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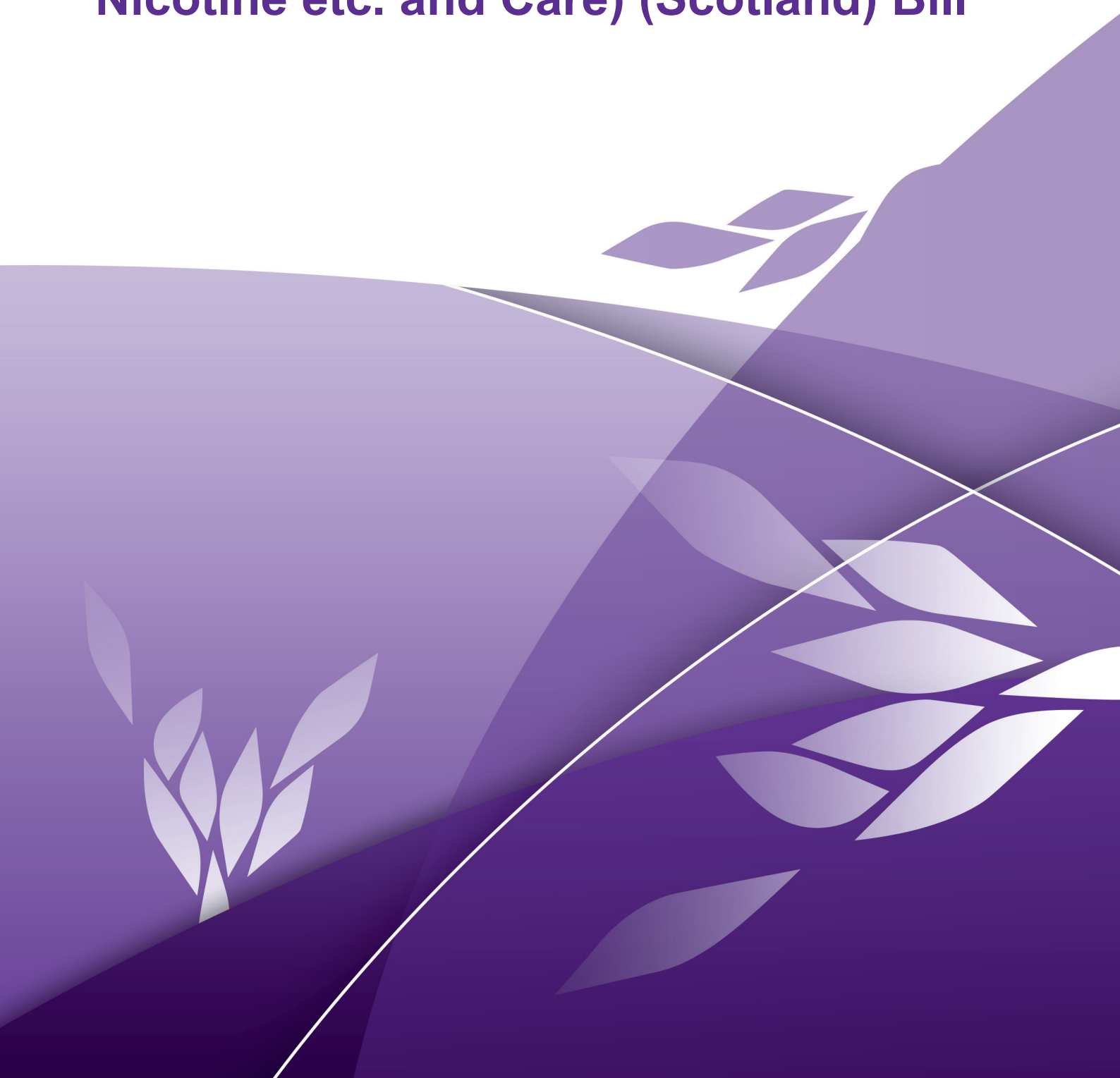
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Web

Health and Sport Committee

Stage 1 Report on Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill



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Health and Sport Committee

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Health and Sport Committee

To consider and report on health policy, the NHS in Scotland, sport and other matters falling within the responsibility of the Cabinet Secretary for Health, Wellbeing and Sport, and measures against child poverty.



