should be eliminated in almost all locations."

²⁷ http://www.who.int/fctc/text_download/en/ - 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.*"

²⁸ http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf

2.22 In building on the TPD, the Scottish Government is acting on public health and public interest grounds, which in respect of health is partly based on taking a precautionary approach to minimise the potential for negative consequences of NVPs use, as discussed above. This is balanced against the potential health benefits for smokers. This is discussed more fully in the Policy Memorandum accompanying the Bill, along with the public interest reasons for controlling NVPs.²⁹

Age restriction

2.23 The Scottish Government is clear that neither tobacco nor NVPs should be accessible to young people who are under the age of 18. There are particular health, including neurological, risks associated with nicotine use for young people and children. This is discussed more fully in the policy memorandum accompanying the Bill. There is support amongst the industry for a mandatory age restriction and many suppliers and retailers of NVPs have already voluntarily agreed to prohibit sales to persons aged under 18. The Electronic Cigarette Industry Trade Association (ECITA) has called on governments to regulate the age of sale.³⁰

2.24 Survey evidence to date shows that a small proportion of 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. 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.³¹ Young people were able to buy NVPs most easily from market stalls and car boot sales, specialist NVP retailers and independent pharmacies. Sales were less frequent from national newsagents and large retailers.

2.25 Action is being taken elsewhere to ban sales to those under 18. The UK Government has already introduced age restriction and proxy purchase regulations which apply to England and Wales³², along with a ban on proxy purchase. The Government in Northern Ireland has consulted on a draft Bill to do the same.³³ Age restrictions in other jurisdictions are noted in the Bill's accompanying policy memorandum.

Mandatory registration for the sale of NVPs

2.26 Currently there is no way of knowing where NVPs are sold in Scotland. Many retailers which sell tobacco also sell NVPs but there are also many outlets which only sell NVPs, including independent shops, pop-up kiosks and pharmacies. Information provided from Trading Standards Officers indicates that NVPs are currently sold from a wider diversity of retail outlets than tobacco. If measures are introduced to regulate NVP sales, it will be necessary for enforcement officers to identify these retailers in order to assist with advice and enforcement functions in relation to the NVP-related offences.

²⁹ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

³⁰ http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf

³¹ MacGregor, J (2014) *Youth Access to E cigarettes and associated products*, Commissioned by Public Health England for the Trading Standards Institute

³² <http://www.legislation.gov.uk/ukdsi/2015/9780111130568>

³³ <http://www.northernireland.gov.uk/news-dhssps-030914-proposals-underway-to>

2.27 Anyone intending to sell tobacco products in Scotland must first register on the Scottish Tobacco Retailers Register (the Register), which was constituted under Chapter 2 of the Tobacco and Primary Medical Services (Scotland) Act 2010.³⁴ International experience had shown that age restrictions on the sale of tobacco were difficult to enforce effectively without some form of registration or licensing.³⁵ The Bill will introduce mandatory registration for any business wishing to sell NVPs and refills using an extended form of the existing register to tobacco retailers. The new registration requirement will enable enforcement authorities to:

- identify where NVPs are being sold;
- provide guidance to those who are selling NVPs to support compliance with the law; and
- monitor and take necessary action against retailers who breach the relevant provisions.

2.28 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.

Introducing an offence of proxy purchase for NVPs

2.29 This measure will support a ban on sales of NVPs to those under the age of 18 years. Without this offence, persons aged 18 or over could purchase the NVP on behalf of an under 18 year old without committing an offence. It provides consistency across sales regulation for NVPs, tobacco and alcohol.

Banning the sale of NVPs from vending machines

2.30 This measure will support a ban on sales of NVPs to those under the age of 18 years as vending machines cannot satisfactorily include a process for the vendor to verify age. 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. Tobacco vending machines are already prohibited and, as such, this measure will provide consistency across NVPs and tobacco.

³⁴ <http://www.legislation.gov.uk/asp/2010/3/contents>

³⁵ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/16857.aspx>

3. NVP ADVERTISING AND PROMOTION

Background

3.1 Marketing of NVPs is extensive and uses a wide variety of channels. Tobacco advertising was largely banned by the Tobacco Advertising and Promotion Act 2002 (TAPA).³⁶ The TPD requires member states to implement a ban on cross-border advertising and promotion to protect primarily young people, citing concerns that nicotine-containing e-cigarettes could re-normalise smoking behaviour. The cross-border forms of advertising and promotion of nicotine-containing electronic cigarettes which will be banned include:

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

3.2 The TPD does not cover domestic advertising, although it encourages Member States to consider regulation within their own jurisdiction. It advises that “it is appropriate to adopt a restrictive approach to advertising electronic cigarettes”.³⁷ Examples of domestic advertising include point-of-sale, billboards, posters, brand-stretching, nominal pricing and free distribution.

3.3 Young adults are heavily exposed to NVP marketing, particularly through the internet. 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.³⁸ The results of the survey demonstrate that pupils are 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).

3.4 Formal analyses of the content of websites, adverts and promotional materials in the UK and the USA have also 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.³⁹

³⁶ <http://www.legislation.gov.uk/ukpga/2002/36/contents>

³⁷ See specifically Recitals 43 and 48, EU Tobacco Products Directive 2014/40/EU: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_127_R_0001

³⁸ The Scottish Government will publish a summary of these data in summer 2015.

³⁹ For example, see reports drawing on research undertaken for Cancer Research UK prior to the CAP/BCAP rules being introduced: de Andrade, M., Hastings, G and Angus, K (2013). *The Marketing of E-cigarettes. A report for Cancer Research UK*.

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

de Andrade, M., Hastings, G and Angus, K (2013). Promotion of electronic cigarettes: Tobacco marketing reinvented? *British Medical Journal*, 347.

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

3.5 There is a well-established evidence base for the association between smoking and an individual's exposure and receptivity to tobacco marketing. This has underpinned legislative measures to protect young people and adult non-smokers from exposure to tobacco advertising.⁴⁰ This offers useful lessons for NVPs and is discussed in more detail in the Policy Memorandum. 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. 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 (e.g. adult smokers rather than adult non-smokers and children). Spill-over is inevitable and we know 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.

Rationale for Government Intervention

3.6 The primary aim of the power in the Bill is to enable a ban on most forms of domestic advertising to prevent nicotine addiction as a result of the use of NVPs by young people and children and, secondary to that, by non-smoking adults. This forms part of the Scottish Government's precautionary approach to NVPs given the significant uncertainties and unknowns about their impact as discussed in paragraphs 2.17 – 2.19 and in further detail in the Bill's accompanying Policy Memorandum.⁴¹

3.7 Internationally, bans on domestic advertising have been implemented in around 39 countries.⁴² To date, within the UK, no action has been taken to legislate on domestic advertising and promotion of NVPs over and above the TPD which must be transposed into domestic law by May 2016. However, in November 2014, the UK Committee of Advertising Practice (CAP) and the Broadcast Committee of advertising Practice (BCAP) published new advertising rules for NVPs to ensure they are promoted in a responsible way.⁴³ The CAP/BCAP rules require that adverts should not target children.

3.8 The Scottish Government welcomes the current CAP/BCAP rules. However, experience with tobacco and other products (e.g. alcohol and junk food) show that it

Bauld, L., Angus, K, and de Andrade, Marisa (2014) *E-cigarettes 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)

⁴⁰ These include the 2002 advertising ban; recent legislation to ban tobacco displays in shops; and the development of regulations on standardised packaging of tobacco products:

<http://www.legislation.gov.uk/ukpga/2002/36/contents>

<http://www.legislation.gov.uk/asp/2010/3/contents>

<https://www.gov.uk/government/consultations/standardised-packaging-of-tobacco-products>.

⁴¹ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

⁴² The World Health Organisation undertook a study in 2014 that showed that comprehensive advertising, promotion and sponsorship bans on electronic cigarettes 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)

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

is not possible to create a regime where children are not exposed to advertising which is aimed at adults or to affect only certain groups of adults. In addition, the rules set by the CAP/BCAP codes could be open to interpretation about what might or might not target or appeal to young people and adult non-smokers. In response to the TPD ban on cross-border advertising, it is reasonable to assume that companies might divert resources into domestic advertising. The Scottish Government believes that a comprehensive ban on 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.

3.9 It is not the intention of Scottish Government policy to prevent those who might benefit from the use of NVPs from having access to factual material or being made aware of where NVPs are being sold. Balancing this with the aim of protecting children, a point of sale exemption would be an appropriate channel for the provision of information about the products. It is generally accepted that the price of NVPs compared to tobacco can be a motivator for current smokers to try the product. That is why the Bill does not attempt to regulate substantial discounts.

4. SUPPORTING AGE RESTRICTION FOR THE PURCHASE OF BOTH TOBACCO AND NICOTINE VAPOUR PRODUCTS

Tobacco and NVPs: challenge 25

Background

4.1 The Bill will make it an offence for businesses selling tobacco products and NVPs if they fail to operate an age verification policy. The age verification policy means that steps should be taken to establish the age of a person attempting to buy tobacco products or NVPs if it appears that the customer may be under the age of 25. However, the Bill does permit retailers to operate the policy at a higher age if they wish to.

4.2 An age verification policy is a statutory requirement in alcohol licensing legislation⁴⁴. Schemes are in place, 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 old or over before making a sale of an age-restricted product.

4.3 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.

⁴⁴ <http://www.legislation.gov.uk/asp/2010/18/part/1/crossheading/age-verification-policy>

Rationale for Government intervention

4.4 It can be difficult to judge age by appearance. This could potentially result in tobacco and NVP products being sold illegally to under 18 year olds if the retailer does not ask for proof of age. Enforcement data shows that there are a number of retailers who make illegal sales of tobacco products to persons under 18 despite legislation setting an age restriction for the sale and purchase of tobacco at age 18 since 2007.⁴⁵ There is also evidence that NVPs are being sold to persons under 18 despite a voluntary ban by retailers being in place.⁴⁶

4.5 The age verification policy for tobacco and NVPs will support retailers in making legal sales by reducing the number of persons under 18 accessing and consuming age-restricted products. Age-verification schemes have been welcomed and widely applied by many retailers as they encourage responsible practice⁴⁷ and they encourage young people to carry valid identification as defined in the regulations for alcohol and tobacco sales.⁴⁸ Improved trade practice, including age verification, and enforcement mechanisms, including test purchasing, have been partly credited with a reduction in sales of alcohol to those under 18 years of age.⁴⁹

4.6 The provision empowers retailers to say to a customer that proof of age is needed as a matter of law. It creates an expectation that individuals who look younger than 25 and do not have identification will have their purchase declined rather than there being an expectation or pressure on the seller to sell. This measure will also support a common approach across NVP, tobacco and alcohol sales.

⁴⁵ <http://www.scotss.org.uk/reference/etsep2014.pdf>

⁴⁶ MacGregor, J (2014) *Youth Access to E cigarettes and associated products*, Commissioned by Public Health England for the Trading Standards Institute.

⁴⁷ 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>.

⁴⁸ 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

⁴⁹ 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>.

⁴⁹ 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>.

Tobacco and NVPs: sales by under-18s

Background

4.7 This proposal supports the enforcement of the age of sale restriction and associated provisions, with the aim being to prevent or reduce the use of tobacco and NVPs by persons under 18 in order to protect and improve public health in Scotland. It also helps protect persons under 18 who sell.

Rationale for Government intervention

4.8 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. This is reflected in advice from the Tobacco Retailers Alliance which recommends that “under-18s are supervised, as refusing sales to people in the same age range can be extremely difficult and young people are often more easily intimidated.”⁵⁰ This could be exacerbated if the proposals in the Bill are introduced which will require retailers have an age-verification policy in place (Challenge 25).

4.9 This proposal is akin to section 107 of Licensing (Scotland) Act 2005 on the unsupervised sale of alcohol by a child or young person and aims to introduce some consistency with alcohol provisions. A person under 18 should be authorised to make sales by the person under whose name the tobacco or NVP business is registered.

4.10 However, the proposed legislation recognises that this may be disproportionate for very small shops. As such, a responsible person will not need to be present when the person under 18 makes a sale provided the under 18 has the necessary authorisation from the registered person.

5. SMOKE-FREE HOSPITAL GROUNDS

Background

5.1 *Creating a Tobacco-free Generation* included an action for all NHS Boards to implement smoke-free policies across NHS grounds by the end of March 2015. This built on existing Scottish Government guidance to Boards on the development and implementation of smokefree policies and the creation of health-promoting hospitals.⁵¹ ⁵² To support Boards to take a consistent approach across Scotland and to raise public awareness, NHS Health Scotland developed implementation guidance for Boards and launched a national information campaign in March 2015⁵³.

⁵⁰ www.tobaccoretailersalliance.org.uk/index.php?option=com_content&view=article&id=23&Itemid=19

⁵¹ http://www.sehd.scot.nhs.uk/mels/CEL2012_01.pdf

⁵² <http://www.scotland.gov.uk/Publications/2005/12/21153341/33417>

⁵³ <http://www.smokefreegrounds.org/>

5.2 Boards have reported difficulties in enforcing the ban as there is no sanction they can apply if someone refuses to comply with the policy. The provision in the Bill provides a power to define in regulations a no-smoking perimeter around buildings on NHS hospital sites. It will effectively extend the indoor smoking ban under the Smoking, Health and Social Care (Scotland) Act 2005 to include the outdoor no-smoking areas. The Bill introduces the following offences;

- For an individual to smoke within no-smoking area;
- For a person in management and control of a no-smoking area within NHS hospital grounds to knowingly permit smoking there; and
- For a person in management and control of a specific building within the hospital grounds, not to display signage at entrances buildings.

5.3 The Bill will give Scottish Ministers a number of powers to define in regulations when the no-smoking area will apply on NHS hospital grounds and to determine the distance of the no-smoking perimeter.

Rationale for Government Intervention

5.4 In Scotland, there is public support for the principle of smoke-free hospital grounds. An ASH/YouGov survey in 2014 indicated that 73% would be in favour of a complete ban on smoking in hospital grounds.⁵⁴ This is consistent with public opinion in many other high-income countries with well-developed tobacco control laws. A majority of respondents to the written consultation on this proposal were also in favour of national legislation. This included all but one of the 18 health boards and health partnerships which responded to a question on this.

5.5 In considering whether to introduce legislation, the Scottish Government has had to consider which areas legislation should apply to and how the provisions could be enforced in a consistent and proportionate manner across Scotland.

5.6 The grounds of NHS sites vary considerably across Scotland, from small GP practices and offices, to large and complex acute hospital sites. Many people who use these facilities as patients will have impeded mobility due to an illness or disability. 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, will not face a legal penalty.

5.7 In considering the option of legislation, which would see penalties issued to those who do not comply, the Scottish Government needs to balance the impact of such action with our commitment to treat all users of hospitals, particularly those who are most vulnerable, with dignity and respect.

⁵⁴ http://d25d2506sfb94s.cloudfront.net/cumulus_uploads/document/4cpqacbw8/YG-Archive-140314-ASH-Scotland.pdf

5.8 A no-smoking perimeter will focus on the areas where there is the highest traffic of people leaving and entering the building and where there is a risk of smoke entering the building and protect those who do not wish to be exposed to smoke. For areas beyond the perimeter, NHS 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.

5.9 This approach will support our policy aim for health promoting hospitals by protecting a smoke-free space around a hospital in law. It is well established that one of the factors which influences whether a quit attempt will be successful is the extent to which a smoker is exposed to 'cues'.⁵⁵ Evidence shows that quitting is made more difficult if a smoker's environment is populated with smokers⁵⁶. Therefore, this approach will support patients, staff and visitors who have given up smoking, or are trying to give up, by providing a supportive environment in which to quit. This will be especially true for patients who have been advised to quit, or abstain for periods of medical treatment, and for staff, patients or visitors who are trying to quit and regularly attend a hospital site.

6. CONSULTATION

6.1 Part 1 of the Bill has been developed in a collaborative way, with extensive involvement from colleagues both across and outwith the Scottish Government and from a wide range of interests.

Within Government

6.2 Discussions have been on-going with colleagues across the Scottish Government to develop the Bill, including:

- Directorate for Communities
- Directorate for Enterprise, Environment, and Innovation
- Directorate for Finance
- Directorate for Learning and Justice
- The Crown Office and Procurator Fiscal Service

Business

6.3 Scottish Government officials carried out face-to-face meetings with a variety of stakeholders, including representatives from COSLA; Trading Standards and Environmental Health; Health Boards; Police Scotland, public health stakeholders; retail associations, the e-cigarette industry including individual businesses and Electronic Cigarette Industry Trade Association; pharmacy organisations; and individual vaping advocates. Site visits were also held at a range of retail premises which sold NVPs and tobacco. These included grocers, newsagents, petrol stations, wholesalers, pharmacies and NVP specialist stores.

⁵⁵ <http://www.tobaccoinaustralia.org.au/downloadchapters/>

⁵⁶ <http://www.tobaccoinaustralia.org.au/downloadchapters/>

6.4 To date there have been a number of conversations with specific businesses and with business organisations around NVPs and strengthening tobacco control. Scottish Government officials have held formal meetings with the following e-cigarette businesses: blu (an Edinburgh-based brand of NVPs and a subsidiary of Lorillard); E-lites (a brand of NVPs and a subsidiary of JTI); and Jac Vapour (a Scottish SME). All of these are small or medium sized enterprises, although the first two are subsidiaries of large international tobacco companies. All stated that they do not sell to, or produce goods for, under-18s so they would be minimally impacted by the age restriction provisions. They would all be impacted by the domestic advertising ban but could not provide us with estimated costs for loss of sales revenues.

6.5 Scottish Government officials visited branches of: the specialist NVP shop chain Vaporized; Batleys wholesalers (national chain); Spar stores/BP garages (large national chain); Key Store convenience stores (large national chain); Boots the Chemist (large national chain); Lindsay and Gilmour pharmacies (national chain); Margiotta convenience stores (chain in the Edinburgh area); and en-juice which sells and manufactures NVP liquid (small independent company, based in Glasgow). Scottish Government officials also visited an independent mini-market and two newsagents in Edinburgh, all of which are small local businesses. Sales of NVPs were not a significant part of the overall business for any of these companies with the exception of Vaporized and en-juice, whose sole business is the sale, promotion or production of e-cigarettes, e-liquids and related accessories. Scottish Government officials held formal meetings with the following trade organisations: ECITA, the Scottish Grocers Federation, National Federation of News Agents, Scottish Wholesale Association and the Petrol Retailers Association.

6.6 As the Bill progresses, the Scottish Government will continue its consultation and engagement with COSLA, the new Scottish Local Government Partnership, individual local authorities, Health Boards, the industry, public health stakeholders and other organisations with an interest.

Public Consultation

6.7 A public consultation paper, *Electronic Cigarettes and Strengthening Tobacco Control in Scotland*, was published on 10 October 2014 and closed on 2 January 2015⁵⁷. It contained 49 questions and covered all of the NVP and tobacco-related policies included in the Bill, as well as questions on the use of NVPs in enclosed public places, smoking in cars with children, and smoke-free children and family areas. 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.⁵⁸ There were 78 responses from individual members of the public and 94 responses from organisations. These organisational responses covered a range of categories, including academic groups, the electronic cigarette industry, the tobacco industry, retailers, pharmacies, NHS health boards and partnerships, local authorities and other public bodies.