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Note: The membership of the Committee changed during the period covered by this report, as follows:

Malcolm Chisholm replaced Richard Simpson on 2 September.

Introduction

1. The Health (Tobacco, Nicotine etc. and Care)(Scotland) Bill (hereafter referred to as “the Bill”) was introduced on 4 June 2015 by the Cabinet Secretary for Health, Wellbeing and Sport, Shona Robison MSP.
2. The Bill is in 3 parts and proposes to:

Part 1: Introduce controls on the sale of Nicotine Vapour Products (NVPs), such as e-cigarettes, as well as powers to restrict or prohibit domestic advertising of NVPs. It also proposes further controls on the sale of tobacco and seeks to make it an offence to smoke tobacco in a designated zone outside of buildings on NHS hospital sites.

Part 2: Introduce a ‘duty of candour’ for health/care organisations.

Part 3: Introduce offences of wilful neglect and ill-treatment for health/care professionals and organisations.
3. This report considers the evidence received by the Committee on each part of the Bill, and provides the Committee’s views and recommendations on the Bill as well as whether to recommend to the Parliament that the general principles of the Bill be agreed to. The report also identifies two areas where the Scottish Government proposes Stage 2 amendments and on which the Committee has yet to take evidence.
4. In order to inform our scrutiny of the Bill we issued a call for written evidence between 3 July and 5 August 2015 and then took oral evidence from witnesses and the Scottish Government. (Please see Annexe A for the full list of those who provided written and oral evidence). Where this report refers to “respondents”, this means the responses received to our call for written submissions unless otherwise stated.
5. In relation to part one of the Bill we also sought to engage a wider audience in the Committee’s scrutiny through use of an online survey¹; Facebook; youth events held in the Parliament over the summer, as well as video blogs from a Festival of Politics event held in the Scottish Parliament and with the Inverclyde Youth Council. We also met informally with members of Haemophilia Scotland, the Scottish Infected Blood Forum and the Hepatitis C Trust as well as staff members from Ardgowan Hospice in Greenock.
6. We thank all those who provided the Committee with evidence which has been



Meeting with Haemophilia Scotland, the Hepatitis C Trust and the Scottish Infected Blood Forum

invaluable in helping us to reach our views.

7. The Finance Committee² and Delegated Powers and Law Reform Committee³ also considered and reported on the Financial Memorandum and the delegated powers within the Bill. Where appropriate we have included their recommendations within this report.

Executive Summary

General Principles of the Bill

8. We support the general principles of the Bill and recommend that the Scottish Parliament agrees to them.
9. Whilst we make a number of recommendations aimed at improving the Bill, our views on each of the key areas of the Bill can be summarised as follows:
 - a. We consider that the Bill provides a necessary and proportionate approach to restricting the sale and advertising of Nicotine Vapour Products whilst the evidence base on their potential harm and impact on smoking cessation continues to develop.
 - b. We agree with the Bill's proposal to provide for an enforceable area in hospital grounds within which smoking is prohibited, albeit we support a different approach to that proposed by the Scottish Government in relation to how the limit of that area is determined in subsequent regulations.
 - c. We support the duty of candour proposed in the Bill as enabling health and social care organisations to learn from incidents of unintentional harm and improve their care so that such harm does not arise in future.
 - d. Finally we agree with the creation of new offences of ill-treatment or wilful neglect that would apply to adult health and social care workers and to adult health and social care providers. These extend similar provisions that already exist for some patients in some health settings to all health and social care settings thereby recognising a wider range of circumstances when people may be vulnerable to ill-treatment or neglect.