⁵⁷ <http://www.gov.scot/Publications/2014/10/5471>

⁵⁸ <http://www.gov.scot/Publications/2015/05/7711>

6.8 Stakeholders' responses to the proposals were broadly positive, especially towards those which aim to protect young people from accessing NVPs and tobacco. However, concerns were raised in relation to specific proposals, including those where there was general consensus on a particular topic.

6.9 A majority of respondents thought that some form of registration should be introduced for the sale of NVPs. The NVP industry and the pharmacy retail sector were concerned about tobacco and NVPs being conflated or seen as equivalent, especially if NVP retailers were required to register on the Scottish Tobacco Retailers Register or another joint register. However, many retailers who sell tobacco also sell NVPs and having two separate registers would place additional administrative burden on these businesses. Although tobacco and NVP retailers will be on one register, they will have to declare whether they are selling tobacco, NVPs or both. The Tobacco and Primary Medical Services (Scotland) Act 2010, which introduced the Scottish Tobacco Retailers Register, only refers to 'the register,' so the Scottish Government would be able to change this to a more appropriate name.

6.10 A majority of respondents thought there was a need to restrict domestic advertising. However, opinions varied across and within respondent groups. The majority of public health stakeholders advocated a comprehensive ban, with some advocating no exceptions and others suggesting a more nuanced approach which allows for limited exemptions for marketing aimed only at current smokers. The NVP industry, the tobacco industry and retail associations opposed restrictions on domestic advertising and promotion as they argued this would impede businesses' ability to grow and compete. Several respondents from a variety of sectors advocated waiting to see how effective the rules introduced in 2014 by the UK Committee of Advertising Practice and Broadcast Committee of Advertising Practice prove to be at encouraging responsible marketing before introducing any legislation.

6.11 There was support for national legislation for smokefree hospital grounds and that it should apply to all NHS grounds (not just hospitals). There was also support for a ban across all grounds, not just a perimeter around a building, although many respondents provided qualifications or conditions associated with their response. These were the views of most NHS Boards and health partnerships.

6.12 The Scottish Government has also worked with Young Scot to provide an opportunity for young people to contribute to development of policy on tobacco control. *Creating a Tobacco-Free Generation* included an action to establish a Youth Commission on Smoking Prevention. The Commission was established by the Scottish Government in collaboration with Young Scot and included young people aged 12-22 from across Scotland. After a year of work, the Commission published their final report⁵⁹ on 14 October 2014. The report contained a number of recommendations, including:

⁵⁹<http://www.youngscot.net/wp-content/uploads/2015/02/Youth-Commission-on-Smoking-Prevention.pdf>

- 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.
- 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.

7. OPTIONS

7.1 All references to NVPs, e-liquids and accessories in this section refer to non-medicinal products, which may or may not contain nicotine when purchased. Any NVPs which are licensed as a medicinal product by the MHRA in the future will be subject to separate medicines regulation which is applied at the UK level.

PROPOSAL 1 - MINIMUM AGE FOR SALES OF NVPs

7.2 Information on current levels of use by adults and children is provided in Part 1, Section 2 of this document. Current evidence shows that around 1% of under-18s in Scotland use NVPs on a regular basis. A large proportion of retailers in Scotland already apply a voluntary age restriction policy and the industry umbrella body ECITA recommends that its members include age restriction labelling on their products and do not sell to under-18s.

Option 1 – Do nothing. This is the baseline against which other options are assessed. There is currently no restriction on the age that a person can be sold an NVP or related product in Scotland.

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.

Sectors and groups affected

7.3 Young people and children under the age of 18. Businesses, including small and medium enterprises (SMEs), micro businesses, large retailers and specialist high street shops will have to comply with the legislation. Local authorities will be responsible for enforcing the legislation. Government and society.

Costs

Option 1

7.4 Under option 1, persons under 18 will continue to be able to buy NVPs from retailers who do not operate a voluntary policy of not selling to under-18s.

Responsible retailers will continue to refuse sales to under-18s. The Scottish Government is not able to quantify costs for this option based on current evidence.

Options 2 & 3

Costs to the NVP industry

7.5 Restricting the sale of NVPs, liquids and accessories could have an impact across the supply chain for these products, on manufacturers, importers, distributors and retailers. Levels of use of NVPs by under-18s are low so the impact should be small. Responsible manufacturers already recognise that these are not products for children; they label their products accordingly and state in promotional material and websites that NVPs are products for over 18s. The Scottish Government is only aware of one manufacturer in the sector in Scotland. This company manufactures e-liquids and sells their products within and outwith Scotland. The Scottish Government does not have data on how much of its revenue is generated from sales within Scotland so the Scottish Government is unable to calculate the impact of the age restriction legislation in Scotland.

Costs to retailers and wholesalers

7.6 The Scottish Government does not have robust data on the number of businesses in Scotland which sell NVPs. It appears that almost all direct retail premises selling tobacco also sell NVPs (approximately 9,800 businesses are registered to sell tobacco in Scotland). In addition a very diverse range of businesses which do not sell tobacco do sell NVPs. NVPs are sold in many categories of business, including grocery stores, pharmacies, and specialised NVP stores. Based on the current evidence and on engagement with retailers in Scotland, it is likely that the impact of either Options 2 or 3 would be very small. Many retailers already apply a voluntary ban on sales of electronic cigarettes to under 18s and survey data indicate that less than 1% of under-18s use NVPs regularly.⁶⁰

7.7 Detailed information on the wholesale sector is not available. It is expected that the impact on wholesalers from this legislation will be small, based on the fact that any reduction in profits from this legislation will derive from a reduction in demand from retailers. Since many retailers already have a voluntary ban on selling NVPs to under 18s and given the very low proportion of under 18s that use NVPs, it is assumed that the impact on wholesalers would be small.

7.8 To estimate the direct costs to businesses, a top-down approach based on estimating the size of the NVP market attributable to under 18s in Scotland, was taken. This is based on the value of the retail market for NVPs in Scotland, which has been estimated at £36 million in 2015.⁶¹ This figure includes an estimation of

⁶⁰ *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/>

⁶¹ This is based on estimates provided to the Scottish Government in February 2015 by ECigIntelligence, using IRI data, where the estimated value of the Scottish market in 2015 was between £30m and £40m.

online sales in Scotland. The population of 11 to 17 year olds in Scotland was 405,625 in 2013. Survey data show that less than 1% of 13 and 15 years olds in Scotland use NVPs once a week or more.⁶² This means that in Scotland, approximately 4,056 young people under the age of 18 year may be using NVPs more than once a week and that under-18s potentially represent 2% of the market with a value of approximately £700,000. Assuming a 40% profit margin⁶³, it is estimated that the total cost of banning sales of NVPs to under-18s in Scotland could lead to approximately £280,000 of profit loss in the first year to Scottish businesses. This assumes 100% compliance with the policy.

7.9 Using a range of the estimations of the value of the retail market for NVPs in Scotland supplied by Ecig Intelligence, it is suggested that this loss to retailers could be between £232,000 and £324,500 in the first year.

7.10 These estimations have a number of caveats. The market and the estimation of its value, covers a diverse range of products with a very wide range of prices: from single cigalikes which retail for as little as £1, starter kits costing under £20, to sophisticated, refillable customisable tank systems which cost many times more. The Scottish Government does not know whether younger users would be more likely to use cheaper devices than other age groups. The Scottish Government would expect competition to have an impact on profit margins as retailers increasingly compete on price.

7.11 This is a dynamic market. Demand for NVPs could continue to increase or may reduce in the next few years. There is English data which suggest a slowdown in the rate of growth in the market.⁶⁴ This could also have an impact on prices, which in turn will dictate the value of the market.

7.12 It is not possible to establish the value of the under-18s market using a bottom-up approach based on an estimate of typical usage levels by individual users. NVP usage patterns are more varied and complex than tobacco smoking patterns where smokers can be asked to estimate how many cigarettes they smoke in a day. Many factors influence an individual's NVP use, including the nicotine strength of the liquid, the type of device (tank or cigalike) and the experience of the user. In addition, many users 'graze' on NVPs throughout the day rather than have discrete periods where they smoke a whole cigarette. They may also be 'dual users', that is, they use both NVPs and tobacco, perhaps in different contexts. Additionally, innovation will continue to bring different products into the market.

⁶² Data from the Young People in Scotland Survey in late 2014 showed that 2% of 11 to 18 years old in secondary schools reported using e-cigarettes at least once a week. The Scottish Government will publish a summary analysis of these data in summer 2015.

⁶³ A 40% profit margin for e-cigarettes was noted in, 'High margin options and growing fast, *Scottish Grocer*, March 2013: <http://www.scottishgrocer.co.uk/2013/03/high-margin-options-and-growing-fast/>. An estimated 40% profit margin figure was also provided to the Scottish Government by the National Federation of Retail Newsagents in a consultation meeting on 02/12/14. The minutes are available on the Scottish Government website.

⁶⁴ West, R., Brown, J., Beard, E. 'Latest trends in electronic cigarette use in England. Smoking Toolkit Study' (updated January 2015): <http://www.smokinginengland.info/latest-statistics/>)

7.13 It is expected that the reduction in sales from the age restriction on NVPs will be partly offset by increased spending on other products.

Costs of staff training and awareness-raising for business

7.14 It is anticipated that there will be some small one-off costs to retailers in relation to staff training and awareness for an age of sale restriction along with small on-going costs in relation to staff churn. Tobacco retailers are already familiar with age-restricted products and some private sector stakeholders confirmed during consultation that they do not foresee substantial costs in relation to this legislation. It is not possible to accurately quantify costs to businesses.

Costs of enforcement to Local Authorities

7.15 There will be costs to local authorities as Trading Standards Officers will primarily be required to monitor and enforce the legislation. Although the proposal for NVPs is similar to existing legislation on tobacco, Option 2 or 3 will add to the work of Trading Standards. The NVP market is still maturing and the Scottish Government does not have robust data on the number of retailers of NVPs as there is no mechanism for identifying such businesses. During a two-week period in March 2015, Trading Standards in 21 local authorities undertook a survey to try to establish the number of NVP retailers on their high streets. Trading Standards staff visited a wide variety of premises to determine whether they sold NVPs, tobacco, both, or neither. They visited a total of 1,190 retailers, of these: 53 sold tobacco only; 181 sold NVPs only; and 186 sold both tobacco products and NVPs. If this sample is representative of the combined tobacco and NVP retail sector in Scotland, this means that approximately 13% sell only tobacco, 43% sell only NVPs, and the remaining 44% sell both types of product. Based on these approximate figures, it could be assumed that the number of retailers which Trading Standards will need to visit to provide advice, support and undertake enforcement action could increase by 76%.

7.16 The Scottish Government already fund Local Authorities for the enforcement of tobacco legislation. Funding of £1.5 million is provided in their baseline General Revenue Grant as part of the annual local government finance settlement (not ring fenced). If Trading Standards enforce the new provisions for NVPs at the same level as currently agreed for tobacco products (10% of NVP retailers visited for test purchasing purposes; a further 20% of NVP retailers visited for business advice and support), COSLA had estimated that the additional on-going cost of enforcing the new provisions would be an additional £2 million per year. This figure is based on the number of additional retailers, the resource required to enforce the extension of the register and inflation (since the introduction of the Tobacco and Primary Medical Services (Scotland) Act 2010). Taking into account inflation on current funding of £1.5 million per annum, this would bring the figure to £1.68 million per year. However, using the data provided by Trading Standards, the approximate additional number of retailers which will need to be supported is 24% less for NVP-only retailers, compared to the number of retailers selling tobacco products. This brings the additional cost per year to £1.28 million per annum. The level of enforcement for NVPs requires further consideration and could be set a lower rate than the current level for tobacco. The Scottish Government anticipates that the new additional on-going enforcement costs will be in the region of £1 million to £1.5 million per year. As the market is still maturing and subject to swift change, the Scottish Government

will continue to monitor the number and variety of retailers and continue dialogue with COSLA and other local authority partners to assess and refine future costs.

7.17 There will be some initial one-off costs for local authorities associated with updating fixed penalty notice books and staff training. Based on current funding provided to Trading Standards, this is estimated to be in the region of £15,000.

7.18 In summary, for local authorities:

- In the first year, the total cost for enforcement **of all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

Costs to the Scottish Government

7.19 There will be initial costs to raise public and retailer awareness and to provide retailers with information about the necessity to comply with all of the NVP and tobacco provisions in the Bill. Information packs will be posted to retailers and there will be an update of the main Scottish Government and the Scottish Tobacco Retailers Register websites. The total combined costs of communication and awareness-raising for all tobacco and NVP provisions are estimated to be in the region of £47,000 and will be met from existing public health programme budgets. This estimate is based on a recent exercise undertaken to provide a letter, guidance document, a poster and flyer to alert 31,500 businesses in Scotland that they would need to comply with legislation that requires all retailers (food and non-food) to charge for each new single-use carrier bag.

7.20 There will be costs to the Scottish Government associated with the development of guidance for retailers which will be undertaken as part of the normal business of the Scottish Government Directorate of Population Health Improvement.

Costs of prosecution

7.21 Trading Standards have a proven track record of taking a measured approach to enforcement of tobacco regulation. They aim primarily to provide advice and support to businesses and retailers, only taking enforcement action when needed. When enforcement action is required this is largely dealt with using their powers to issue fixed penalty notices. The level of offences referred to the Procurator Fiscal is low, with only the most serious offences or persistent cases referred for prosecution. Between 2011 and 2014 there were only 4 proceedings for sale of tobacco to under 18s and 2 police warnings. Although there are a larger number of premises involved in retailing NVPs, using the estimates described in paragraph 7.15, the Scottish Government estimates the number of prosecutions as a result of Part 1 of the Bill to increase by approximately 6-7 cases per annum. The costs of prosecution are shown in Table 2.

7.22 Additional costs associated with prosecutions for all measures in Part 1 of the Bill (Tobacco, NVPs and Smoking) are estimated to be between £7720 - £8,740 (The

breakdown of these costs are explored further in the financial memorandum accompanying the Bill)⁶⁵

Table 2 — Unit cost of criminal procedures

	Average prosecution costs per procedure (COPFS)	Average court costs per procedure (SCTS)	TOTAL (excluding legal aid costs)	Average legal assistance costs per procedure (SLAB)	TOTAL (including legal aid costs)
Sheriff Court Summary Procedure	£342	£357	£699	£612	£1311

Source: Costs of the Criminal Justice System in Scotland Dataset (2013)

Benefits

Option 1

7.23 There are no quantifiable benefits from option one.

Options 2 and 3

Benefits to young people

7.24 The Scottish Government believes that there is no reason for children to use NVPs and is acting to minimise the impact of several unknown consequences of the use of NVPs. Option 2 and 3 reduce the possible health consequences of young people using NVPs containing nicotine which can have negative impacts on child and adolescent health and of young non-smokers possibly becoming addicted to nicotine. These benefits cannot be quantified.

Benefits to retailers

7.25 Options 2 and 3 provide benefits to retailers as they deliver a consistent message that NVP and related products are not suitable for, and should not be sold to, children and people under 18. This will require all retailers to operate the same sales policy as opposed to the existing situation where some retailers operate a voluntary age-restriction policy and some do not. Age-restriction brings NVPs into line with other age-restricted products such as tobacco and alcohol and reduces confusion. There is an existing legislative framework around proof of age for other age-restricted products with which retailers are already familiar.⁶⁶ These benefits cannot be quantified.

⁶⁵

http://www.scottish.parliament.uk/S4_Bills/Health%20Tobacco%20Nicotine%20etc.%20and%20Care%20Scotland%20Bill/b73s4-introd-en.pdf

⁶⁶ SSI 2013/202 - The Sale of Tobacco (Prescribed Documents) (Scotland) Regulations 2013: <http://www.legislation.gov.uk/ssi/2013/202/contents/made>

Benefits to Local Authorities

7.26 Local authorities will retain the revenue from Fixed Penalty Notices issued and collected which will help to offset the costs of administering them.

Benefits to the Scottish Government and the NHS

7.27 The Scottish Government believes that there is no reason for children to use NVPs and is acting to minimise the health impacts and several unknown consequences of the use of NVPs. Options 2 and 3 reduce the possible health consequences of young people using NVPs containing nicotine which can have negative impacts on child and adolescent health and of young non-smokers possibly becoming addicted to nicotine. These benefits cannot be quantified.

Option 3

Benefits for young people

7.28 This will avoid the potential for young people to be criminalised as a result of buying or attempting to buy NVPs or associated products as the offence applies only to the person who sells the product.

PROPOSAL 2 - PROXY PURCHASE OF NVPs

7.29 There is currently no offence of purchasing an NVP in behalf of a young person under the age of 18.

Option 1 - Do nothing. This is the baseline against which other options are assessed.

Option 2 - Create an offence for an adult to purchase NVPs for a child or person aged under 18. This is the preferred option. The Scottish Government deems that the introduction of legislation on proxy purchase is necessary to complement the ban on sales of NVPs to under 18s and to protect young people.

Sectors and groups affected

7.30 Young people and children under the age of 18. Businesses, including SMEs, micro businesses, large retailers and specialist high street shops will have to comply with the legislation. Local authorities will be responsible for enforcing the legislation. Government and society.

Costs

Option 1

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

⁶⁶ E.g., ScotCen Social Research/NHS Health Scotland (2013) *Final report: Licensing Act (Scotland) 2005*, p 68.

7.31 There are no direct costs attached to option 1. Children and young people under 18 would legally have access to NVPs which had been purchased on their behalf by an adult.

Option 2

Costs to retailers, wholesalers and manufacturers

7.32 The proxy purchase offence is being introduced to support the introduction of an age-restriction for NVP sales. This proposal is unlikely to add any costs over and above those estimated for age-restriction. Based on current evidence and consultation responses from stakeholders, it is likely that any additional impact of this proposal in isolation would be small.

Costs of enforcement to Local Authorities

7.33 Trading standards will enforce the proxy purchase offence in conjunction with the age-restriction for NVP sales, so this proposal is unlikely to result in additional costs over and above those estimated for age-restriction and other NVP, tobacco and smoking provisions in the Bill. For local authorities:

- In the first year, the total cost for enforcement **of all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

Costs to the Scottish Government

7.34 There will be initial costs to raise public and retailer awareness and to provide retailers with information about the necessity to comply with all of the NVP and tobacco provisions in the Bill. Information packs will be posted to retailers and there will be an update of the main Scottish Government and the Scottish Tobacco Retailers Register websites. The total combined costs of communication and awareness-raising for all tobacco and NVP provisions are estimated to be in the region of £47,000 and will be met from existing public health programme budgets. This estimate is based on a recent exercise undertaken to provide a letter, guidance document, a poster and flyer to alert 31,500 businesses in Scotland that they would need to comply with legislation that requires all retailers (food and non-food) to charge for each new single-use carrier bag.

7.35 There will be costs to the Scottish Government associated with the development of guidance for retailers which will be undertaken as part of the normal business of the Scottish Government Directorate of Population Health Improvement.

Costs of Prosecution

7.36 Trading Standards have a proven track record of taking a measured approach to enforcement of tobacco regulation. They aim primarily to provide advice and support to businesses and retailers, only taking enforcement action when needed. When enforcement action is required this is largely dealt with using their powers to issue fixed penalty notices. The level of offences referred to the Procurator Fiscal is low, with only the most serious offences referred for prosecution.

7.37 Between 2011 and 2014 there were 11 proceedings for proxy purchase of tobacco on behalf of under 18s, of which only 7 resulted in a prosecution and fine. A further 12 fiscal fines and 2 police warnings were issued. Although there are a larger number of premises involved in retailing NVPs, using the estimates described in paragraph 7.15, the Scottish Government estimates the number of prosecutions as a

result of Part 1 of the Bill to increase by approximately 6-7 cases per annum. The costs of prosecution are shown in Table 2.

7.38 Additional costs associated with prosecutions for all measures in Part 1 of the Bill (Tobacco, NVPs and Smoking) are estimated to between £7720 - £8,740 (The breakdown of these costs are explored further in the financial memorandum accompanying the Bill)⁶⁷

Benefits

Benefits to young people

7.39 The Scottish Government believes that there is no reason for children to use NVPs and is acting to minimise the impact of several unknown consequences of the use of NVPs. Option 2 further reduces opportunities for children and young people to access NVPs and so reduces the possible health consequences although the impacts of this proposal in isolation would be small. These benefits cannot be quantified.

Benefits to retailers

7.40 This option provides an indirect benefit to retailers as it delivers a consistent message that NVP and related products are not suitable for and should not be sold or given to under 18s.

Benefits to Local Authorities

7.41 Local authorities will retain the revenue from Fixed Penalty Notices issued and collected which will help to offset the costs of enforcement.

Benefits to the Scottish Government and the NHS

7.42 The Scottish Government believes that there is no reason for children to use NVPs and is acting to minimise the impact of several unknown consequences of the use of NVPs. Option 2 reduces the possible health consequences of young people using NVPs. These benefits cannot be quantified.

PROPOSAL 3 – BAN ON SALES OF NVPs FROM VENDING MACHINES

Option 1 - Do nothing. This is the baseline against which other options are assessed

Option 2 - Introduce a ban on the sale of NVPs from vending machines. This is the preferred option.

Sectors and groups affected

7.43 Young people and children under the age of 18. Businesses in the vending machine supply chain will have to comply with the legislation. Local authorities will be responsible for enforcing the legislation. Government and society.

⁶⁷http://www.scottish.parliament.uk/S4_Bills/Health%20Tobacco%20Nicotine%20etc.%20and%20Care%20Scotland%20Bill/b73s4-introd-en.pdf

Option 1

Costs

7.44 The Scottish Government are not aware of any vending machines currently being used to supply NVPs in Scotland.

Benefits

7.45 The Scottish Government are not aware of any vending machines currently being used to supply NVPs in Scotland.

Option 2

Costs

7.46 The Scottish Government are not aware of any vending machines currently being used to supply NVPs in Scotland. The Scottish Government does not envisage any costs as a result of a ban on vending machines supplying NVPs in Scotland.

Benefits

Benefits to young people

7.47 Although the Scottish Government is not aware of any vending machines currently supplying NVPs in Scotland, this proposal prevents the possibility of NVPs being sold from vending machines in future and is ancillary to the age of sale restriction. The proposal's primary aim is to prevent or reduce the use of NVPs by persons under 18 to protect and improve public health in Scotland.

Benefits to the Scottish Government

7.48 The Scottish Government believes that there is no reason for children to use NVPs and is acting to minimise the impact of several unknown consequences of the use of NVPs. Option 2 reduces the possible health consequences of young people accessing and using NVPs if in the future NVPs were to be sold from vending machines. These benefits cannot be quantified.

PROPOSAL 4 – MANDATORY REGISTRATION TO RETAIL NVPs

Option 1 - Do nothing. This is the baseline against which other options are assessed. There is currently no requirement to register as a retailer of NVPs.

Option 2 - Create an entirely separate regulatory regime 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. This is the chosen option.

Sectors and groups affected

7.49 Businesses that retail NVPs, Government and Local Authorities

Costs

Option 1

Costs to Local Authorities and to the Scottish Government

7.50 This option would result in indirect costs to central and local government as it would be more difficult to identify NVP retailers and to support and enforce compliance with the NVP policies in the Bill. It is not possible to quantify these costs for either local or central government.

Option 2

Costs to retailers

7.51 This option will result in a small cost to businesses in undertaking the administrative requirements to register and to familiarise themselves with the legislation. However, retailers who already sell tobacco should be registered on the Scottish Tobacco Retailers Register in compliance with the Tobacco and Primary Medical Services (Scotland) Act 2010 and would therefore have to comply with two different regulatory regimes and thereby two different registers. As of September 2014, there were 9,803 retail premises on the Register. The NVP market is still maturing and the Scottish Government does not have robust data on the number of retailers of NVPs as there is no mechanism for identifying such businesses. During a two-week period in March 2015, Trading Standards in 21 local authorities undertook a survey to try to establish the number of NVP retailers on their high streets. Trading Standards staff visited a wide variety of premises to determine whether they sold NVPs, tobacco, both, or neither. They visited a total of 1,190 retailers: of these 53 sold tobacco only, 181 sold NVPs only, and 186 sold both tobacco products and NVPs. If this sample is representative of the combined tobacco and NVP retail sector in Scotland, this means that approximately 13% sell only tobacco, 43% sell only NVPs, and the remaining 44% sell both types of product.

7.52 Costs of this proposal will be minimal but would place an additional administrative burden of dealing with two regulatory regimes and two registers. The administrative requirements will require register and to familiarise themselves with the legislation. Registration can be online or on a paper form and there is no fee for registration. The system allows businesses with multiple premises to register initially and then add additional premises to their record.

7.53 The Scottish Government is aware that some businesses which currently retail NVPs sell very low volumes of stock and so it reasonable to assume that some retailers may decide not to stock NVPs if they are required to register. This would reduce their revenue from sales of NVPs.

Costs to Local Authorities

7.54 As stated for the other proposals in this BRIA and explained under the costs for proposal 1:

- In the first year, the total cost for enforcement **of all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

7.55 In 2013-2014 there were 9 Fixed Penalty Notices (FPNs) issued for selling tobacco whilst unregistered. This indicates a high level of compliance across Scotland with the existing tobacco register. The Scottish Government anticipates that the low level of cost involved and the support available from trading standards would encourage similar compliance with a separate NVP register. There would be an additional burden on trading standards in enforcing two separate regulatory regimes.

Costs of prosecution

7.56 Although there is a very high level of compliance, in 2011/12 there were three cases taken to court (none in either the preceding or following years) of which only one resulted in a prosecution and fine. Although there are a larger number of premises involved in retailing NVPs, using the estimates described in paragraph 7.15, the Scottish Government estimates the number of prosecutions as a result of Part 1 of the Bill to increase by approximately 6-7 cases per annum. The costs of prosecution are shown in Table 2.

7.57 Additional costs associated with prosecutions for all measures in Part 1 of the Bill (Tobacco, NVPs and Smoking) are estimated to between £7720 - £8,740 (The breakdown of these costs are explored further in the financial memorandum accompanying the Bill)⁶⁸

Costs to the Scottish Government

7.58 There would be a cost to central government in creating a new NVP retail register. There would be an initial one-off cost to the Scottish Government of approximately £20,000 for the creation of a new register. This is based on costs for establishing the current register, which was built and is maintained by an external contractor. For the continuing administration and maintenance of a dedicated NVPs retail registration scheme and database, it is estimated that additional on-going maintenance costs would be in the region on £13,200 per annum.

7.59 There will be initial costs to raise public and retailer awareness and to provide retailers with information about the necessity to comply with all of the NVP and tobacco provisions in the Bill. Information packs will be posted to retailers and there will be an update of the main Scottish Government and the Scottish Tobacco Retailers Register websites. The total combined costs of communication and awareness-raising for all tobacco and NVP provisions are estimated to be in the region of £47,000 and will be met from existing public health programme budgets. This estimate is based on a recent exercise undertaken to provide a letter, guidance document, a poster and flyer to alert 31,500 businesses in Scotland that they would

⁶⁸http://www.scottish.parliament.uk/S4_Bills/Health%20Tobacco%20Nicotine%20etc.%20and%20Care%20Scotland%20Bill/b73s4-introd-en.pdf

need to comply with legislation that requires all retailers (food and non-food) to charge for each new single-use carrier bag.

7.60 There will be costs to the Scottish Government associated with the development of guidance for retailers which will be undertaken as part of the normal business of the Scottish Government Directorate of Population Health Improvement.

Option 3

Costs to retailers

7.61 This option will result in a small cost to businesses in undertaking the administrative requirements to register and to familiarise themselves with the legislation. This would result in a smaller burden than option 1 for those who want to retail tobacco but NVPs as they will only need to familiarise themselves with one regulatory regime and one register. For those retailers already selling tobacco or tobacco and NVPs they will continue to work within the regulatory framework and with a register that they are already familiar with. Registration can be online or on a paper form and there is no cost for registration. The system allows businesses with multiple premises to register initially and then add additional premises to their record.

7.62 Businesses which already sell tobacco should be registered on the Scottish Tobacco Retailers Register in compliance with the Tobacco and Primary Medical Services (Scotland) Act 2010. As of September 2014, there were 9,803 retail premises on the Register. The NVP market is still maturing and the Scottish Government does not have robust data on the number of retailers of NVPs as there is no mechanism for identifying such businesses. During a two-week period in March 2015, Trading Standards in 21 local authorities undertook a survey to try to establish the number of NVP retailers on their high streets. Trading Standards staff visited a wide variety of premises to determine whether they sold NVPs, tobacco, both, or neither. They visited a total of 1,190 retailers: of these 53 sold tobacco only, 181 sold NVPs only, and 186 sold both tobacco products and NVPs. If this sample is representative of the combined tobacco and NVP retail sector in Scotland, this means that approximately 13% sell only tobacco, 43% sell only NVPs, and the remaining 44% sell both types of product.

7.63 The Scottish Government is aware that some businesses which currently retail NVPs sell very low volumes of stock so some retailers may decide not to stock NVPs if required to register which would reduce revenue from sales of NVPs. It is possible that pharmacies will stop stocking NVPs if they were required to register on a database which includes tobacco retailers, although this represents a very small element of the NVPs sector and would have a minimal impact on pharmacy outlets as sales of NVPs in pharmacies are extremely low. Pharmacists would still be able to sell e-cigarettes licensed by the MHRA for medicinal if they come on to the market without requiring to register.

Costs to Local Authorities

7.64 There would be costs to enforcement agencies associated with facilitating registration, providing support to business and enforcing the legislation, especially given the number and diversity of businesses which sell NVPs. However, this would be less burdensome than option two as enforcement agencies will continue to work within the current enforcement regime and manage only one register. In 2013-2014

there were 9 Fixed Penalty Notices (FPNs) issued selling tobacco whilst unregistered. This indicates a high level of compliance across Scotland with the tobacco register. The Scottish Government anticipates that the low level of cost involved for retailers and the support available from trading standards would encourage similar compliance with a combined register and registration system.

Costs of prosecution

7.65 Although there is a very high level of compliance, in 2011/12 there were three cases taken to court (none in either the preceding or following years) of which only one resulted in a prosecution and fine. Although there are a larger number of premises involved in retailing NVPs, using the estimates described in paragraph 7.15, the Scottish Government estimates the number of prosecutions as a result of Part 1 of the Bill to increase by approximately 6-7 cases per annum. The costs of prosecution are shown in Table 2.

7.66 Additional costs associated with prosecutions for all measures in Part 1 of the Bill (Tobacco, NVPs and Smoking) are estimated to between £7,720 - £8,740 (The breakdown of these costs are explored further in the financial memorandum accompanying the Bill)⁶⁹

Costs to the Scottish Government

7.67 There will be initial set up costs to extend the existing national Retailer Register to include information on businesses which sell NVPs. This is estimated to be in the region of £15,000. This is £5,000 less than option 2. This is based on quotes from the supplier and takes the mid-range of the quotes. The register was built and continues to be maintained externally. For the continuing administration and maintenance of the registration scheme and database, it is estimated that additional on-going maintenance costs will be in the region on £13,200 per annum. There may be opportunities within this option to provide a degree of separation within the register that clearly distinguishes tobacco and NVPs as two separate products.

7.68 There will be an on-going costs on the Scottish Government to deal with the additional enquiries and updates to retailer information generated by extending the scheme to retailers of NVPs. This maintenance of the register will be a matter for the Scottish Government as part of the normal business of the Directorate of Population Health Improvement.

7.69 There will be initial costs to raise public and retailer awareness and to provide retailers with information about the necessity to comply with all of the NVP and tobacco provisions in the Bill. Information packs will be posted to retailers and there will be an update of the main Scottish Government and the Scottish Tobacco Retailers Register websites. The total combined costs of communication and awareness-raising for all tobacco and NVP provisions are estimated to be in the region of £47,000 and will be met from existing public health programme budgets. This estimate is based on a recent exercise undertaken to provide a letter, guidance

⁶⁹http://www.scottish.parliament.uk/S4_Bills/Health%20Tobacco%20Nicotine%20etc.%20and%20Care%20Scotland%20Bill/b73s4-introd-en.pdf

document, a poster and flyer to alert 31,500 businesses in Scotland that they would need to comply with legislation that requires all retailers (food and non-food) to charge for each new single-use carrier bag.

7.70 There will be costs to the Scottish Government associated with the development of guidance for retailers which will be undertaken as part of the normal business of the Scottish Government Directorate of Population Health Improvement.

Benefits

Option 1

7.71 This option would benefit businesses as they would not be required to undertake the administration associated with the requirement to register. It would have no benefits for local authorities, the Scottish Government, the NHS or the public.

Options 2 & 3

Benefits to retailers

7.72 Options 2 and 3 will both benefit businesses as their inclusion on the register would identify them as a legitimate and responsible retailer of the product. This would support implementation and enforcement of the Bill proposals and help prevent trade in products which are non-compliant which should reduce the risk of loss to legitimate traders.

Benefits to Local Authorities

7.73 These options would benefit government and enforcement agencies by enabling the identification of businesses in order to provide guidance, support and enforcement the Bill proposals. Local authorities will retain the revenue collected through FPNs.

7.74 The Scottish Government is aware that some businesses which currently retail NVPs sell very low volumes of stock so some retailers may decide not to stock NVPs if required to register which would reduce the number of outlets that Trading Standards would need to monitor.

Benefits to the Scottish Government

7.75 Options 2 and 3 will both support implementation of the NVP policies in this Bill.

PROPOSAL 5 – DOMESTIC ADVERTISING AND PROMOTION OF NVPs

Option 1 - Do nothing. This is the baseline against which other options are assessed. The EU TPD, to be introduced by May 2016, and the CAP/BCAP rules, introduced in November 2014, are described in section 3. The TPD requires member states to implement a ban on certain forms of advertising and promotion. The CAP/BCAP rules are intended to ensure that NVPs are promoted in a responsible way and are enforced by the Advertising Standards Authority. This option would allow the continuation of marketing through billboards, leafleting, brand sharing, free distribution, nominal pricing, point of sale and domestic advertising events which would be subject to the CAP/BCAP rules.

Option 2 - Introduce a ban on all forms of domestic advertising and promotion of NVPs, including billboards, leafleting, brand-sharing, free distribution, nominal pricing, point of sale and domestic event sponsorship.

Option 3 – Introduce a ban on all forms of domestic advertising (free distribution, domestic events sponsorship, brand-stretching, etc.). The intention is to exempt point of sale and the Bill does not attempt to regulate substantial discounts. This is the preferred option.

Sectors and groups affected

7.76 Businesses, including small and medium sized enterprises, micro businesses, large retailers and specialist high street stores will have to comply with the legislation. Local authorities will be responsible for enforcing the legislation. Government and society.

Costs

Option 1

Costs to business

7.77 There are no costs associated with option 1.

Costs to the NHS and the Scottish Government

7.78 Young people and children will continue to be exposed to a wide range of domestic marketing which promotes the use of NVPs. If the marketing is appealing to young people and children their exposure will lead to a proportion of them initiating the use of NVPs. There would be costs to government if continued advertising undermined the de-normalisation of smoking behaviours.

Option 2

Costs to business

7.79 Although there is a high level of awareness of NVPs in Scotland, less than a fifth of current smokers and around 3% of ex-smokers in Scotland are using NVPs⁷⁰. A total ban on domestic marketing and promotion – on top of the TPD and CAP/BCAP restrictions for e-cigarettes will reduce the numbers of new users entering this market. It could cause a decline in overall market size as existing users fall out of the market if either returning to combustible cigarettes or stopping their use of NVPs.

7.80 It is extremely difficult to isolate the value that domestic advertising brings to retailers within a whole marketing and promotion budget and the Scottish Government is unable to estimate the loss of revenue that this option would bring.

7.81 The Scottish Government is not aware of another market in Scotland which could be used as a model for estimating the impact of a comprehensive ban on NVP promotion and marketing. Tobacco products had been on sale for many decades with a well-established market, a history of highly sophisticated marketing activity and a high degree of consumer loyalty for some brands before they were subjected to a blanket ban on their marketing, so they do not offer a good comparator.

⁷⁰ ASH Scotland (May 2014) Briefing paper on 'Electronic cigarettes/E-cigarettes': <http://www.ashscotland.org.uk/media/6093/E-cigarettesbriefing.pdf>

Costs to smokers

7.82 Currently, 23% of the population in Scotland are smokers.⁷¹ There is on-going debate over the potential value of NVPs as aids to help people quit smoking or to reduce their tobacco consumption. See section 3 for a discussion of who uses NVPs and why. The existing evidence for NVPs as a tool for either smoking cessation or harm reduction is neither strong nor conclusive and it is too early to be able to comprehensively assess the positive or negative health impacts of NVPs. The Policy Memorandum which accompanies the Bill has a discussion of the possible impacts of NVPs for individual and public health.⁷²

7.83 It is difficult to assess the impact of a domestic ban on advertising and promotion on current smokers in Scotland, particularly in isolation from other factors including new policies, existing advertising codes and the introduction of the TPD in May 2016. It is not possible to estimate the impact of a ban in terms of whether it will stop current smokers who might benefit from using NVPs from finding out about them. A high proportion of current smokers report wanting to stop but a low number report successfully quitting. Data from the 2013 Scottish Health Survey show that 72% of smokers would like to stop and that 77% of current smokers have tried to stop at least once.⁷³ Most NVPs users are smokers or ex-smokers and say that their main reasons for using NVPs are to help them to reduce their tobacco use or to quit smoking completely.⁷⁴ This may be in a pattern of dual use or they might have completely replaced tobacco with NVPs. Others are involved in a pattern of dual use where there is no intention to quit. There is almost universal awareness of NVPs amongst smokers although the Scottish Government does not have good data on how much smokers know and understand about NVPs. As has been discussed in Section 2, there is insufficient data and too many variables involved (in terms of users, products and use patterns) to establish how effective are NVPs in supporting quit attempts which will be sustained over the longer term.

7.84 A ban on advertising may result in less competition in the market which could lead to increased prices for consumers. Conversely, without the benefit of advertising, the sector may see reductions in prices due to constraints on non-price competition, which would benefit consumers.

Costs to the NHS

7.85 Banning all NVP marketing would reduce the uptake of NVPs amongst smokers who might benefit from the use of NVPs to help them stop smoking, which could have costs to the NHS, which cannot be quantified.