Specific parts of the Bill

Part 1 – Restricting the sale of Nicotine Vapour Products

10. The Bill proposes to introduce restrictions on the sale of nicotine vapour products (NVPs) such as e-cigarettes. These restrictions will include: a minimum purchase age of 18; a requirement for NVP retailers to register on the tobacco retailer register, and the power to restrict or prohibit domestic advertising and promotions.

11. The Policy Memorandum (PM) for the Bill describes the main objectives of part 1 of the Bill as supporting the aims of its tobacco control strategy- *Creating a Tobacco-free Generation*.⁴ This strategy sets a target to reduce smoking prevalence rates to 5% or less by 2034. The PM explains that “whilst adult smoking rates in Scotland have fallen from 31% in 1999 to 23% in 2013, in order to achieve a tobacco-free generation additional legislation and policy measures are necessary. This Bill forms part of the wider tobacco control policy approach whilst addressing the new and expanding area of Nicotine Vapour Products (NVPs)”.⁵

Help versus Harm

12. ASH Scotland estimated that there are currently 2.6 million adults in the UK using electronic cigarettes. Of these 1.1 million are ex-smokers while 1.4 million continue to use tobacco along with their electronic cigarette use.⁶
13. In its PM the Scottish Government recognises that NVPs provide opportunities as well as challenges for public health, internationally and within Scotland. NVPs may prove a useful cessation tool for some smokers but there is not the weight of evidence from good quality clinical trials and longitudinal data which would allow the public health community to advocate their use or advise on how they can be used, in an attempt to quit.⁷ As a result, the Scottish Government explains that it is taking an in-part precautionary approach in the Bill aimed at limiting the likelihood of potential future negative impacts of using NVPs on health and tobacco control.
14. During our evidence-taking the findings from different research studies were published on different aspects of NVPs; some supported the view that NVPs can help smokers reduce their smoking. Following a recent review of the available evidence, Public Health England concluded:

” “While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals that are present pose limited danger. It had previously been estimated that EC [e-cigarettes] are around 95% safer than smoking. This appears to remain a reasonable estimate.”⁸
15. In light of the available evidence, Public Health England concluded that:

” “Emerging evidence suggests some of the highest successful quit rates are now seen among smokers who use an e-cigarette and also receive additional support from their local stop smoking services.”
16. We heard similar views from witnesses such as Professor Bauld of the University of Stirling, who explained that global evidence suggests that the best way to stop smoking involves a combination of using a stop smoking aid (such as Nicotine Replacement Therapy (NRT) or NVPs) and support from a trained person but that—

” “A recent study shows that people in the UK who stop smoking using electronic cigarettes are 60 per cent more likely to be successful at stopping smoking than those who use will power alone or who buy nicotine replacement therapy over the counter.”⁹

17. Such views were borne out by the responses to our online survey with comments such as—

” “I smoked for 30 years, tried everything to stop – only Vaping has worked.”¹⁰

18. NHS Ayrshire and Arran highlighted that they would like more evidence on "which e-cigarettes products work best" as it is difficult for those in the smoking cessation field to say "This product will work for you or that product won't".¹¹

19. The Committee received evidence from some witnesses that the public and healthcare professionals' perception of the harm of NVPs is exaggerated and does not reflect the evidence that they are less harmful than tobacco. Some witnesses therefore called for consistent guidance for healthcare professionals on the appropriate way to treat an NVP user.¹² Other witnesses highlighted concerns that if NVPs are treated like tobacco in society then it will be more difficult for the public to consider them as a better alternative to smoking.

20. The Committee heard that nicotine when it is delivered in a cleaner form is not a harmful drug and in that regard the harm from smoking relates to the other 4,000 chemicals in combustible nicotine.¹³ The New Nicotine Alliance explained that —

” “The risk from e-cigarettes is probably 95% less than that from tobacco but there is room for improvement.”¹⁴

21. Professor Bauld explained that nicotine is dependence forming but primarily in tobacco where it is thought that some of the other constituents in tobacco work with the nicotine “to really hook people”. The nicotine in NRT on the other hand is not dependence forming, people do not generally get hooked on NRT and people do not continue to buy it and use it—

” “The evidence we are seeing is that people are not as reliant on the nicotine in e-cigarettes as they are on nicotine when they are smoking. Although we need longer-term studies to really understand the relationship in e-cigarettes.”¹⁵

22. Therefore whilst witnesses suggested that NVPs may be less harmful than smoking cigarettes they are not harmless. Witnesses such as the Electronic Cigarette Industry Trade Association (ECITA) elaborated on this explaining that whilst much is known about the basic chemistry of NVPs including what the product is made up of and how the chemicals behave in combination when heated up, what is less well known is the long term impacts on the lungs of inhaling products (whether such products include nicotine or not).¹⁶ In that regard ECITA

stressed it was important that standards and rules for manufacturing should be put in place.

23. ASH Scotland highlighted that whilst NVPs are not as harmful as tobacco—

“There have been one or two flavourings that have had immediate risks attached, such as butterscotch, with diacetyl, and cinnamon, particularly when they are heated at high temperature, which is another factor.”¹⁷

24. NHS Western Isles explained that "E-cigarettes are not harmless. The best health outcomes still come from being free from any addictive substances and the measures to protect young people from the commercial interest who would sell them such devices are justified and proportioned".

25. Article 20 of the EU Tobacco Products Directive (TPD) which is intended to come into force in May 2016 will introduce a two-tier system in which NVPs that contain more than 20mg/ml of nicotine will have to be licensed as medicines, whilst those products below 20 mg/ml will be allowed to remain as consumer products.¹⁸ The Committee heard that this, in practice, will mean that products over 20mg/ml will cease to be sold due to the requirements and cost associated with medicinal licensing.¹⁹ Under the TPD all ingredients and the nicotine content must be listed. Health warnings, instructions for use and information on addictiveness must also appear on packaging and any accompanying information leaflet.

26. The European Court of Justice (ECJ) is currently considering a challenge to article 20 of the directive from a UK e-cigarette manufacturer and retailer (Pillbox 38 Ltd, trading name "Totally Wicked"). The company is challenging article 20 on a number of grounds, including that it is a disproportionate restriction to the free movement of goods. The Advocate General is expected to issue her opinion in December 2015 with the ECJ ruling sometime after that. Depending on the ruling, the expected enactment date of article 20 may be affected. (Case [C-477/14](#))

27. ECITA explained that "We hope to see a shift towards doing more testing and providing better information to consumers ahead of tobacco products directive implementation".²⁰

28. In evidence the Minister for Public Health explained that—

"My worry is that we simply do not know enough about the long-term effects of NVPs....In drafting the legislation we felt we needed to be cautious and tread a very fine line between promoting NVPs as healthy products for stopping smoking and promoting them as things that people can use as a recreation."²¹

29. The Committee agrees with the Scottish Government and witnesses that, given the evidence base on the long-term harm of using NVPs is still developing, it is prudent to take a proportionate and balanced approach to the availability for sale of NVPs.
30. From the evidence we received, NVPs do have a role to play as a useful smoking cessation tool alongside trained support.
31. We recommend that the Scottish Government considers whether the NHS should provide national guidance on the currently known risks and benefits of using NVPs to stop smoking. This would assist those wanting to quit smoking to make an informed choice about using NVPs to quit smoking (alongside accessing any support provided by smoking cessation classes).
32. In light of the need for a robust evidence base to demonstrate the impact on health of using NVPs, and the extent of their contribution to smoking cessation, we seek further information from the Scottish Government on how it is supporting research in this area.

Definition of Nicotine Vapour Products

33. The Bill defines NVPs as non-medicinal consumer products which deliver vapour for inhalation by an individual. Whilst most NVPs contain nicotine in differing concentrations some do not. This Bill includes both nicotine and non-nicotine NVPs within its definition. There are a wide range of names used to refer to NVPs including ENDS (electronic nicotine delivery system), tanks, e-shisha and e-cigarettes. There are also a wide range of NVP-related products, including refills, liquids, charges and other components, all of which are included within the Bill's definition of NVP as well as any substance which is intended to be vaporised by these devices such as e-liquids or e-juice, whether or not they contain nicotine.