⁷¹ Scottish Government (2014) *Scotland's People Annual report: Results from 2013 Scottish Household Survey* (<http://www.gov.scot/Publications/2014/08/7973/9>)

⁷² <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

⁷³ See Scottish Health Survey 2013 Supplementary Web Tables Part 6 – Smoking: <http://www.gov.scot/Topics/Statistics/Browse/Health/scottish-health-survey/Publications/Supplementary2013>

⁷⁴ “Among current users of electronic cigarettes, the principal reasons given by ex-smokers are “to help me stop smoking entirely” (56%) and “to help me keep off tobacco” (34%). The principal reasons given by current smokers are to “help me stop smoking entirely” (32%) and “to help me reduce the amount of tobacco I smoke, but not stop completely” (32%).” ASH (Action on Smoking and Health). 2014 *Use of electronic cigarettes in Great Britain*. http://www.ash.uk/files/documents/ASH_891.pdf

Costs of enforcement to Local Authorities

7.86 There will be costs to Local Authorities as Trading Standards Officers will be required to monitor and enforce the ban which will be similar to the existing ban for tobacco products which is enforced by Trading Standards. As noted for the age restriction and other proposals, the Scottish Government does not have an accurate estimate of the number of outlets selling NVPs, nor is it known how many businesses promote or gain revenue from the promotion of NVPs.

7.87 As stated for the other proposals in this BRIA and explained under the costs for proposal 1:

- In the first year, the total cost for enforcement **of all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

Costs of sanctions

7.88 The new offences created by the Bill largely mirror those already in existence for tobacco products under the Tobacco and Primary Medical Services (Scotland) Act 2010 and the Tobacco Advertising and Promotion Act 2002. There has been a high level of compliance with the Tobacco Advertising and Promotion Act 2002. There have been no cases referred for prosecution in Scotland since its introduction. Although not directly comparable the Scottish Government considers that it is reasonable to assume that the number of criminal proceedings would be small.

Option 3

7.89 This option presents the same arguments as for option 2. However, it is envisaged that most point of sale advertising will be permitted to allow the consumers to access information about NVPs to enable them to make informed choices about whether to use NVPs. The Bill does not attempt to regulate substantial discounts either.

Costs to business

7.90 It is very difficult to separately estimate the impact of a ban on domestic advertising from the costs presented for option 2. The same difficulties that are present when calculating the isolated impact of domestic advertising applies to domestic advertising exempting most advertising at point of sale. Isolating the impact of point of sale advertising and promotion on the growth of the customer base is not currently possible. It is possible to assume that the costs to retailers and smokers will be in similar categories to those for option 2 but of a smaller scale.

Costs of enforcement to Local Authorities

7.91 There will be costs to Local Authorities as Trading Standards Officers will be required to monitor and enforce the ban which will be similar to the existing ban for tobacco products which is enforced by Trading Standards. There are many more premises selling NVPs than sell tobacco. A large proportion of retailers who sell tobacco also sell NVPs. However, there are also NVP-only retailers, including specialised NVPs shops, pop-up shops and stalls, and a range of other retailers.

7.92 As stated for the other proposals in this BRIA and explained under the costs for proposal 1:

- In the first year, the total cost for enforcement **of all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

Costs of sanctions

7.93 The new offences created by the Bill largely mirror those already in existence for tobacco products under the Tobacco and Primary Medical Services (Scotland) Act 2010 and the Tobacco Advertising and Promotion Act 2002. There has been a high level of compliance with the Tobacco Advertising and Promotion Act 2002. There have been no cases referred for prosecution in Scotland since its introduction. Although not directly comparable, the Scottish Government considers that it is reasonable to assume that the number of criminal proceedings would be small.

Costs to the Scottish Government

7.94 There will be initial costs to raise public and retailer awareness and to provide retailers with information about the necessity to comply with all of the NVP and tobacco provisions in the Bill. Information packs will be posted to retailers and there will be an update of the main Scottish Government and the Scottish Tobacco Retailers Register websites. The total combined costs of communication and awareness-raising for all tobacco and NVP provisions are estimated to be in the region of £47,000 and will be met from existing public health programme budgets. This estimate is based on a recent exercise undertaken to provide a letter, guidance document, a poster and flyer to alert 31,500 businesses in Scotland that they would need to comply with legislation that requires all retailers (food and non-food) to charge for each new single-use carrier bag.

7.95 There will be costs to the Scottish Government associated with the development of guidance for retailers which will be undertaken as part of the normal business of the Scottish Government Directorate of Population Health Improvement.

Benefits

Option 1

Benefits to business

7.96 Under option 1, manufacturers and retailers will still have the ability to use domestic advertising to promote their products, potentially increasing their customer base and revenue. Commercial information would be widely and freely available about NVPs to smokers who might benefit from their use. This option might also result in other people, including under-18s, purchasing NVPs.

Benefits to consumers

7.97 Marketing of products which could be a useful tool for helping people to quit or reduce their tobacco use will still reach consumers who smoke.

Benefits to the NHS, the Scottish Government and society

7.98 Commercial information would be widely and freely available about NVPs to smokers who might benefit from their use and this might also result in people, especially under-18s, who might otherwise start smoking using NVPs as an alternative. Averting poor health as a result of smokers and potential future smokers choosing NVPs over tobacco could result in savings for the NHS.

Option 2

Benefits to business

7.99 A domestic ban on advertising in conjunction with the TPD and the CAP/BCAP rules would mean a significant reduction in the manufacturers' budget spend on advertising. This saving could be directed into research and development of new and existing products to the benefit of manufacturers and consumers. This would require to be set against any reduction in sales attributable to the domestic advertising ban.

7.100 Manufacturers of NVPs products have invested heavily in the marketing of their products. Estimates provided by the market research company, Nielsen and drawn from large retailers and pharmacy chains but not from small and specialist companies, show that in Scotland over £2.5 million was spent on NVP marketing by such companies between 2012 and 2014. These businesses' marketing expenditure rose markedly from £242,000 in 2012 to £1,425,200 in 2013, and then dropped in 2014 to £853,000.⁷⁵ It is not possible to establish how much has been spent in Scotland on domestic forms of advertising for NVPs. Within the marketing spend totals, the spend on outdoor forms of advertising, which constitute a substantial proportion of domestic advertising (e.g. billboards, bus-stops), was £149,561 in 2012, £504,326 in 2013, and decreased to £174,249 in 2014. It is not clear what proportion of domestic spend is made up by outdoor marketing.

Benefits to consumers

7.101 Without the benefit of advertising, the sector might see reductions in prices due to a reduction in non-price competition which would benefit consumers.

Benefits to the Scottish Government and the NHS

7.102 Banning NVP marketing would reduce the uptake of NVPs amongst non-smokers, including young people. This may potentially reduce harm if it later emerged that there were negative health impacts from long-term NVP use, or if it emerged that NVP use led people to use tobacco where it could be shown that they would otherwise not have used tobacco.

Option 3

Benefits to business

7.103 Option 3 presents a broadly similar scenario as option 2 in terms of benefits to manufacturers and retailers. However, this option allows manufacturers and retailers

⁷⁵ These figures are drawn from unpublished data provided to the Scottish Government by the market research company Nielsen.

to use point of sale advertising and promotion and substantial discounts which could lead to growth or retention of an existing customer base and so increased or sustained revenues.

Benefits to consumers

7.104 Allowing point of sale advertising and promotion will mean that consumers who smoke can access information about NVPs in settings where they may otherwise purchase tobacco as well as in settings where tobacco is not sold, including specialist NVP shops. Without the benefit of most forms of advertising, the sector might see reductions in prices due to more competitive pressures which would benefit consumers.

Benefits to the Scottish Government and the NHS

7.105 This option will strike a balance between informing existing smokers about NVPs where they are offered for sale while protecting young people and non-smokers from exposure to a wide range of promotional material. As a result of this, people who smoke may be informed to make decisions to replace tobacco with NVPs which would reduce tobacco related harm in the long-term. Limiting exposure to NVP marketing amongst young people and non-smokers would reduce the risk of uptake of NVPs amongst this group and therefore reduce the risk of any future potential harm as a result of nicotine addiction.

7.106 The aim of this proposal is to reduce the visibility and attraction of NVPs and related products to persons under the age of 18 and to adult non-smokers while ensuring it is still possible for smokers to find out about the products. As with the ban on tobacco advertising, The Scottish Government would expect very high rates of compliance.

PROPOSAL 6 – AGE VERIFICATION FOR TOBACCO AND NVP SALES (CHALLENGE 25)

Option 1 - Do nothing. This is the baseline against which other options are assessed.

Option 2 - Require retailers to operate an age verification policy for the sale of tobacco and NVPs. This is the chosen option.

7.107 The Bill will require retailers to operate an age verification policy. A policy is one where steps are taken to establish a customer's age if they appear under the age of 25 before a sale of tobacco, NVPs or related products can be made. The sale will be allowed to those customers who prove that they are over 18.

Sectors and groups affected

7.108 Young adults, businesses including SMEs, micro businesses, large retailers and specialist high street shops, government and society.

Costs

Option 1

7.109 This option will not result in any direct costs to businesses, the Scottish Government or the NHS. Not would there be significant costs to individuals as permitted forms of age verification ID are widely available.

Option 2

Costs to retailers

7.110 An age verification policy is already a requirement in statute for alcohol sales and some businesses apply this measure voluntarily to tobacco sales. Option 2 will have a small impact on businesses, mostly those businesses who do not already sell alcohol and aren't therefore not familiar with alcohol sales legislation. In the absence of reliable and up to date data on both the extent to which an age-verification policy is already used by tobacco retailers and the number of NVPs retailers, it is not possible to quantify this.

Costs to Local Authorities

7.111 There will be costs to Local Authorities as Trading Standards officers will be required to monitor and enforce the regulation in addition to their existing tobacco control duties. There are 9,803 businesses on the tobacco register and there is an assumption that a high proportion of them also sell NVPs. The NVP market is still maturing and the Scottish Government does not have robust data on the number of retailers of NVPs as there is no mechanism for identifying such businesses. During a two-week period in March 2015, Trading Standards in 21 local authorities, undertook a survey to try to establish the number of NVP retailers on their high streets. Trading Standards staff visited a wide variety of premises to determine whether they sold NVPs, tobacco, both, or neither. They visited a total of 1,190 retailers: of these 53 sold tobacco only, 181 sold NVPs only, and 186 sold both tobacco products and NVPs. If this sample is representative of the combined tobacco and NVP retail sector in Scotland, this means that approximately 13% sell only tobacco, 43% sell only NVPs, and the remaining 44% sell both types of product. Based on these approximate figures, it could be assumed that the number of retailers which Trading Standards will need to visit to provide advice, support and undertake enforcement action could increase by 76%. The Scottish Government does not know what proportion of these businesses already operate an age verification policy.

7.112 As stated for the other proposals in this BRIA and explained under the costs for proposal 1:

- In the first year, the total cost for enforcement of **all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

Costs to the Scottish Government

7.113 There will be initial costs to raise public and retailer awareness and to provide retailers with information about the necessity to comply with all of the NVP and tobacco provisions in the Bill. Information packs will be posted to retailers and there will be an update of the main Scottish Government and the Scottish Tobacco Retailers Register websites. The total combined costs of communication and awareness-raising for all tobacco and NVP provisions are estimated to be in the region of £47,000 and will be met from existing public health programme budgets. This estimate is based on a recent exercise undertaken to provide a letter, guidance document, a poster and flyer to alert 31,500 businesses in Scotland that they would need to comply with legislation that requires all retailers (food and non-food) to charge for each new single-use carrier bag.

7.114 There will be costs to the Scottish Government associated with the development of guidance for retailers which will be undertaken as part of the normal business of the Scottish Government Directorate of Population Health Improvement.

Costs of enforcement

7.115 Local authorities will have the power to enforce the proposal, giving them and the police powers of entry and of issuing fixed penalty notices in relation to the offences in this proposal.

Costs to individuals

7.116 There will be no new costs. Young people who wish to purchase tobacco or NVPs already need to have a valid form of ID. This proposal may mean that they need to carry their ID with them up until their late 20s. Those who also wish to purchase alcohol already have to do this to comply with alcohol sales legislation. There are many forms of legitimate ID available, including ones which bear no cost.

Benefits

Option 1

7.117 There would be no additional regulatory requirements on businesses. There would be no benefits for central or local government.

Option 2

7.118 This may help reduce the number of sales made to persons under 18 as part of a package of proposals on age restriction in the Bill. There is a lack of robust evidence on the effectiveness of challenge 25 but reports suggest that along with other alcohol measures it is reducing under-age sales of alcohol.⁷⁶

⁷⁶ "Final report: Licensing Act (Scotland) 2005" (June 2013) of the Monitoring and Evaluating Scotland's Alcohol Strategy (MESAS) project led by NHS Health Scotland (<http://www.healthscotland.com/scotlands-health/evaluation/planning/MESAS/MESASstudyportfolio.aspx>).

Benefits to business

7.119 This option will support staff and business to ensure that they are making legal sales of tobacco and NVPs. It will provide a consistent and clear framework for requiring ID across all retailers of tobacco, NVPs and alcohol. By increasing compliance with age-restriction legislation, this option will help reduce underage access to tobacco and NVPs. This option also supports other age restriction proposals within the Bill.

Benefits to Local Authorities

7.120 Local Authorities will retain the revenue from Fixed Penalty Notices issued and collected which will help to offset the cost of administering them.

Benefits to individuals

7.121 This proposal will provide a consistent approach to purchasing tobacco, NVPs and alcohol. By reducing access to age-restricted goods, and therefore consumption, by those under 18, it will help to protect and improve public health in Scotland.

PROPOSAL 7 - UNAUTHORISED SALES OF TOBACCO AND E-CIGARETTES BY UNDER-18S

Option 1 – Do nothing. This is the baseline against which other options are assessed.

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. A record of the authorisation is required to be kept on the premises and produced for enforcement purposes. If there is no record, it will be assumed that the person under 18 is not authorised to make sales. This is the chosen option.

7.122 Options 2 and 3 support the enforcement of the age of sale restriction. The rationale is that persons under 18 may feel less confident in challenging the age of a customer and refusing to make a sale on the grounds of age to someone who is close to them in age.

Sectors and groups affected

7.123 Young people under the age of 18, businesses, including, SMEs, micro businesses, large retailers and specialist high street shops, government and society will be affected.

Costs

Option 1

7.124 This option would result in no direct costs to government or businesses or consumers.

Option 2

Costs to retailers

7.125 This option could result in direct costs for tobacco and NVP retailers associated with familiarisation with the new legislation and staff training. It would also require a responsible person to be on duty at all time in order to make sales of tobacco or NVP products. This could result in additional wage costs if this member of staff was additional to, or a substitute for, an employee under 18. From 1 October 2015, the national minimum hourly wage for someone aged over 20 will increase to £6.70, for 18-20 year olds it will increase to £5.30, whereas for 16–18 year olds it will be £3.87. In the course of the consultation process, stakeholders thought that the costs of training and familiarisation for this policy would be bundled together with age restriction, proxy purchase and challenge 25. Businesses who sell alcohol are already required by law to have such a policy in place.

7.126 It is not possible to calculate an overall cost of this legislation because of the difficulty in establishing the exact numbers of retailers affected. If the Scottish Government based calculations on estimations provided by Trading Standards already set out in the BRIA, it would still not be possible to identify how many of these businesses employ staff who are under 18.

Costs to the Scottish Government

7.127 There will be initial costs to raise public and retailer awareness and to provide retailers with information about the necessity to comply with all of the NVP and tobacco provisions in the Bill. Information packs will be posted to retailers and there will be an update of the main Scottish Government and the Scottish Tobacco Retailers Register websites. The total combined costs of communication and awareness-raising for all tobacco and NVP provisions are estimated to be in the region of £47,000 and will be met from existing public health programme budgets. This estimate is based on a recent exercise undertaken to provide a letter, guidance document, a poster and flyer to alert 31,500 businesses in Scotland that they would need to comply with legislation that requires all retailers (food and non-food) to charge for each new single-use carrier bag.

7.128 There will be costs to the Scottish Government associated with the development of guidance for retailers which will be undertaken as part of the normal business of the Scottish Government Directorate of Population Health Improvement.

Costs to Local Authorities

7.129 There will be costs to Local Authorities as Trading Standards Officers will be required to undertake support, monitoring and enforcement action for this new activity. As stated for the other proposals in this BRIA and explained under the costs for proposal 1:

- In the first year, the total cost for enforcement **of all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

7.130 Local authorities will retain the revenue from FPNs which are issued which will help offset the costs of administering them.

Costs of Prosecution

7.131 Between 2007/08 and 2011/12 there were only 3 prosecutions for unsupervised sale of alcohol by a child or young person. The Scottish Government considers that the number of prosecutions, if any, would be low.

Option 3

Costs to retailers

7.132 This option could result in direct costs for tobacco and NVP retailers associated with familiarisation with the new legislation and staff training. In the course of the consultation process, stakeholders' views were that the costs of training and familiarisation for this policy would be bundled together with age restriction, proxy purchase and challenge 25. Businesses who sell alcohol are already required by law to have such a policy in place.

7.133 It is not possible to calculate an overall cost of familiarisation with this legislation because of the difficulty in establishing the numbers of retailers affected. There are 9,803 businesses on the tobacco register and there is an assumption that a high proportion of them also sell NVPs. If the Scottish Government based calculations on estimations provided by Trading Standards already set out in the BRIA, it would still not be possible to identify how many of these businesses employ staff who are under 18.

Costs to the Scottish Government

7.134 There will be initial costs to raise public and retailer awareness and to provide retailers with information about the necessity to comply with all of the NVP and tobacco provisions in the Bill. Information packs will be posted to retailers and there will be an update of the main Scottish Government and the Scottish Tobacco Retailers Register websites. The total combined costs of communication and awareness-raising for all tobacco and NVP provisions are estimated to be in the region of £47,000 and will be met from existing public health programme budgets. This estimate is based on a recent exercise undertaken to provide a letter, guidance document, a poster and flyer to alert 31,500 businesses in Scotland that they would need to comply with legislation that requires all retailers (food and non-food) to charge for each new single-use carrier bag.

7.135 There will be costs to the Scottish Government associated with the development of guidance for retailers which will be undertaken as part of the normal business of the Scottish Government Directorate of Population Health Improvement.

Costs to Local Authorities

7.136 There will be costs to Local Authorities as Trading Standards Officers will be required to undertake support, monitoring and enforcement action for this new activity. As stated for the other proposals in this BRIA and explained under the costs for proposal 1:

- In the first year, the total cost for enforcement **of all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

7.137 Local authorities will retain the revenue from FPNs which are issued which will help offset the costs of administering them.

Costs of Prosecution

7.138 Between 2007/08 and 2011/12 there were only three prosecutions for unsupervised sale of alcohol by a child or young person. Because of the high rate of compliance with this legislation and the nature of this proposal.

Benefits

Option 1

Benefits for retailers

7.139 There would be no additional statutory requirement for businesses to consider the age of staff who will sell tobacco or NVPs and related products over existing rules on obligations under current employment law.

Option 2

Benefits to Retailers

7.140 This option could benefit businesses by bringing the sale of tobacco and NVPs in line with alcohol. It would put in place additional support for employees under the age of 18 to make legal sales of tobacco and NVPs which would also be a benefit to business.

Benefits to Local Authorities

7.141 Local Authorities will retain the revenue from Fixed Penalty Notices issued and collected which will help offset the costs of administering them.

Option 3

Benefits to Retailers

7.142 This option could benefit businesses by bringing the sale of tobacco and NVPs in line with alcohol without the necessity for a staff member over 18 to always be present. It would put in place additional support for employees under the age of 18 to make legal sales of tobacco and NVPs which would also be a benefit to business.

Benefits to Local Authorities

7.143 Local Authorities will retain the revenue from Fixed Penalty Notices issued and collected which will help offset the costs of enforcement.

PROPOSAL 8 - INTRODUCTION OF NATIONAL LEGISLATION FOR SMOKE-FREE NATIONAL HEALTH SERVICE HOSPITAL GROUNDS

Option 1 - Do nothing. This is the baseline against which other options have been assessed. In line with the Scottish Government's Tobacco Control Strategy, *Creating a Tobacco-Free Generation*, all NHS Boards had introduced a non-statutory smoke-free grounds policy. NHS Boards have, however, raised concerns about low levels of compliance and potential difficulties in enforcement of a policy which is not supported by national legislation.

Option 2 - Make it an offence:

- to smoke in the entire grounds associated with all NHS buildings
- for someone in management and control of the grounds to knowingly permit smoking
- for someone in management and control of a building not to display signage at entrances to the building
- for NHS Boards to not display signage on entrance to the grounds

Option 3 – This is the chosen option. Make it an offence:

- for a person to smoke within the defined no-smoking area around each building in the grounds of and NHS hospitals only
- for someone in management and control of the no-smoking area to knowingly permit smoking
- for someone in management and control of a specific building not to display signage at entrances the building
- for NHS Boards to not display signage on entrance to the grounds

Sectors and groups affected

7.144 National Health Service Boards, staff, patients and visitors, smokers in hospital grounds, government.

Costs

Option 1

Costs to the Scottish Government and NHS Boards

7.145 Without the support of legislation, there may continue to be challenges for compliance amongst staff, patients and visitors. This means that the full benefits of the policy may not be realised.

Option 2

Costs to NHS Boards

7.146 It is not possible to accurately calculate the overall costs to Boards as each will be responsible for implementing the legislation and there is a level of flexibility as to how this can be achieved in addition to their existing smoke-free grounds policy. This option will cover a very large number of NHS premises as it would include GPs, dentists and any other NHS providers. Therefore, it could be assumed that option 2

could have overall higher, but unquantifiable, costs relative to option 3 which covers only NHS hospitals.

Costs to the Scottish Government

7.147 The legislation would require signage to be displayed at entrances to NHS premises grounds to ensure that staff, visitors and patients are aware that it is an offence to smoke within a perimeter of the buildings. The Scottish Government would be responsible for providing signage to all NHS Boards. This option will cover a very large number of NHS premises as it would include GPs, dentists and any other any other NHS providers. Therefore, it could be assumed that option 2 could have overall higher but unquantifiable costs relative to option 3 which covers only NHS hospital grounds.

Cost to Local Authorities

7.148 This proposal will have relatively lower resource demands on local government as NHS Boards may wish to work in partnership with local Environmental Health Officers to ensure compliance with the smoke-free grounds policy. Option 2 will cover a very large number of NHS premises as it would include GPs, Dentist and any other NHS providers. Option 2 would have overall higher but unquantifiable costs relative to option 3 which covers only NHS hospitals.

Costs of prosecution

7.149 The smoking ban created by the Smoking, Health and Social Care (Scotland) Act 2005 was introduced in Scotland in 2006. There has been a high level of compliance and the legislation is now largely self-enforcing. This is demonstrated with only 21 offences proceeding to court over the six year period after the legislation was introduced in 2006 (there were no cases proceeding to court in 2006). Since the provisions in the Bill will only extend to NHS hospitals, the numbers proceeding to court are expected to be negligible.

Option 3

Costs to NHS Boards

7.150 There are 149 hospitals within the 14 territorial NHS Boards in Scotland. It is not possible to accurately calculate the overall costs to Boards as each will be responsible for implementing the legislation and there is a level of flexibility as to how this can be achieved in addition to their existing smoke-free grounds policy. This option will result in modest costs to inform staff and visitors about the new legislation through existing communication channels which boards already use, for example, through staff communication and induction packs, and for patients and visitors in routine information as well as in appointment and admission letters.

7.151 NHS Boards have developed a range of models for implementation and enforcement to suit local needs in relation to their existing policies for smoke-free grounds (e.g. using wardens or including this in existing staff roles, local advertising campaigns, hatching, audio recordings, and small credit card sized cards with information for members of the public). Costs will vary for different hospitals and NHS Boards. If NHS Boards opt to add additional measures, based on previous NHS tender exercises from large hospital sites, the additional costs could range from £10,260 to £41,064 per annum at each site.

7.152 It is expected that the need for such activity will decrease as the legislation becomes embedded and people are more aware of the policy and comply.

7.153 There will be on-going costs associated with compliance in terms of training staff and undertaking the relevant compliance activity, much of which would be subsumed within costs associated with the existing smoke-free grounds policy. Environmental Health Officers will be responsible for enforcement, they will be able to issue fixed penalty notices or refer a case for prosecution. They will not be expected to monitor day to day compliance. Boards will decide on how they can best achieve compliance with the legislation. The costs of compliance arrangements will vary by Board.

Costs to the Scottish Government

7.154 The legislation will require signage to be displayed at entrances to NHS hospital grounds to ensure that staff, visitors and patients are aware that it is an offence to smoke within a perimeter of the buildings. The Scottish Government will be responsible for providing signage to all health boards. The total signage costs are expected to be in the range of £99,000 to £198,000. This cost range is based on the amount paid by Greater Glasgow and Clyde NHS Board for signage (£70 per 1 x 1 meter outdoor sign and £10 per A3 poster with case for indoors). There are 149 hospitals listed on the Scottish Government Estates and Asset Management System (excluding mental health hospitals and specialist hospitals). The lower estimate assumes that on average 5 outdoor and 20 indoor signs are required per hospital. The higher estimate assumes that 10 outdoor signs and 40 indoor signs are required. Boards will also be provided with indoor signs which they themselves can print.

7.155 To inform the public of the forthcoming legislation which will make it an offence to smoke within a set perimeter of hospital buildings, Scottish Ministers will establish a communications programme in advance of the regulations coming into force. Costs are anticipated to be in the region of £300,000. This is based on costs for a similar recent campaign on changes to the law on the drink driving limit and a campaign run by the NHS to raise awareness of their smoke-free grounds policy.

Cost to Local Authorities

7.156 Compared to the costs for enforcement of the proposals in this BRIA, which will all require enforcement by Trading Standards Officers, this proposal will have lower resource demands on local government. NHS boards may wish to work in partnership with local Environmental Health Officers to ensure compliance with the smokefree grounds policy. As stated for the other proposals in this BRIA and explained under the costs for proposal 1:

- In the first year, the total cost for enforcement **of all the Bill's NVP, tobacco and smoking provisions** is estimated to be between £1 million and £1.5 million.
- There will be an ongoing per annum enforcement cost of between £1 million and £1.5 million.

Costs of prosecution

7.157 The smoking ban created by the Smoking, Health and Social Care (Scotland) Act 2005 was introduced in Scotland in 2006. There has been a high level of

compliance and the legislation is now largely self-enforcing. This is demonstrated with only 21 offences proceeding to court over the six year period after the legislation was introduced in 2006 (there were no cases proceeding to court in 2006). Since the provisions in the Bill will only extend to NHS hospital grounds, the numbers proceeding to court are expected to be negligible.

Benefits

Option 1

7.158 There would be no substantive benefits from option 1.

Option 2

Benefits to the Scottish Government and the NHS

7.159 This option will support compliance with, and enforcement of, existing NHS Board smoke free policies. It will provide a consistent approach across Scotland and support the vision, aims and objectives set out in Scottish Government's Tobacco Control Strategy to reduce tobacco consumption and related harm.

7.160 Smoking-related morbidity and mortality is estimated to cost NHS Scotland at least £323-510 million, accounting for 13,500 deaths (a quarter of all deaths) and 56,000 hospital admissions per year.⁷⁷ There would be unquantifiable improvements in public health as a result of this legislation in terms of: patients who are being treated in hospital recovering faster and more successfully if they do not smoke during treatment; patients being encouraged to stop smoking; and staff who are encouraged to stop smoking. The policy also contributes to wider efforts to de-normalise tobacco use in Scottish society.

Option 3

Benefits to the Scottish Government and the NHS

7.161 This option will support compliance with, and enforcement of, existing NHS Board smoke free policies. It will provide a consistent approach across Scotland and support the vision, aims and objectives set out in Scottish Government's Tobacco Control Strategy to reduce tobacco consumption and related harm.

7.162 There tend to be concentrations of smokers around building entrances and there is also the risk of smoke-drift into buildings through windows, doors and vents. Option 3 still supports the clear message that smoking is not appropriate in and around hospitals, but offers a more proportionate and gradualist approach to achieving a smoke-free NHS than introducing an offence for smoking anywhere across the entire grounds of a hospital and other NHS buildings.

7.163 Smoking-related morbidity and mortality is estimated to cost NHS Scotland at least £323-510 million, accounting for 13,500 deaths (a quarter of all deaths) and

⁷⁷ ScotPHO Smoking Ready Reckoner – 2011 Edition - http://www.scotpho.org.uk/downloads/scotphoreports/scotpho120626_smokingreadyreckoner.pdf

56,000 hospital admissions per year.⁷⁸ There would be unquantifiable improvements in public health as a result of this legislation in terms of: patients who are being treated in hospital recovering faster and more successfully if they do not smoke during treatment; patients being encouraged to stop smoking; and staff who are encouraged to stop smoking. The policy also contributes to wider efforts to de-normalise tobacco use in Scottish society.

8. SCOTTISH FIRMS IMPACT TEST

8.1 Scottish Government officials carried out face-to-face meetings with a variety of stakeholders, including representatives from COSLA; Trading Standards and Environmental Health; NHS Boards; Police Scotland, public health stakeholders; retail associations, the NVP industry including individual businesses and ECITA; pharmacy organisations; and individual vaping advocates. Site visits were also held at a range of retail premises which sold NVPs and tobacco. These included grocers, newsagents, petrol stations, wholesalers, pharmacies and NVP specialist stores.

8.2 To date there have been a number of conversations with specific businesses and with business organisations around NVPs and strengthening tobacco control. We have held formal meetings with the following NVP businesses: blu (an Edinburgh-based brand of NVPs and a subsidiary of Lorillard); E-lites (a brand of NVPs and a subsidiary of JTI); and Jac Vapour (a Scottish SME). All of these are small or medium sized enterprises, although the first two are subsidiaries of large international tobacco companies. All stated that they do not sell to or produce goods for under-18s so they would be minimally impacted by the age restriction provisions. They would all be impacted by the domestic advertising ban but could not provide us with estimated costs for loss of sales revenues.

8.3 We visited branches of: the specialist NVP shop chain Vaporized; Batleys wholesalers (national chain); Spar stores/BP garages (large national chain); Key Store convenience stores (large national chain); Boots the Chemist (large national chain); Lindsay and Gilmour pharmacies (national chain); Margiotta convenience stores (chain in the Edinburgh area); and en-juice which sells and manufactures NVP liquid (small independent company, based on Glasgow);. We also visited an independent mini-market and two newsagents in Edinburgh, all of which are small local businesses. Sales of NVPs were not a significant part of the overall business for any of these companies with the exception of Vaporized and en-juice, whose sole business is the sale, promotion or production of e-cigarettes, e-liquids and related accessories. We held formal meetings with the following trade organisations: ECITA, the Scottish Grocers Federation, National Federation of News Agents, Scottish Wholesale Association and Petrol Retailers Association.

8.4 As the Bill progresses, the Scottish Government will continue its consultation and engagement with COSLA, the new Scottish Local Government Partnership,

⁷⁸ ScotPHO Smoking Ready Reckoner – 2011 Edition - http://www.scotpho.org.uk/downloads/scotphoreports/scotpho120626_smokingreadyreckoner.pdf

individual local authorities, Health Boards, the industry, public health stakeholders and other organisations with an interest.

9. COMPETITION ASSESSMENT

9.1 The proposal to ban domestic advertising with the exception of point of sale has the potential to indirectly limit the number of suppliers in the market and limit the ability of suppliers to compete through reducing their options for non-price competition. A full competition assessment is included as Appendix A.

10. TEST RUN OF BUSINESS FORMS

10.1 There will be amendments made to the forms required for retailers of NVP to register and new forms for authorisations for under 18s to retail tobacco products and/or NVPs. The Scottish Government will test run the forms with those who will be using them to ensure that they are easy to use.

11. LEGAL AID IMPACT TEST

11.1 The introduction of these regulations should have no impact on the Legal Aid Fund. The Scottish Legal Aid Board has confirmed this assessment.

12. ENFORCEMENT, SANCTIONS AND MONITORING

12.1 Local Authority Officers will primarily be responsible for the enforcement of the measures contained with Part 1 of the Health (Tobacco, Nicotine etc. and Care Bill). There will also be a smaller role for the criminal justice system. The Scottish Government will consider with Local Authorities what monitoring requirements are needed. The Scottish Government can regularly monitor from its own data cases proceeded against in court.

12.2 The principle enforcement role will lie with Trading Standards Officers for the NVP and tobacco provisions and with NHS Boards and Local Authority Environmental Health Officers for the prohibition of smoking outside NHS hospital buildings. A detailed programme of monitoring activity will be developed in advance of the Bill coming into force.

12.3 Setting a minimum age for the purchase of NVPs will be enforced and monitored by Trading Standards, and will be monitored for impacts through survey data on levels of use by young people and children (including the Scottish Government's Scottish Adolescent Lifestyle and Substance Use Survey). Three other policies are being introduced to support the age of sale restriction for NVPs: a proxy purchase offence; a ban on vending machine sales; mandatory registration for NVP retailers. As there is a dearth of information about the size of the NVP retail sector it will be necessary to first of all establish a baseline against which compliance and progress will be monitored. The domestic advertising ban is intended to ensure

as far as possible that primarily smokers are exposed to NVPs marketing. It will support the age restriction but it will not be possible to assess its impact on under-age levels of use in isolation from the effects of other factors: other provisions in the Bill; the existing CAP/BCAP codes; the ban on cross-border advertising which the EU TPD will introduce in 2016; market factors which cannot be predicted which would influence levels of use and availability of products; and other factors such as media stories and public awareness through non-commercial channels. Compliance will be monitored by ASA and Trading Standards.

12.4 In terms of evaluating the effect that these provisions will have on smoking rates and on health, it would be extremely difficult to meaningfully assess the impact of individual provisions within the Bill in isolation as they are complementary and mutually reinforcing. They will also occur within a wider context of ongoing changing attitudes to smoking and to the use of NVPs, the effect of the EU TPD, the effects of the CAP/BCAP, a market which is still maturing against a backdrop of falling rates of smoking amongst young people and a fairly steady rate of adult smoking rates after a period of marked decline. A framework for monitoring and evaluating the measures will be developed in advance of them being implemented.

12.5 NHS Boards will be responsible for implementing and monitoring compliance with the legislation to create a smoke-free perimeter around NHS hospital buildings. The Scottish Government will monitor the policy and review its fitness for purpose.

Sanctions for non-compliance

Sale and purchase of Tobacco and NVPs

12.6 Section 4 (5) of the Bill provides that the penalty for committing the offence in section 4 A (1) is, on summary conviction, a fine not exceeding level 4 on the standard scale (currently £2,500)

Age verification policy

12.7 Section 4 B (7) of the Bill provides that a person who commits an offence under subsection (1) is liable, on summary conviction, to a fine not exceeding level 2 on the standard scale (currently £500).

Sales by persons under 18

12.8 Section 4 C (7) of the Bill provides that a responsible person who commits an offence under section 4 C (1) is liable, on summary conviction, to a fine not exceeding level 1 on the standard scale (currently £200).

Purchase of NVPs on behalf of a person under 18

12.9 Section 6 A (2) of the Bill provides that a person who commits this offence is liable, on summary conviction, to a fine not exceeding level 5 on the standard scale (currently £5,000).

Extension of vending machine prohibition

12.10 A person who has the management or control of premises on which a vending machine for the sale of NVPs is available who commits an offence, will be liable to the penalty set out in section 9 (2) of the 2010 Act, on summary conviction, of a fine not exceeding level 4 on the standard scale (currently £2,500).

Advertising and brand sharing

12.11 Section 17 (3) of the Bill specifies the maximum penalty which regulations may prescribe for offences as, on summary proceedings, imprisonment not exceeding 12 months or a fine not exceeding the statutory maximum (currently £10,000) or both and on conviction or indictment, imprisonment not exceeding two years or an unlimited fine or both.

Free Distribution and nominal pricing

12.12 Section 18 (3) of the Bill specifies the maximum penalty which regulations may prescribe for offences as, on summary proceedings, imprisonment not exceeding 12 months or a fine not exceeding the statutory maximum (currently £10,000) or both and on conviction or indictment, imprisonment not exceeding two years or an unlimited fine or both.

Sponsorship

12.13 Section 19 (3) of the Bill specifies the maximum penalty which regulations may prescribe for offences as, on summary proceedings, imprisonment not exceeding 12 months or a fine not exceeding two years or an unlimited fine or both.

Offence of permitting others to smoke outside hospital buildings

12.14 Subsection (4) of the Bill provides that a person who commits the offence under this section is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale (currently £2,500).

Offence of smoking outside hospital buildings

12.15 Subsection (3) of the Bill provides that a person who commits the offence of smoking in a no-smoking area is liable, on summary conviction, to a fine not exceeding level 3 on the standard scale (currently £1,000).

Display of warning notices in hospital buildings and on hospital grounds

12.16 Subsection (5) of the Bill provides that a person who commits an offence of failing to display signage at the entrance to hospital buildings in compliance with this section is liable to a fine not exceeding level 3 on the standard scale (currently £1,000).

13. IMPLEMENTATION AND DELIVERY PLAN

13.1 The following policies will be implemented as soon as possible on passage of the Bill:

- Minimum age of 18 for the sale of NVPs
- Ban on the proxy purchase of NVPs
- Mandatory registration for the sale of NVPs

13.2 The following policies will require the development of regulations, guidance and forms. It is unlikely that relevant consultations would take place before summer 2016:

- Banning certain forms of domestic advertising and promotion of NVPs
- Prohibition of sales of NVPs from vending machines
- 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

13.3 Where guidance is required, the Scottish Government would work with the relevant bodies to develop joint guidance.

14. POST-IMPLEMENTATION REVIEW

14.1 The Scottish Government will monitor implementation as discussed in section 12. Any further review processes will be considered.

Summary and recommendation

Which option is being recommended and why? Refer to analysis of the costs and benefits in reaching the decision. Summarise, using the table below, the information gathered for each option.