Nicotine Vapour Product

34. In our report we refer to NVPs based on the definition provided within the Bill, except when quoting directly from witnesses.
35. The Bill's definition of NVPs excludes any licensed medicinal product or device. It would appear that there is only one NVP licensed as a medicine in the UK but it is currently not on sale to the general public.²² The Committee heard from a number of witnesses²³ that the Medicines and Healthcare Products Regulatory Agency process for registering an NVP as a medicinal product is so complex,

cumbersome and expensive that few companies have been willing to put forward NVPs for licencing as medicines. This complexity was reflected in the diversity of NVP delivery systems (including the number of manufacturers involved in their production). Witnesses explained that the ability to vary the amount of nicotine delivered had contributed to the effectiveness of NVPs in assisting people to stop smoking.

36. The New Nicotine Alliance highlighted that manufacturers have the freedom to innovate, which has led to great diversity in the range of NVPs. So if one device does not adequately assist smoking cessation then another NVP product might.²⁴
37. ECITA suggested that the attraction of NVPs to smokers might be reduced or lost if the products had to be broken down and reformulated in order to get a medicines licence.²⁵

38. It is concerning to hear that the complexity and cost of registering an NVP as a medicinal product are such that it is unlikely that any NVPs will be registered. As such a potential prize in further encouraging smokers to quit could be lost.
39. We believe that, if the NVP industry is serious about the effectiveness of NVPs to aid smoking cessation, then it is important that the industry works together to pursue licencing of NVPs as medical products.
40. We also invite the Scottish Government to consider working with the UK Government to assess whether the current Medicines and Healthcare Products Regulatory Agency process presents any unreasonable barriers to licensing complex products such as NVPs as medicinal products.

Age restrictions

41. The Bill proposes to legislate for NVPs for the first time. The Bill would make it an offence to sell an NVP to a person under the age of 18. Anyone found guilty of such an offence could be liable to a fine of up to £2,500. Local authorities would enforce the restrictions largely replicating the measures in place for restricting the sale of tobacco products.
42. The Bill would allow a defence that the accused had taken reasonable steps to establish that the customer was over 18 if they had been shown convincing documentation of their age (a similar defence exists for tobacco). However, the Bill would not make it an offence for someone under the age of 18 to attempt to buy or possess an NVP. The PM explains that this differs from tobacco legislation and recognises that under-18s should not be criminalised for attempting to purchase a product less harmful (based on current evidence) than tobacco.²⁶
43. Other provisions in this part of the Bill include:

- A requirement for a tobacco or NVP retailer to operate an age verification policy - the policy set out in the Bill is the 'Challenge 25' scheme, whereby the retailer must ask for proof of age from anyone who looks to be under 25. A retailer found guilty of not operating an age verification scheme could be liable for a fine of up to £500.
 - Making it an offence for an adult to buy an NVP on behalf of a person under the age of 18 (also known as a 'proxy purchase') - a person found guilty of such an offence could be liable for a fine of up to £5000.
 - A power to ban the sale of NVPs from vending machines – this would be in line with tobacco products.
 - Prohibiting someone under the age of 18 from selling tobacco products or NVPs unauthorised.
44. In its PM, the Scottish Government explains that it is well established that young people are particularly vulnerable to nicotine addiction, there are detrimental effects of nicotine on adolescent brain development and they are more likely to take health risks and discount the future consequences of their behaviours. The Scottish Government comments that there are no good reasons for persons under the age of 18 to use NVPs. The PM also highlights the risk that the use of NVPs in everyday life could “re-normalise” smoking-type behaviours.
45. There was wide support in written and oral evidence and from those who responded to our online survey for the Bill's proposals to restrict the sale of NVPs to those over 18. There was also broad support for the requirement for retailers to verify the age of those wanting to buy tobacco or NVPs if they look under 25.
46. The BMA Scotland, in written evidence, highlighted international evidence suggesting that e-cigarettes may act as a gateway to smoking. They cite evidence that the experiences in other countries such as Italy, Korea and the US (where e-cigarette use has rapidly increased over a similar length of time as in the UK) highlight the need to closely monitor use among children and young people.
47. Professor Bauld however provided the findings of a summary of 24 published peer-reviewed journal articles on e-cigarette use in youth. That summary showed that the more regular use of NVPs is found only in young people who have also smoked tobacco. Rates of experimentation (or “ever use”) in young people who have never smoked were also low in all the surveys, from 2-5 percent.²⁷
48. The concept of a “gateway drug” is controversial in the field of addiction studies and disagreements persist as to whether any progression in drug use is evidence of causality; that is, does the use of one drug cause a person to use another? In relation to whether e-cigarettes can re-normalise smoking, the World Health Organisation contends that the existence of a gateway or re-normalising effect can only be assessed with empirical data which, it believes, is currently very limited.²⁸
49. While there was broad support for implementing an age restriction on the purchase of NVPs, the Scottish Grocers Federation and the Association of Convenience Stores Ltd expressed concern that the Bill would provide Scottish

Ministers with the power to amend the age specified in the age verification regime. This was because they considered it could only cause inconsistency in practice. They considered that the Challenge 25 age verification scheme has become an effective benchmark for preventing underage sales (of tobacco and alcohol) and they recommended that the Bill should reflect the Alcohol etc.(Scotland) Act 2010.²⁹

50. We are content that the provisions in the Bill restricting the sale of NVPs to those over 18 are sensible, particularly given the detrimental impact of nicotine on adolescent health. This approach also provides consistency with existing alcohol restrictions. We also welcome that the Bill will not criminalise those under-18s who attempt to purchase NVPs given that evidence suggests that NVPs are less harmful than cigarettes.
51. We agree with the provisions relating to an age verification policy and a defence of due diligence. They build on existing practice in relation to selling tobacco.
52. We are content with the provisions on proxy purchasing and the approach to retail staff aged under 18 selling NVPs. These mirror those already in place for selling other age restricted products such as alcohol and should not therefore place an additional burden on retailers and local government.
53. We note, however, that some concerns were raised about the power in the Bill for Ministers to amend the age set for the age verification policy. We therefore seek further information from the Scottish Government on how it envisages it would use this power and in what circumstances.

Vending Machines

54. Some witnesses, primarily those from the NVP industry such as Fontem Ventures (a fully owned subsidiary of Imperial Tobacco Group), believed that NVPs should be able to be sold via vending machines. They contended that, by placing vending machines in over-18 establishments or limiting access to vending machines through interactions with staff first, the age of vending machine users can be controlled.³⁰
55. However, most submissions supported the ban on NVP sales through vending machines. For example, the National Federation of Retail Newsagents explained that this ban would support the efforts of retailers to uphold minimum age restrictions. The Scottish Government noted that it was not generally accepted for age-restricted products to be sold through vending machines, highlighting that self-service vending machines cannot satisfactorily include a process for the vender to verify the age.³¹

56. We are content with the provision to ban NVP sales from vending machines given the difficulties in ensuring a robust age verification scheme for sales from these machines.