- Summary costs and benefits table**

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
PROPOSAL 1: AGE RESTRICTION FOR SALE OF NVPs		
1 - Do nothing.	Businesses: unquantifiable Scottish Government, Local Authorities, NHS: none	Unquantifiable
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.	Scottish Government, Local Authorities, NHS: unquantifiable	Businesses: estimated £280k of lost profits in the first year from lost sales to under-18s (estimated range of £232k - £325k). Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u> Local Authorities: - in the first year, the total cost

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
		<p>for enforcement of all Bill provisions is estimated to be between £1million and £1.5million (including a one-off cost of £15k for training and updating documentation);</p> <p>- there will be an ongoing per annum enforcement cost of between £1million and £1.5million.</p> <p>Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.</p>
<p>3 - Create an offence for a retailer to sell an NVP to an under 18. This is the chosen option.</p>	<p>Businesses: unquantifiable</p> <p>Scottish Government, Local Authorities, NHS: unquantifiable</p>	<p>Businesses: estimated £280k of lost profits in the first year (estimated range of £232k - £325k).</p> <p>Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u></p> <p>Local Authorities:</p> <p>- in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and</p>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
		<p>£1.5million (including a one-off cost of £15k for training and updating documentation);</p> <p>- there will be an ongoing per annum enforcement cost of between £1million and £1.5million.</p> <p>Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.</p>
PROPOSAL 2: CREATE AN OFFENCE OF PROXY PURCHASE OF NVPs		
1 - Do nothing.	Unquantifiable	Unquantifiable
2 - Create an offence for an adult to purchase NVPs on behalf of a child or young person aged under 18. This is the preferred option.	Scottish Government, Local Authorities, NHS: unquantifiable benefits	<p>Businesses: none in addition to Proposal 1.</p> <p>Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u></p>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
		<p>Local Authorities:</p> <ul style="list-style-type: none"> - in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and £1.5million (including a one-off cost of £15k for training and updating documentation); - there will be an ongoing per annum enforcement cost of between £1million and £1.5million. <p>Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.</p>
PROPOSAL 3: BAN ON SALES OF NVPs FROM VENDING MACHINES		
1 - Do nothing.	None	None
2 - Introduce a ban on the sale of NVPs from vending machines. This is the preferred option.	None	<p>Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u></p>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
PROPOSAL 4: MANDATORY REGISTRATION TO RETAIL NVPs		
1 - Do nothing.	Businesses: none	Businesses: none Local Authorities: unquantifiable impact on enforcement.
2 - Create an entirely separate register and regulatory regime for retailers of NVPs.	Businesses: unquantifiable Local Authorities: unquantifiable benefits for enforcement	Businesses: minimal administrative costs. Scottish Government: <ul style="list-style-type: none"> - In the first year, the cost of establishing the new Register would be £20k. - On-going maintenance costs of the Register estimated to be around £13k. - £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u> Local Authorities: <ul style="list-style-type: none"> - in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
		<p>£1.5million (including a one-off cost of £15k for training and updating documentation);</p> <p>- there will be an ongoing per annum enforcement cost of between £1million and £1.5million.</p> <p>Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.</p>
<p>3 – Extend the existing Tobacco Retailers Register to NVPs, where businesses will be required to identify the type of business they are carrying on and whether they are selling tobacco, NVPs or both. This is the chosen option.</p>	<p>Businesses: unquantifiable</p> <p>Local Authorities: unquantifiable benefits for enforcement</p>	<p>Businesses: minimal administrative costs.</p> <p>Scottish Government:</p> <ul style="list-style-type: none"> - In the first year, the cost of establishing the new Register would be £15k. - On-going maintenance costs of the Register estimated to be around £13,200. - £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
		Local Authorities: - in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and £1.5million (including a one-off cost of £15k for training and updating documentation); - there will be an ongoing per annum enforcement cost of between £1million and £1.5million. Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.
PROPOSAL 5: DOMESTIC ADVERTISING AND PROMOTION OF NVPs		
1 - Do nothing.	Unquantifiable	Unquantifiable
2 - Introduce a ban on all forms of domestic advertising and promotion of NVPs, including billboards, leafleting, brand-sharing, free	Businesses: none Scottish Government, NHS, Local Authorities: unquantifiable /	Businesses: unquantifiable but likely to be significant. NHS: unquantifiable if fewer

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
distribution, nominal pricing, point of sale, substantial discounts and domestic event sponsorship.	unknown	<p>smokers switch to NVPs in order to reduce tobacco related harm.</p> <p>Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u></p> <p>Local Authorities:</p> <ul style="list-style-type: none"> - in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and £1.5million (including a one-off cost of £15k for training and updating documentation); - there will be an ongoing per annum enforcement cost of between £1million and £1.5million. <p>Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.</p>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
<p>3 - Introduce a ban on all forms of domestic advertising (free distribution, domestic events sponsorship, brand-stretching, etc.), with the exception of in-store point of sale advertising. This is the preferred option.</p>	<p>Businesses: none</p> <p>Scottish Government, NHS, Local Authorities: unquantifiable / unknown</p>	<p>Businesses: unquantifiable but likely to be significant.</p> <p>Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u></p> <p>Local Authorities:</p> <ul style="list-style-type: none"> - in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and £1.5million (including a one-off cost of £15k for training and updating documentation); - there will be an ongoing per annum enforcement cost of between £1million and £1.5million. <p>Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.</p>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
PROPOSAL 6: AGE VERIFICATION FOR TOBACCO AND NVP SALES (CHALLENGE 25)		
1 - Do nothing.	None	None
2 - Require retailers to operate an age verification policy for the sale of tobacco and NVPs. This is the chosen option.	<p>Businesses: unquantifiable benefits for compliance with age restriction</p> <p>Local Authorities: unquantifiable benefits for enforcement</p>	<p>Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u></p> <p>Local Authorities:</p> <ul style="list-style-type: none"> - in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and £1.5million (including a one-off cost of £15k for training and updating documentation); - there will be an ongoing per annum enforcement cost of between £1million and £1.5million. <p>Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.</p>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
PROPOSAL 7: UNAUTHORISED SALES OF TOBACCO AND NVPs BY UNDER-18S		
1 - Do nothing.	None	None
2 - Require a responsible adult person to specifically authorise and be present for each sale of tobacco or NVPs by an under 18.	<p>Businesses: unquantifiable benefits for compliance with age restriction</p> <p>Local Authorities: unquantifiable benefits for enforcement</p>	<p>Businesses: unquantifiable in cases if some sales cannot be made or additional / higher paid staff are needed.</p> <p>Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u></p> <p>Local Authorities:</p> <ul style="list-style-type: none"> - in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and £1.5million (including a one-off cost of £15k for training and updating documentation); - there will be an ongoing per annum enforcement cost of between £1million and £1.5million.

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
		Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.
3 - Require a responsible person to authorise an employee under 18 to sell tobacco or NVPs.	<p>Businesses: unquantifiable benefits for compliance with age restriction</p> <p>Local Authorities: unquantifiable benefits for enforcement</p>	<p>Businesses: minimal</p> <p>Scottish Government: £47k one-off costs for communication and awareness-raising <u>for all of the NVP and tobacco provisions in the Bill.</u></p> <p>Local Authorities:</p> <ul style="list-style-type: none"> - in the first year, the total cost for enforcement of all Bill provisions is estimated to be between £1million and £1.5million (including a one-off cost of £15k for training and updating documentation); - there will be an ongoing per annum enforcement cost of between £1million and £1.5million. <p>Prosecution costs: for all measures in Part 1 of the Bill are estimated to between £7720 - £8,740.</p>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
PROPOSAL 8: INTRODUCTION OF NATIONAL LEGISLATION FOR SMOKE-FREE NATIONAL HEALTH SERVICE HOSPITAL GROUNDS		
1 - Do nothing.	None	None
2 - Make it an offence to smoke anywhere in the grounds of NHS buildings.	<p>Scottish Government, Local Authorities, NHS: unquantifiable benefits for health</p> <p>Businesses: £99,000-198,000 as a one-off benefit for the supplier who provides signage</p>	<p>Scottish Government:</p> <ul style="list-style-type: none"> - £300k one-off costs for a public marketing campaign to raise awareness of the new smokefree rules. - Unquantifiable signage costs <p>Local Authorities: modest additional cost (accounting for current funding provided to enforce other smoke-free legislation), unquantified enforcement costs</p> <p>NHS: unquantified compliance costs in addition to existing smokefree policies.</p> <p>Prosecution costs: negligible.</p>

Options	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
<p>3 – Make it an offence to within a designated perimeter around all buildings on NHS hospital sites. This is the chosen option</p>	<p>Scottish Government, Local Authorities, NHS: unquantifiable benefits for health</p> <p>Businesses: £99,000-198,000 as a one-off benefit for the supplier who provides signage</p>	<p>Scottish Government:</p> <ul style="list-style-type: none"> - £300k one-off costs for a public marketing campaign to raise awareness of the new smokefree rules. - one-off costs of £99k -198k to provide signage to NHS boards <p>Local Authorities: modest additional cost (accounting for current funding provided to enforce other smoke-free legislation), unquantified enforcement costs</p> <p>NHS: unquantified compliance costs in addition to existing smokefree policies.</p> <p>Prosecution costs: negligible</p>

PART 2

DUTY OF CANDOUR

PURPOSE AND INTENDED EFFECT

15. Background

15.1 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. 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.

15.2 The Berwick Report⁸⁰ 'A promise to learn – a commitment to act' emphasised the importance of the requirement that patients 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.

15.3 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 reoccurrence to someone else. Health and care organisations have a responsibility to ensure that all of these are reliably undertaken.

⁷⁹ <http://www.midstaffspublicinquiry.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)

15.4 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

15.5 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'.

15.6 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

15.7 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

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.

Care. It is intended to contribute to improving the safety and quality of health care.⁸⁸

15.8 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' 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.

15.9 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.

15.10 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 received.⁹² 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 has published two reports following reviews of NHS Boards annual reports.^{93 94}

15.11 '*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.

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

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>

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

Ahs

⁹⁴

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

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.

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.

15.12 All care homes, care at home services, childminders, daycare of children, adoption and fostering services, 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.

15.13 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 includes 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 child-minders.

15.14 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.

16. Objective

16.1 The overarching aim of the duty of candour element of the Bill is to support the implementation of a consistent approach across health and social care settings when there has been an unexpected event or incident that has resulted in death or harm.

16.2 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 in this Bill reflects 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.

17. Rationale for Government intervention

17.1 We want the people of Scotland to feel confident when they access our healthcare services and with the introduction of the duty of candour, the aim is to focus on satisfactory outcomes by dealing with the source of the disclosable event which has caused or could cause potential harm (either physically or psychologically). The duty of candour procedure 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.

17.2 The decision to introduce legislation follows on from the introduction of a duty of candour by the Care Quality Commission in NHS England in 2014 which was extended in April 2015 to social care settings.

17.3 The new duty of candour on organisations, established by the Bill and subsequent regulations, 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.

17.4 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.

17.5 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.

17.6 The introduction of a statutory duty of candour contributes to one of the sixteen National Outcomes: we live longer, healthier lives

18. Consultation

Within Government

18.1 We have worked with internal health and social care colleagues to develop legislation around duty of candour. These include Primary Medical Services; Integration and Reshaping Care; and Children's Rights and Wellbeing.

Public Consultation

18.2 The public consultation ran for 12 weeks from 15 October 2014 to 14 January 2015 and a total of 109 responses were received. As table 3 illustrates, the majority of respondents were in favour of the introduction of a duty of candour.

Table 3: Response to consultation question: 'Do you agree that the arrangements that should be in place to support an organisational duty of candour should be outlined in legislation?'

Type of respondent	YES	NO	OTHER*
NHS	72%	20%	8%
Third sector	91%	0%	9%
Professional associations, support agencies, and trade unions	69%	19%	13%
Local government organisations	73%	27%	0%
Scrutiny/regulatory bodies	91%	0%	9%
Partnership bodies	86%	0%	14%
Other organisational respondents	75%	13%	13%
Individual respondents	86%	14%	0%
TOTAL	80%	12%	8%

*respondents who expressed mixed or unclear views

Source: *Proposals to Introduce a Statutory Duty of Candour for Health and Social Care Services: Consultation Analysis, Scottish Government (2015)*

18.3 Respondents who agreed with the introduction of a statutory duty of candour offered different explanations for their position, with some offering explicit support for the benefits of legislative action, while others expressed support for the underlying principles and policy aims which the legislation aimed to promote.

Main themes included:

- Legislation was seen to be a useful lever in bringing about changes in attitudes, practices and behaviour
- A legislative approach with detailed requirements and guidance would ensure that the principle of candour was embedded in all health and social care organisations, and that it was implemented consistently.

18.4 Respondents felt that the development of a culture of openness and honesty would be essential to ensuring safe, high quality health and social care services in Scotland.

19. Business

19.1 We met with a number of relevant organisations following our period of public consultation including care at home and care home providers, a dental practitioner, and representatives of two companies who run independent hospitals.

Some of the key concerns raised round the impact of the duty of candour procedure on organisations included:

- to ensure consistency is sustained by all health and social care
- organisations when reporting adverse events
- training for staff to deal with difficult conversations
- develop a culture of how complaints and learning is embedded
- communication skills for staff
- incident to resolution cost and
- what is to be disclosed

20. Options

Sectors and groups affected

20.1 Option 1: do nothing. Ethically and morally, most health and care professionals are already required to tell people about instances of harm. This duty would remain although there would be no statutory duty on organisations to ensure a culture and organisation that supports a consistent approach to disclosure of adverse events.

20.2 Option 2: to Introduce a statutory duty of candour for organisations providing health and social care. The duty, which is set out in the Bill with the procedure to be detailed in regulations, will require that an organisation acts in an open and transparent way with people when things go wrong. It will outline the minimum requirements that must be in place to support the duty of candour

and require that reports are made to describe the implementation of arrangements.

20.3 Maintenance of the status quo in respect of there already being an existing professional duty of candour, guidance in relation to reporting, organisational responses to harm and established procedures in support of public protection was considered against the need for new statutory arrangements for organisations. The variation in implementation of current guidance and 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.

20.4 Healthcare Improvement Scotland has visited all NHS 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.

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”

20.5 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.

20.6 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.

20.7 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 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.

21. Benefits

21.1 Option 1: do nothing. There would be no change to current policies and practice or to individual professional responsibilities. There would be no additional benefits.

21.2 Option 2: to introduce a statutory duty of candour for health and social care. The legislation aims to make providers of health and social care increase transparency and openness in the organisation, facilitating a culture in which staff is supported to report incidents where harm may have been caused. Staff will be encouraged to speak candidly to service users and /or relatives in the event of harm (including death) resulting from treatment.

22. Costs

22.1 Option 1: do nothing. Ethical, professional and policy guidance is generally insufficient in significantly improving rates of disclosure. Under current policies, there may be a lack of support for professionals from their employer organisations resulting in a reluctance or failure to support adverse events. This in turn means patients and service users are not fully informed, nor do individuals and organisations have the opportunity to learn from any adverse event.

22.2 Option 2: to introduce a statutory duty of candour for health and care services. Although ethically and morally health and care professionals are already required to tell people about instances of harm, by introducing an obligation on organisations which is intended to support a consistent approach to disclosure it is likely to result in an increased number of incidents disclosed. It is also likely to significantly enhance staff wellbeing as a result of improved support and training for disclosure.

22.3 There are likely to be a number of costs associated with the introduction of this legislation and any increase in reporting. The main elements of these costs are:

- apology and review; support, training and implementation; monitoring and finally publication of reports.

Table 4. Costs of disclosure, apology and review

	2016 - 17	2017-18	2018-19 onwards
	Non-recurring costs	Non-recurring costs	Non-recurring costs
Scottish Administration	£100,000	£75,000	£50,000
NHS	—	—	—
Local Authorities	—	—	—
Other bodies	—	—	—
Total	£100,000	£75,000	£50,000

There are no recurring costs.

22.4 The principles and approach that will be made explicit through the duty of candour provisions of the Bill, and Regulations made under those provisions, are consistent with current policy and strategies reflected through work in support of improvements in complaint handling, reporting and learning from adverse events. Current work programmes already established means that there will be no additional cost and additional funding will be made available to support the further training and implementation requirements.

22.5 The Scottish Government does not anticipate any additional cost on the NHS in Scotland arising from disclosure, apology and review of the duty. This element of the provisions is already mirrored in the guidance issued by Healthcare Improvement Scotland through its own Reporting and Learning from Adverse Events Framework.

22.6 Local Authorities already have mechanisms in place to support disclosure, apology and case reviews where there has been an unexpected incident resulting in harm.

22.7 The Scottish Government anticipates that some indirect costs may occur for smaller organisations that do not have existing systems and processes to support disclosure, apology and review of events resulting in harm. We will work with stakeholders to develop a suite of resources and guidance which are intended to support organisations through the process.

23. Savings

23.1 It is possible that there are some incidents that result in harm that would have traditionally been subject to complaints or claims procedures.

24. Support

24.1 The Bill, and regulations made using the powers in the Bill, will require organisations to ensure that support is provided to people who have been affected by unexpected incidents or events resulting in harm. Support will be provided through existing mechanisms and services which will therefore not result in direct costs as a result of this procedure. There may be direct costs where specific training tailored to specific clinical and care staff is needed. The nature of costs will depend on existing staff support services and the range of specialist psychological care provision that is already in place.

Table 5. **Costs of Support***

	2016-17	2017-18	2018-19 Onwards
	Recurring Costs	Recurring Costs	Recurring Costs
Scottish Administration	—	—	—
NHS	£228,000	£230,280	£232,583
Local Authorities	£114,000	£115,140	£116,691
Other bodies	£114,000	£115,140	£116,691
Total	£456,000	£460,560	£465,965

There are no non-recurring costs

*Table 5 is based on the requirement for 10 whole time equivalent Band 6 staff who would be a counsellor/mental health nurse/therapist, allocated in a ratio of 50% to NHS Scotland, 25% to Local Authorities and 25% to other organisations – the ratio being determined by a review of the balance of incidents likely to fall within the duty of candour procedure

24.2 The Scottish Government does not anticipate any additional direct costs arising from the duty of candour procedure as a result of the requirement to provide support. Organisations will require advice and training to implement the support elements of the provisions – this advice and guidance will be developed as part of the wider guidance, training and implementation support costs.

24.3 The Scottish Government anticipates that in most cases the existing resources for support services through staff support and counselling, psychological care and specialist mental service will be sufficient to ensure that people who require support will access this through existing services. It is anticipated that in the cost on local authorities that most cases will be supported through existing services.

24.4 The Scottish Government anticipates that in most cases, for other bodies, individuals and businesses, there will be no direct costs in respect of the

provision for support for people affected. Again, businesses and individuals will access existing services available through NHSScotland.

24.5 In terms of savings, it is likely that the early identification of support needs for staff and people affected by unexpected or unintended incidents resulting in harm will reduce the likelihood of more clinically significant emotional and psychological reactions developing, reactions which would otherwise have required more intensive clinical and care responses through the provision of specialist interventions and support.

Table 6. **Cost of training and implementation**

	2016-17		2017-18		2018-19 onwards
	Recurring	Non-recurring	Recurring	Non-recurring	Recurring
Scottish Administration	—	£182,000	£45,000	—	£25,000
NHS	—	—	—	—	—
Local authorities	—	—	—	—	—
Other bodies	—	£125,000	£15,000	—	£15,000
Total	—	£307,000	£60,000	—	£40,000

24.6 The Scottish Government recognises the importance of ensuring that all organisations which will be required to implement the duty of candour procedure have access to training and implementation support. Training and implementation support resources will be developed for use by all organisations that have to implement the duty. The costs of providing this training are based on training that was developed by NHS Education for Scotland on complaints handling and the power of apology training, which was delivered by workshops as well as DVDs.

24.7 The Scottish Government anticipates that NHS Boards, along with local authorities will be able to incorporate the requirements for the duty of candour procedure within their existing processes to support staff training and induction programmes.

24.8 However, the Scottish Government anticipates that smaller organisations are likely to have additional costs in relation to the requirement for

training to be provided to those staff required to implement the duty of candour procedure. The development of training and implementation resources for these organisations will remove the requirement for organisations to deliver bespoke training.

25. Monitoring

25.1 The duty of candour procedure will require Healthcare Improvement Scotland, the Care Inspectorate and Scottish Government to implement arrangements to monitor the duty of candour procedure. We are working closely with both Healthcare Improvement Scotland and the Care Inspectorate to establish a monitoring group who will assist with this strand of work.

25.2 The Scottish Government does not anticipate any additional cost associated with monitoring of the implementation of the duty of candour provisions of the Bill. The existing procedures currently in place will be developed to incorporate the monitoring of the duty of candour procedure. The Scottish Government does not anticipate that NHS Scotland will incur any additional costs associated with monitoring of the duty of candour. NHS Boards are already required to collate and report information on specified incidents and events as part of procedures already in place as part of requirements such as the NHS complaints procedure and national framework for reporting and learning from adverse events.

25.3 In terms of Local Authorities the Scottish Government does not anticipate any additional costs as they already gather this information as part of public protection procedures. For other bodies, individuals and businesses, there will also be no significant costs of monitoring the duty of candour procedure as this will be incorporated within existing processes of organisations such as Healthcare Improvement Scotland and the Care Inspectorate.

25.4 For those organisations that are not currently regulated by Healthcare Improvement Scotland or the Care Inspectorate, a process will be required to submit a report on duty of candour procedures within their organisations on an annual basis to the Scottish Government. This would require a small amount of additional administrative time, but it is anticipated that some of this burden could be mitigated against by the introduction of an online resource with guidance and templates for producing the report.

26. Publication of Reports

26.1 The duty of candour provisions of the Bill would require that all organisations subject to the duty to submit and publish an annual report. Reports must cover the number and nature of incidents, an assessment of the extent to which the responsible person carried out the duty, information about policies and procedures, any changes to policy and procedure as a result of incidents to which the duty has applied and such other information as the responsible thinks fit.

26.2 The Scottish Government do not anticipate that there would be any significant additional costs for NHS Scotland. Boards are already required to produce reports for a range of monitoring, review and accreditation processes and will be expected to integrate duty of candour reporting within those processes. This will also be the requirement for local authorities.

26.3 Most other organisations which are covered by the duty of candour procedure are regulated by Healthcare Improvement Scotland or the Care Inspectorate and are already required to collate and report information in respect of incidents and complaints as part of their requirements of their registration. The Care Inspectorate collects annual data and information from organisations such as care homes. As part of existing processes, these bodies are required to report to the Care Inspectorate any incidents that occur with service users. The Care Inspectorate has indicated that there would be no additional cost as they would incorporate this as part of their statutory responsibilities.

26.4 The Scottish Government recognise that for some small organisations, this will require some additional administrative time, but it is anticipated that some of this burden could be mitigated against by the introduction of an online resource with guidance and templates for producing the Report.

27. Scottish Firms Impact Test

27.1 The duty of candour procedure will reinforce existing mechanisms for reporting when incidents occur that result in harm. It is intended that the duty of candour provision of the Bill will be about openness, honesty and transparency along with learning and improvement.

During the consultation period there were specific points raised by respondents which include:

- The proposal would present difficulties for certain types of services/organisations (e.g. small community based organisations and prison health services).
- The new duty would need to operate in an integrated way across the health and social care sectors
- Respondents from pharmacy and dental sectors thought the requirement was not practicable or meaningful in small community-based settings and was more relevant to large organisations
- Respondents raised a number of concerns about the monitoring and enforcement of the duty of candour. These largely related to the practicalities of enforcement, and the potential for unintended consequences.

27.2 It was also determined that regulatory relationships with reporting bodies and businesses need to remain open to ensure advice and guidance from Healthcare Improvement Scotland and the Care Inspectorate can be easily accessed when required in order to deal with adverse events when they arise and effectively and thoroughly.

27.3 It will be important to have discussions about guidance and reporting mechanisms in order to support the duty of candour in the Bill. The Scottish Government along with Healthcare Improvement Scotland and the Care Inspectorate will work together with other key stakeholders to this end.

28. Competition Assessment

Will the proposal directly limit the number or range of suppliers?

The proposal will not directly affect the number or range of suppliers of health and/or social care. The legislation will apply to all health and care settings.

Will the proposal indirectly limit the number or range of suppliers?

The proposal will not indirectly affect the number or range of suppliers of health and/or social care. The legislation will apply to all adult health and care settings. It does not constitute a barrier to entry into the market.

Will the proposal limit the ability of suppliers to compete?

The legislation will apply to all adult health and care settings. Much of the activity covered will be within NHSScotland. It will have no impact on competition within the health and social care sector.

Will the proposal reduce suppliers' incentives to compete vigorously?

The legislation will apply to all adult health and care settings. Much of the activity covered will be within NHSScotland. Suppliers within the private sector will all be equally affected. There will be no impact on their ability to compete.

29. Test run of business forms

29.1 No new forms are anticipated

30. Legal Aid Impact Test

30.1 As the new duty of candour provisions do not create any offences, there will be no impact anticipated on the Legal Aid budget.

31. Enforcement, sanctions and monitoring

31.1 Annual reporting will be a requirement of the duty of candour procedure and will be monitored through existing mechanisms to scrutinise and review the quality of care. Our proposals not to introduce civil penalties or criminal sanctions were strongly supported.

31.2 The proposals are intended to make it clear to all those who use health and social care services and all those who provide them what is expected when harm has occurred. The duty of candour procedure will emphasise learning, change and improvement – three important elements that we know will make a

significant and positive contribution to quality and safety in health and social care settings.

31.3 The proposals reflect the Scottish Government's commitment to putting people at the heart of our 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. The duty of candour procedure in Scotland would also sit alongside a range of other activities already being pursued in this area.

31.4 We acknowledge that there are still some parts of our health and social care system where there is not yet a well-developed appreciation of the complexities and common contributors to harm when it happens and it is important that these complexities are managed in a candid manner ensuring all healthcare professionals learn from adverse events to ensure continued learning is adopted and sustained. However, the main consequence of a breach of the duty of candour should be the serving of a notice to a responsible person seeking relevant information and details of the incident and as specified in the notice. However, clear guidelines will be an essential component in terms of notification of incidents by the relevant person and for the purpose of compliance. This will require all relevant information about the incident to be submitted to the relevant organisational body within a specified time frame which will be set out in the serving notice.

31.5 It has been established that implemented guidance will be a key factor to ensuring that alignment, clarity and consistency is sustained and with the assistance from those with practical experience of the issues, we will be able to shape the guidance by on-going testing, learning and change as we identify what works best.

32. Implementation and delivery plan

32.1 The overarching aim of the duty of candour element of this Bill is to support the implementation of a consistent approach across health and social care settings when there has been an unexpected event or incident that has resulted in death or harm. Although there are existing mechanisms and processes currently in place to support the reporting of adverse events for health and social care settings, further development and guidance is needed in order to embed the new duty of candour procedure. This will also include adapting training programmes as well as to ensure staffs feels supported when dealing with difficult conversations as a result of a disclosable event.

32.2 The new guidance will be reviewed and monitored by the Scottish Government and key stakeholders to ensure they are having the desired effect and to ensure consistency is embedded into existing processes.

33. Summary and recommendation

Summary costs and benefits table

Option	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	No benefit	No cost
2	<p>The duty (with the detail of the procedure to be set out in Regulations) will outline the minimum requirements that must be in place to support the duty of candour and require that reports are made to describe the implementation of arrangements.</p> <p>The legislation aims to make providers of health and social care increase transparency and openness in the organisation, facilitating a culture in which staff is supported to report incidents where harm may have been caused. Staff will be encouraged to speak candidly to service users and /or relatives in the event of harm (including death) resulting from treatment.</p>	<p>All healthcare professionals are already obligated to tell people about instances of harm, by introducing an obligation on organisations which is intended to support a consistent approach to disclosure; it is likely to result in an increased number of incidents disclosed. It is also likely to significantly enhance staff wellbeing as a result of improved support and training for disclosure.</p> <p>There are likely to be a number of costs associated with the introduction of this legislation and any increase in reporting. The main elements of these costs are: Apology and review, support, training and implementation, monitoring and finally publication of reports.</p>

Table 7. **Summary of costs of the duty of candour**

	2016-17		2017-18		2018-19 onwards	
	Recurring costs	Non-recurring costs	Recurring costs	Non-recurring costs	Eventual recurring costs	Total Non-recurring costs
Disclosure, apology and review	—	£100,000	—	£75,000	—	£50,000
Support	£456,000	—	£460,560	—	£465,965	—
Training and implementation	—	£307,000	—	£60,000	—	£40,000
Total	£456,000	£407,000	£460,560	£135,000	£465,965	£90,000
TOTAL	£863,000		£595,560		£555,965	

PART 3

OFFENCES OF WILFUL NEGLECT OR ILL-TREATMENT IN HEALTH AND SOCIAL CARE SETTINGS

PURPOSE AND INTENDED EFFECT

34. Background

34.1 People in Scotland receive high quality care and treatment in an array of health and social care situations, the delivery of which is carried out by a variety of dedicated professionals. The vast majority of staff employed in these settings work to the very best of their ability in providing these services. However, as we know from the events elsewhere, for example, at Mid-Staffordshire NHS Foundation Trust, and at Winterbourne View, there can be instances where people receiving care are deliberately mistreated or neglected by those who have been trusted to look after them.

34.2 Although such incidents of deliberate neglect or mistreatment may be uncommon, we need to ensure that the criminal justice system is able to deal with these cases effectively when they arise.

34.3 There are existing offences of wilful neglect or ill-treatment in respect of mental health patients (set out in section 315 of the Mental Health (Care and Treatment) (Scotland) Act 2003 and in respect of adults with incapacity (set out in section 83 of the Adults with Incapacity (Scotland) Act 2000). Both of these offences intentionally relate to narrowly defined groups of people and we feel that there is good reason to extend the offences of wilful neglect or ill-treatment beyond these groups.

35. Objective

35.1 The Scottish Government's proposal is to create offences similar to that which presently exists in relation to mental health patients. The proposed offences would cover the wilful neglect or ill-treatment of adults receiving care or treatment in a range of health and care services.

36. Rationale for Government intervention

36.1 No measure of deliberate neglect or mistreatment is acceptable and we feel that the criminal law should reflect this. Only certain groups are currently covered under the Mental Health (Care and Treatment) (Scotland) Act 2003 and the Adults with Incapacity (Scotland) Act 2000. In order to ensure consistency and address a current gap in legislation, the Scottish Government plans to introduce criminal offences in relation to wilful neglect or ill-treatment beyond these groups to cover all adults receiving care in a health or social care setting.

36.2 The Government has five objectives that underpin its core purpose. This legislation will contribute to two National Objectives: Healthier Scotland and Safer and Stronger.

It will also contribute to two of the 16 national outcomes:

- we live longer, healthier lives,
- we live our lives safe from crime, disorder and danger

37. Consultation

37.1 The legislation has been developed in a collaborative way involving colleagues from across and outwith the Scottish Government.

Within Government

37.2 We have worked with colleagues across the Scottish Government to develop this legislation. This includes, but is not restricted to, the following teams: Primary Medical Services; Integration and Reshaping Care; Children's Rights and Wellbeing; and Criminal Law and Licensing.

Public Consultation

37.3 The formal consultation ran for a period of 12 weeks from 10 October 2014 to 2 January 2015. In general, consultation respondents were supportive of the introduction of the offences 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 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.

Business

37.4 We met with a number of relevant organisations following our period of public consultation including care at home and care home providers, a dental practitioner, and representatives of two companies who run independent hospitals.

38. Options

Option 1: Do nothing

38.1 Under option 1 the situation would remain as it is at present. The offences outlined in the Mental Health (Care and Treatment) (Scotland) Act 2003 and in respect of adults with incapacity in the Adults with Incapacity (Scotland) Act 2000 would remain but there would be no expansion of protection to wider patient/care groups.

Option 2 : create offences of wilful neglect or ill-treatment in health and social care.

38.2 Under option 2 there would be new offences of wilful neglect or ill-treatment which would cover adult health and social care settings, both in the private and public sectors.

39. Sectors and groups affected

39.1 The new offences will apply to all those who provide health or social care for adults. All parts of the justice system, including the Scottish Prison Service, Police and the Crown Office and Procurator Fiscal Service (COPFS), would be affected.

40. Benefits

40.1 Option 1: there would be no action and therefore no additional benefits. There is a potential disbenefit that patients not covered by the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2000 could be at increased risk of suffering wilful neglect or ill-treatment.

40.2 Option 2: this would provide consistency for all users of health and social care, irrespective of their mental capacity or mental health. Everyone in all formal health and social care settings would be afforded access to justice.

40.3 The legislation and associated sanctions may have a deterrent effect. The prevention of ill treatment would then result in benefits for both individuals and society. Should incidents of wilful neglect and/or ill-treatment occur then the legislation would ensure that those responsible were held fully accountable.

40.4 It is not possible to quantify the benefits from deterrent effect, increased consistency and accountability.

41. Costs

41.1 Option 1: there would be no action and therefore no cost to government or to providers of health and social care services. There is a potential cost to those not covered by the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2000 who could be at increased risk of suffering wilful neglect or ill- treatment.

41.2 Option 2: the offence should not create sizable additional costs or liabilities on individual practitioners and/or providers beyond what is normally expected of quality of care. Firms we engaged with during the development of the BRIA were of the view that wilful neglect or ill-treatment was well below the standard of care which they would expect to provide and so not a burden to them in financial or regulatory terms.

Number of cases.

41.3 It is difficult to provide an estimate of how many cases there will be as a result of the new offences. We have based our assumptions on costs relating to the existing offence in relation to people receiving mental health care or treatment. Tables 1 provides the number of prosecutions for wilful neglect or ill-treatment under mental health legislation.

Table 8 — Prosecutions for wilful neglect/ill-treatment under mental health legislation (where main offence)

	Mental Health (Care and Treatment) (Scotland) Act 2003, section 315			Mental Health (Scotland) Act 1984, section 105(1)(a) and (3)		
Financial Year	Prosecutions	Guilty	Not Guilty	Prosecutions	Guilty	Not Guilty
2004-05				1	1	0
2005-06				0	0	0
2006-07				2	1	1
2007-08	1	1	0			
2008-09	1	0	1			
2009-10	2	2	0			
2010-11	1	1	0			
2011-12	3	2	1			
2012-13	8	4	4			
2013-14	4	1	3			

Source: Scottish Government Court Proceedings Database

Number of people affected:

41.4 Within NHSScotland the number of patients treated in acute specialities in 2012/13 was 698,369⁹⁵. Laing and Buisson estimate that across the UK, 1.64 million patients were admitted for surgical procedures in independent hospitals. Pro rata by population this suggests around 136,000 patients in Scotland. However, we know that private health insurance coverage is lower in Scotland than across many parts of the UK and compared with the UK average (8.5% vs. 12%). An estimate of 95,000 is therefore likely to be more realistic and may still be an overestimate. This gives an estimate of 794,000 inpatients across the public and private sector.

41.5 The Care home census of 2013 showed nearly 36,600 individuals resident at the time. These are mainly elderly, over 65 years, but this number includes adults of working age. Excluding those with mental health problems or learning disability leaves 33,687. Around 50,400 of those aged over 65, and 10,500 younger adults received a care home service in 2012-13.⁹⁶ Again, around 4,500 of the younger adults have mental health or learning disabilities: excluding them gives a total across residential and home care of approximately 90,000 individuals.

41.6 It is acknowledged that many of the above individuals may also access hospital services in the course of a year so this may be an overestimate.

41.7 GP services, dentists, A&E attendances and ambulance journeys have been excluded from this estimate (which may counter the previous overestimate)

⁹⁵ <http://www.isdscotland.org/Health-Topics/Hospital-Care/Inpatient-and-Day-Case-Activity/>

⁹⁶ <http://www.scotland.gov.uk/Topics/Statistics/Browse/Health/Data/HomeCare/HSCDHomecare>

as it is considered that there is a lower risk of wilful neglect or ill-treatment, mainly due to the relatively short time that would be spent in those settings although the offences will apply in these settings.

41.8 So although not exhaustive, this initial estimate suggests that around 884,000 additional users of health and social care services in Scotland would be covered by extending the legislation.

41.9 The rate of prosecutions for the existing mental health offence has been used in producing an estimate for the number of prosecutions for the new offence. Taking an average of 2 prosecutions per year for the section 105 and 315 offences, per 15,401 patients receiving mental health care or treatment, and then applying this rate to an estimated 884,000 additional users of health and social care services in Scotland who would be covered by extending the legislation, gives an estimate of a potential 100 prosecutions per year. However, this is likely to be an overestimate as those receiving mental health care or treatment are likely to be more vulnerable and therefore at greater risk of suffering ill-treatment or wilful neglect. There are also possible differences in reporting rates which are not taken into account in this calculation.

Scottish Government:

41.10 There may be some small costs associated with informing the public of the new offences, similar to the publicity provided for the provisions of the Adult Support and Protection (Scotland) Act 2007.

SG/NHS Boards/providers

41.11 NHS Education for Scotland (NES) would need to consider if it was appropriate to update existing staff training materials to reflect the new offences.

Justice system

41.12 Should there be additional cases identified under the extension of the legislation then there would be costs for the police, Crown Office and Procurator Fiscal Service (COPFS), the Scottish Courts and Tribunals Service (SCTS), the Scottish Prison Service (SPS), the Scottish Legal Aid Board (SLAB) and defendants.

41.13 Table 9 sets out the average costs of criminal procedures (assuming all cases are heard in the Sheriff Court). For the new offences, based on calculations of an additional 100 cases per year, and assuming the same split between summary and solemn procedure, the additional cost to the criminal justice system would be around £300,000 per year (as set out in tables 9, 10 and 11). It currently costs £33,153 per year to keep a person in custody. It is difficult to usefully predict how many people will be imprisoned as a result of the new offences, but if one person is held in custody for a period of three years then this would cost £100,000. While sentencing will be for the courts, it is expected that more minor offences will not attract a prison sentence and so the overall impact on prisons will be minimal.

Table 9 — Unit cost of criminal procedures

	Average prosecution costs per procedure (COPFS)	Average court costs per procedure (SCTS)	TOTAL (excluding legal aid costs)	Average legal assistance costs per procedure (SLAB)	TOTAL (including legal aid costs)
Sheriff Court Solemn Procedure	£5158	£1743	£6901	£1892	£8793
Sheriff Court Summary Procedure	£342	£357	£699	£612	£1311

Source: Costs of the Criminal Justice System in Scotland Dataset (2013)

Table 10 — Costs of estimated 100 cases per year

Procedure	Number of cases	Cost per case*	TOTAL*
Sheriff Court Solemn Procedure	21	£6901 - £8793	£173,301 - £184,653
Sheriff Court Summary Procedure	79	£699 - £1311	£91,329 - £103,569
TOTAL COST			£264,630 - £288,222

**Ranges illustrate the differences in costs between 75% and 100% of defendants receiving legal aid.
Totals may not add up due to rounding.*

Table 11 — Breakdown of estimated costs by organisation

	Sheriff Solemn*	Sheriff Summary*	TOTAL*
Number of cases	21	79	100
COPFS	£108,318	£27,018	£135,336
SCTS	£36,603	£28,203	£64,806
SLAB	£28,380 - £39,732	£36,108 - £48,348	£88,080
Total	£173,301 - £184,653	£91,329 - £103,569	£264,630 - £288,222
Totals (rounded)	£173,000 - £185,000	£91,000 - £104,000	£265,000 - £288,000

**Ranges illustrate the differences in costs between 75% and 100% of defendants receiving legal aid. Totals may not add up due to rounding.*

Defendants

41.14 Should prosecutions result from the legislation, defendants, unless they are eligible for legal aid, may incur the costs of mounting a defence. We are not, at present, able to quantify these. Tables 10 and 11 provide figures based on 75% and 100% of defendants claiming legal aid.