Scottish Tobacco and Nicotine Product Retailer Register

57. The Bill would require those selling NVPs to register on the Scottish Tobacco Retailers Register (STRR). The Bill would rename the register the Scottish Tobacco and Nicotine Vapour Product Retailers Register.
58. The Scottish Government explains in the Policy Memorandum that the register will be useful for local authority officers to identify retailers of NVPs in order to “assist with advice and enforcement functions”.³²
59. A number of submissions³³ highlighted concerns about NVP retailers being included within the tobacco register as it could send a confusing message that NVPs are as harmful as tobacco. Some called for NVP retailers to be listed in an entirely separate register or for an register to be created for retailers of age restricted products.³⁴
60. Community Pharmacy Scotland, in written evidence, explained that—
- ” “The stigma of having to be on the tobacco retailers register will likely mean that many community pharmacies will choose not to supply NVPs. This will reduce the likelihood of "vapers" coming into contact with trained healthcare staff who may be able to advise them on reducing their use of NVPs or encourage them to enter NHS smoking cessation services.”
61. They acknowledged that it would be up to individual members to decide whether to register if there was a separate register for NVPs, but they considered that it would be a positive step away from the tobacco register.³⁵
62. In contrast, the Scottish Grocers Federation supported a single register. It explained that it would prefer not to have a separate register for NVPs, given that the current tobacco register “has full compliance, is cost free and is not onerous to access and register with”.³⁶
63. Totally Wicked and Vaporised (CCHG Ltd) did not believe that NVP retailers should be required to register on the Tobacco Register as they are not selling a tobacco product.³⁷
64. In its PM the Scottish Government explains that the STRR is not a licensing tool but allows legitimate businesses to be identified. It recognises that, whilst many tobacco retailers will also sell NVPs and so will already be familiar with the STRR; other retailers only sell NVPs and will therefore be required to register for the first time. As such, the Financial Memorandum identifies that the Scottish Government will fund national awareness raising and communication to help trading standards

officers inform retailers of the implementation of the new legislation. However, it recognised that there would be increased and on-going demand for advice to business from trading standards.

65. Given more evidence on the potential harm of using NVPs is required and the proposals that NVPs are to be an age restricted product, we consider it prudent that retailers should have to register their intentions to sell them. Such registration will also provide important information for local and central government on this developing market which can be used to inform future policy and research.
66. We have some sympathy with the view that NVPs should not be treated the same as tobacco by registering on the same register given that the evidence indicates that NVPs are not as harmful as tobacco products and may help with smoking cessation. However, we also recognise the benefits of retaining the existing STRR in terms of reducing bureaucracy and costs to retailers by building on existing practice.
67. Whilst we are content with the Bill's proposal to rename the register as being for Tobacco or NVPs we recommend that, in the longer term, the Scottish Government considers whether, given the range of age restricted products, the time is right to create one age restricted register. This could neutralise the negative association between tobacco and NVPs but also potentially future-proof the register.

Retail banning orders

68. The Bill extends the penalties used currently for breaches of the STRR, to NVP retailers. These penalties include that if a retailer commits three or more offences (such as selling to people under 18) within a two year period, a local authority can apply to the Sheriff for a retail banning order. The order prevents a retailer from selling both NVPs and tobacco for up to two years and results in the retailer being removed from the register.
69. Some submissions such as that received from the Society of Chief Officers of Trading Standards (SCOTS) in Scotland, highlighted concerns about the operation of banning orders based on its experiences of enforcing tobacco restrictions. SCOTS explained that there have been a limited number of cases where the owner of the business that was banned transferred the lease to a family member and continued to trade from the premises. Whilst SCOTS highlight that ancillary orders can be sought to prevent those banned from "having a connection to a tobacco business", it said that these have proved difficult and time consuming to prove.

70. We seek the Scottish Government's views on whether the Bill should be amended to include a ban on premises as suggested by SCOTS (and others³⁸) who explain that similar powers exist for Licensing Boards in respect of underage alcohol sales.