42. Scottish Firms Impact Test

42.1 This proposal is designed to reinforce a culture of safety and quality for people in Scotland in all health and social care settings and secure access to justice for those ill-treated or neglected. There has been consultation with five Scottish firms who may be affected by these proposals, although it should be noted that the proposals place no duties on business. The firms were of the view that wilful neglect or ill-treatment was well below the standard of care that they would expect to provide and therefore not a burden to them in financial or regulatory terms. A view was expressed that some firms may want to publicise the new offences to staff as part of their training material but that any cost in doing so was likely to be minimal.

43. Competition Assessment

1. Will the proposal directly limit the number or range of suppliers?

The proposal will not directly affect the number or range of suppliers of health and/or social care. The legislation will apply to all adult health and care settings.

2. Will the proposal indirectly limit the number or range of suppliers?

The proposal will not indirectly affect the number or range of suppliers of health and/or social care. The legislation will apply to all adult health and care settings. It does not constitute a barrier to entry into the market.

3. Will the proposal limit the ability of suppliers to compete?

The legislation will apply to all adult health and care settings. Much of the activity covered will be within NHSScotland. It will have no impact on competition within the health and social care sector.

4. Will the proposal reduce suppliers' incentives to compete vigorously?

The legislation will apply to all adult health and care settings. Much of the activity covered will be within NHSScotland. Suppliers within the private sector will all be equally affected. There will be no impact on their ability to compete.

44. Test run of business forms

44.1 No new forms for business are anticipated.

45. Legal Aid Impact Test

45.1 The proposals create new criminal offences of wilful neglect or ill-treatment and therefore will affect the Legal Aid budget. However, we do not see a major impact on the legal aid fund or on SLAB's management of applications.

46. Enforcement, sanctions and monitoring

46.1 The provisions will detail the penalties for those individuals and organisations convicted of the offences.

47. Implementation and delivery plan

47.1 Enforcement will be carried out by Police Scotland and the Crown Office and Procurator Fiscal service. Subject to completing the Parliamentary process, the provisions will be commenced in 2016.

48. Post-implementation review

48.1 A review process will be considered.

49. Summary and recommendation

49.1 Option 2 is the option on which the Scottish Government has consulted and now intends to proceed with.

- **Summary costs and benefits table**

Option	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	No benefit.	No cost.
2	Increased access to justice for those who have been ill-treated or wilfully neglected in health and social care settings. Possible deterrent effect.	Estimated additional cost to the criminal justice system of £300,000. Negligible cost to business as the offence is not a regulatory burden.

ANNEX A: HEALTH (SMOKING, NICOTINE ETC. AND CARE) BILL 2015: COMPETITION ASSESSMENT

1. This competition assessment analyses the likely economic impact of the proposals to restrict the domestic advertising and promotion of NVPs on the competitive ability of producers and retailers and the consequent impact on consumers.
2. The proposal seeks to introduce a ban on domestic advertising and promotion of NVPs with the exception of point of sale, which would continue to allow distribution of information about, and the accessibility of, NVPs. This is aimed at adult smokers to enable them to make informed choices about whether to use NVPs. The types of advertising that would be affected are: advertisement by way of billboards, leafleting, brand sharing, free distribution, nominal pricing, and domestic advertising events.
3. This would be implemented in addition to the introduction of the European Tobacco Products Directive (TPD), due in 2016, and the CAP and BCAP rules which apply across the UK. The TPD requires member states, by May 2016, to implement a ban on cross-border advertising and promotion to primarily protect young people. The cross-border forms of advertising and promotion of NVPs which will be banned include: telecommunications (communication over a distance by cable, telegraph, telephone, or broadcasting), radio, internet, most publications (e.g. newspapers) and events marketing with a cross-border effect (such as televised sporting events).
4. In November 2014, the UK Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP) published new non-statutory advertising rules for NVPs to ensure they continue to be promoted in a responsible way⁹⁷. The Committees 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.

Definition of competition

5. Competition is a process of rivalry between firms seeking to win customers' business. This process of rivalry, where it is effective, encourages firms to deliver benefits to customers in terms of prices, quality and choice. Where levels of rivalry are reduced (say because a proposal restricts the number of firms active in any market) customers have less choice because they have fewer firms from which they can buy goods or services.
6. Firms compete for market share using both price and non-price competition. Competition between firms may focus on offering the lowest price, particularly where the product is standardised (either because of the characteristics of the product in

⁹⁷<http://www.cap.org.uk/News-reports/Mediacentre/2014/~media/Files/CAP/Consultations/ecig%20consultation/Regulatory%20Statement.ashx>

question, or because of regulation). Most suppliers will try and compete in a number of ways in addition to price, for example by developing new 'improved' products, by offering products of differing quality or characteristics, by branding and advertising the differences in their products relative to their competitors', or by using different sales channels.

Definition of markets

7. The Competition and Markets Authority have 4 competition filter questions which can be used as an initial assessment of competition. These are as follows:

Will the proposal directly limit the number or range of suppliers?

Will the proposal indirectly limit the number or range of suppliers?

Will the proposal limit the ability of suppliers to compete?

Will the proposal reduce suppliers' incentives to compete vigorously?

8. Markets and sectors which could potentially be affected both directly (downstream) and indirectly (upstream) have been identified and are listed below.

Directly affected markets/sectors (downstream):

- Sales of NVPs
- Sales of other products by retailers which sell e cigarettes

Indirectly affected sectors (upstream) might include:

- E cigarette manufacturers
- Distributors/wholesalers

Overview of industry

NVPs

9. There is no one simple definition of an "NVP". These are relatively new products which continue to evolve in form, and defining them is not straightforward. They are also known by a range of terms. NVPs or electronic cigarettes 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, etc)

10. Electronic cigarettes/NVPs are consumer products which deliver a vapour, which may or may not contain nicotine, for inhalation by an individual. In the Bill a 'nicotine vapour product' is defined as:

- (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).

It does not include medical products or devices, nor does it include tobacco or smoking related products.

11. The proposal examined in this competition assessment covers devices and liquids which do not contain nicotine as well as those which do. Most NVPs are used with some nicotine content. 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 in different concentrations; and most products contain flavouring. A huge variety of flavours are available, including menthol (the most popular), tobacco, and a vast range of fruity and sweets-based ones (such as caramel, cherry cola, chocolate, bubble gum, vanilla ice cream, and gummy bear flavours). Flavour is understood to be an important dimension of their appeal for smokers who wish to reduce or stop their tobacco use.

12. Inclusion of products which do not contain nicotine in the proposal is on the basis of two factors in particular. One is that it would be extremely impracticable for enforcement authorities to test individual products. 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 hypothetical re-normalisation of smoking behaviours. In addition some devices are re-fillable and so even if the original liquid did not contain nicotine, a refill could.

13. These detailed descriptions illustrate that NVPs are not a standardised product. Producers and suppliers may be involved in the production and/or supply of a part of the device, e.g. liquids, or the device itself, or both.

14. Electronic cigarettes or NVPs were invented in China in 2003 and were initially designed for the delivery of inhaled doses of a vapour which contains nicotine. They were introduced to Europe around 2005 and, in the past five years especially, their availability and their popularity have rapidly increased. Most NVPs are manufactured in China. The products have evolved and diversified considerably and there is now a wide variety of devices on the market, produced by a diversity of manufacturers. Worldwide there is estimated to be more than 500 brands, but the contents of very few have been independently analysed. Products can be poorly or incorrectly labelled and the quality and safety of different devices and liquids are inconsistent. The introduction of the TPD will help address these issues.

15. The Scottish Government is aware of only one manufacturer in this market in Scotland. It manufactures e-liquids. There are no manufacturers of NVPs in Scotland. The Scottish manufacturer of e-liquids sells its liquids within and outwith Scotland. The Scottish Government does not have data on how much of its revenue is generated from Scottish sales.

16. The model of ownership across the industry is diverse: from small independent companies to multinational tobacco companies including PMI, Japan Tobacco and Lorillard. This is a young industry with products and market structure still evolving. ECigIntelligence estimate that the UK market was worth £225 - £300 million in 2014⁹⁸. They observed a number of mergers and acquisitions in 2014. It

⁹⁸ ECigIntelligence: *Territory report : e-cigs in the UK - Market and regulatory analysis* October 2014.

seems likely that as the market continues to mature, there will be consolidation, with many mainstream brands wholly or partly owned by large tobacco companies.⁹⁹

17. In consultation with Scottish Government the Electronic Cigarette Industry Trade Association (ECITA) were able to identify¹⁰⁰ 405 electronic cigarette businesses in the UK, the majority being independent small and medium sized enterprises (SMEs) and only 6 being tobacco owned. ECITA also identified that 12 of these companies (1 tobacco owned) were based in Scotland. They estimate that turnover in the industry is approximately £2bn per annum in the UK supporting 41,000 jobs, 1,200 of which are in Scotland. The Scottish Government cannot validate these figures. It is not possible to identify employment in the industry from National Statistics.

18. There is also diversity in retail locations. Consultation responses suggest that outlets that already retail conventional tobacco cigarettes are also likely to sell NVPs. Tobacco retailers range from small corner shops to supermarkets and in Scotland must be registered on the Scottish Tobacco Retailers Register in compliance with the Tobacco and Primary Medical Services (Scotland) Act 2010. In 2013 Nielsen estimated that the UK spend on electronic cigarettes in convenience stores was over £90m. As of September 2014, there were 9,803 retail premises selling tobacco products on the Register in Scotland. In addition e cigarettes are sold in specialised NVP shops, pop-up shops and stalls, and lounges. Many of these outlets individually represent a very small volume of sales. A survey carried out by Trading Standards Officers in various Local Authorities in Scotland confirmed the breadth of types of retailers selling e cigarettes.

19. The number of specialist shops continues to grow. *Convenience Store*¹⁰¹ reported in Dec 2014 that there were 600 across the UK with more continuing to open. ECigIntelligence¹⁰² state convenience stores, supermarket and petrol stations are the predominant retail outlets. It seems likely that the number of retail outlets is significantly larger than simply the number on the tobacco register but it is not possible to quantify, with any degree of accuracy, how many retailers there are in Scotland.

20. In addition much of the sales volume takes place via the internet, in particular for experienced users and the refillable e-cigs market¹⁰³. *Convenience Store*¹⁰⁴ reported in December 2014 that Nielsen estimated that 45% of sales are now online¹⁰⁵. UK firms, including those based in Scotland, have an internet presence. The internet is becoming a very cluttered market place with a large number of firms and a diversity of products available.

⁹⁹ Quelch, J and Rodriguez, M. (2014) E-cigarettes: Marketing versus Public Health, *Harvard Business Review*, 16 September 2014.

¹⁰⁰ Correspondence with ECITA Feb 2015

¹⁰¹ <http://www.conveniencestore.co.uk/news/e-cigarette-sales-hit-a-wall-in-grocery-stores/511008.article>

¹⁰² ECigIntelligence: *Territory report : e-cigs in the UK - Market and regulatory analysis* October 2014.

¹⁰³ Ibid.

¹⁰⁴ <http://www.conveniencestore.co.uk/news/e-cigarette-sales-hit-a-wall-in-grocery-stores/511008.article>

¹⁰⁵ This estimate is consistent with

21. In a report commissioned by Public Health England,¹⁰⁶ Bauld et al found that NVP companies use a wide variety of advertising and marketing strategies. These include celebrity endorsements, competitions, mobile phone apps, discount vouchers, and computer games, as well as more traditional forms such as billboards, magazines, print media and television. Across the UK, in 2013, they reported that approx £8m was spent by 4 large brands – Skycig, Vype, Gammucci and E-lites. The report concluded that both independent manufacturers and those owned by tobacco companies were investing in almost every kind of advertising and promotion available.

22. Data on marketing spend within Scotland is limited. Nielsen data suggest that over 3 years from 1st Jan 2012 approximately £828k was spent on outdoor advertising for e cigarettes in Scotland.

23. One of the features of NVPs that is emphasised in marketing and advertising is the claim that they are a cheaper alternative to smoking. As described, this is not a market with an homogenous product. Table 1 shows the price of some typical products.

Table 12. Average prices of products available in the Scottish market Feb 2015

Average prices of products available in the Scottish market Feb 2015					
Ciga like starter kit	Cartomiser	Disposable	tank starter kit	clearomiser	10ml e liquid
£13.99	£2.09	£5.98	£20.34	£4.42	£4.49

Source: ECigIntelligence: *Electronic cigarette market in Scotland* : February 2015

24. Websites for retailers of NVPs may contain claims around the value of the financial savings that a smoker might make if switching to e cigs and also a calculator to allow individuals to estimate their own potential savings¹⁰⁷. It is not possible to validate these estimates as they are based on assumptions of patterns of use. The pattern of usage with NVPs, and different types of NVPs, is at present under researched. In a report commissioned by the Scottish Government¹⁰⁸ ECigIntelligence estimated that the value of sales of electronic cigarettes in Scotland in 2015 would be £30-42 million.

25. ASH has estimated that around 2.1 million adults in Great Britain use electronic cigarettes, up from an estimated 700,000 users in 2012.¹⁰⁹ UK surveys

¹⁰⁶ Bauld L et al *E-cigarette uptake and marketing* : A report commissioned by Public Health England . May 2014

¹⁰⁷ E.g <http://www.ecigarettedirect.co.uk/extra-info/save-money.html>

¹⁰⁸ ECigIntelligence: *Electronic cigarette market in Scotland* : February 2015

¹⁰⁹ ASH (Action on Smoking and Health). 2014 *Use of electronic cigarettes in Great Britain*. http://www.ash.org.uk/files/documents/ASH_891.pdf

showed a rapid increase in use by smokers from 2.7% in 2010; to 6.7% in 2012,¹¹⁰ to 18% in 2014.¹¹¹ This suggests that in Scotland there will be around 180,000 users. (*pro rata with population size: Scottish population is approx. 8.6% of GB*¹¹²). So far studies have consistently shown extremely low levels of experimentation in non-smokers (ranging from 0.1-3.8%)¹¹³ and limited use by people under the age of 18.

Impact on producers, wholesalers, retailers

Will the proposal directly limit the number or range of suppliers?

26. The proposal will not directly limit the number or range of firms within the market.

Will the proposal indirectly limit the number or range of suppliers?

27. The proposal may indirectly result in a reduction in the number of firms in the market. Restrictions on advertising remove firms' ability to use certain types of advertising. This will constrain the type of non-price competition open to them as they will be restricted in their ability to communicate product information via the types of advertising affected (advertisement by way of billboards, leafleting, brand sharing, free distribution, nominal pricing, and domestic advertising events). This may be particularly disadvantageous to small start-ups with limited budgets for advertising and marketing. It is difficult to predict the impact but at its most extreme it might result in the failure of some, especially, small companies. The cross national nature of the industry, however, should be considered. Although the BCAP/CAP advertising rules and the TPD restrictions will apply across the UK, these proposals are restricted to Scotland. The SG is not aware of proposals to restrict domestic advertising in other countries of the UK. This may mitigate the impact on individual companies who trade across all countries of the UK.

28. To date, this has been an industry characterised by many small independent companies, although recent acquisitions by large tobacco companies mean that the structure of the market is changing. They have tended to acquire companies

¹¹⁰ Dockrell M, Morrison R, Bauld L, McNeill A. (2013) E-cigarettes: prevalence and attitudes in Great Britain. Nicotine and Tobacco Research 2013 Oct;15(10):1737-44. (<http://www.ncbi.nlm.nih.gov/pubmed/23703732>).

¹¹¹ 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 e-cigarettes <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-e-cigarettes--and-the-relationship-to-smoking>

¹¹² Population Estimates Summary for the UK, mid-2013 <http://www.ons.gov.uk/ons/taxonomy/index.html?nscl=Population#tab-data-tables>

¹¹³ 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>

This review of international studies (up to February 2014) published in a leading journal summarised prevalence data from published sources. It found that prior to 2009, e-cigarette use was negligible but thereafter increased rapidly across Europe and the USA. Some surveys suggest that users are younger, more educated and have a higher income, which is consistent with the expected profile of early adopters of novel consumer products.

producing the cigalike form of product, not just because of their physical form but also because they fit well with their existing marketing and distribution networks¹¹⁴.

29. Restrictions on advertising will act as a barrier to entry to new entrants as they will be restricted in their ability to communicate product information via the types of advertising affected (advertisement by way of billboards, leafleting, brand sharing, free distribution, nominal pricing, and domestic advertising events). This may be particularly disadvantageous to small start-ups with limited budgets for advertising and marketing.

30. Restrictions on the ability to offer new products free, or with nominal pricing so that consumers can sample a product, closes off another possible marketing device for new entrants.

Will the proposal limit the ability of suppliers to compete?

31. The proposal constrains the type of non-price competition open to them as they will be restricted in their ability to communicate product information via the types of advertising affected (advertisement by way of billboards, leafleting, brand sharing, free distribution, nominal pricing, and domestic advertising events). This may be particularly disadvantageous to small start-ups with limited budgets for advertising and marketing.

32. Restrictions on advertising could dissuade product development and innovation as, in conjunction with the restrictions proposed by the TPD, there would be extremely limited means of communicating these to the consumer within Scotland. Again, the international nature of the industry may facilitate continued product development and innovation.

Will the proposal reduce suppliers' incentives to compete vigorously?

33. It is difficult to predict the impact of the advertising restriction on this market. It is a market with many diverse products, not all in direct competition with each other. The lack of ability to use particular forms of advertising may lead to an increase in price competition. Currently, it is seen as a market with high profit margins. The figure of 40% is often quoted¹¹⁵. It seems unlikely that this level of profit margin will be maintained as the market matures.

Impact on consumers

34. Consumers will experience reduced exposure to advertising about e cigarette products. For children, this protects them from marketing about (what is proposed to be) an age restricted product¹¹⁶. For adults who use NVPs this could result in them having limited product knowledge resulting, effectively, in a reduction in consumer choice.

35. Equally the restriction on offering the product free, or at a nominal price, to allow consumers to sample the product prior to purchase may reduce consumers

¹¹⁴ ECigIntelligence: *Territory report : e-cigs in the UK - Market and regulatory analysis* October 2014.

¹¹⁵ Scottish Grocer, March 2013

¹¹⁶ As noted in the BRIA many retailers already operate a voluntary ban on sales to under 18s

ability to gain experience of a breadth of products, or a new product, thus restricting consumer choice.

36. For adults who have not yet used NVPs, the Scottish Government anticipates that a reduction in advertising would result in a reduction in the number of adults who are motivated to buy them for the first time.

37. Point of sale advertising is not affected so consumers would still be able to access this, however, it may be that point of sale in any one retail outlet would not cover a large range of products. So although information will be available consumer choice is likely to be limited.

38. It should be noted that it is estimated¹¹⁷ that almost half of e cig sales are made via the internet. Limited information about products will continue to be available there.

39. It is difficult to predict the resulting impact on retail price. In some parts of the market, if restriction on advertising results in a smaller number of firms and less competition, there may be an increase in price. Conversely the restrictions on the type of advertising permitted may lead to an increase in price competition. Consumers could then benefit from lower prices.

¹¹⁷ Neilsen 2015

Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed: 

Date: 1st August 2015

Maureen Watt
Minister for Public Health

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