Advertising

71. NVP advertising in the UK is currently dealt with under the general UK Advertising Codes and the UK Advertising Standards Agency (ASA) enforces the rules in response to complaints from the public. There are two sets of codes:
- The CAP Code for all non-broadcast marketing which is written and maintained by the Committee of Advertising Practice (CAP)
 - The BCAP Code for broadcast marketing (i.e. TV and radio), which is written and maintained by the Broadcasting Committee of Advertising Practice (BCAP).
72. Following a public consultation (Committees of Advertising Practice 2014c, Annex 2) a CAP and BCAP's Joint Regulatory Statement entitled "New rules for the marketing of e-cigarettes" (CAP and BCAP 2014) came into force on 10 November 2014. The new non-broadcasting rules include provisions which require e-cigarette advertisements to:
- Be socially responsible
 - Not to promote any design, imagery or logo that might be associated with a tobacco brand
 - Not to promote the use of a tobacco product or show the use of a tobacco product in a positive light
 - Make clear that the product is an e-cigarette and not a tobacco product
 - Not to undermine the message that quitting tobacco use is the best option for health
 - Not to encourage non-smokers or non-nicotine users to use e-cigarettes
 - Not to feature characters likely to resonate with youth culture or to appeal to under 18s.
73. These new rules on e-cigarettes will be reviewed towards the end of 2015.
74. The system is a mixture of self-regulation for non-broadcast advertising (i.e. the system is paid for by industry members who draft the rules) and co-regulation with the statutory regulator Ofcom for broadcast advertising.

75. From May 2016, broadcast advertising of NVPs will have to comply with the Tobacco Products Directive (TPD) (2014/40/EU) which will effectively ban the cross border advertising and promotion of NVPs, including: TV and radio advertising, newspaper adverts and sponsorship of events such as televised sport.
76. However, the Directive does not cover non-broadcast advertising (often referred to as “domestic” advertising) such as billboards and point-of-sale adverts. These will continue to be regulated in line with the CAP code. The Directive will also not apply to vaping products that do not contain nicotine.

Bill's Provisions

77. The Bill contains a power for Scottish Ministers to make regulations which would restrict or prohibit the domestic advertising and promotion of NVPs. This regulation making power would also extend to related activities such as prohibiting or restricting advertising through billboards, product displays, bus stops, posters, leaflets and banners. It also gives Ministers the power to specify offences and penalties for contravening any such regulations. The Bill sets out the maximum penalties that may be in regulations, namely:
 - On summary conviction, imprisonment for no longer than 12 months or a fine not exceeding the statutory maximum (£10,000) or both
 - On conviction on indictment, imprisonment for no longer than 2 years, a fine or both.
78. The PM to the Bill explains that "the Scottish Government believes that a comprehensive ban on all NVP domestic advertising and promotion is required to complement the Tobacco Products Directive, but allowances should be made for advertising at point of sale where NVPs are sold. A display of NVPs, the purpose or effect of which is not to promote a NVP, should not be regarded as an advert or promotion, and therefore should not be prohibited".³⁹
79. As NVPs would be age-restricted products the Scottish Government explains that the additional powers it seeks are necessary to enable regulations to reduce the visibility and attraction of NVPs, to children and young people under 18 and to non-smokers.⁴⁰
80. The Bill would also give Ministers the power to regulate free distribution and nominal pricing on NVPs for promotional purposes as well as regulate sponsorship by NVP companies. The Scottish Government explains that these powers are needed to protect children and young people as well as non-smoking adults from being encouraged to try NVPs for free and who may then go on to try other nicotine-based products.
81. Professor Bauld was one of a number of witnesses⁴¹ who supported the Scottish Government's approach to advertising. She argued that the Scottish

Government's approach to advertising NVPs strikes the right balance between "ensuring that effort is made to continue the appeal of those products to current smokers" whilst removing "the forms of advertising that might glamourise products, such as giant billboards".⁴²

82. In written evidence, BMA Scotland, highlighted a review by the US Senate in 2014. That review concluded that e-cigarette companies are employing the same marketing tactics that the tobacco industry first used to attract young customers to their products, for example, sponsored sports, music events and free samples.

83. Some witnesses, such as NVP retailers and tobacco companies, supported the approach adopted by the Advertising Standards Authority (ASA).⁴³ The ASA explained that its approach to restricting advertising of NVPs was informed by the current evidence base which seems to be demonstrating that NVPs are largely used as a substitute product. That is, they are used by smokers who have now switched NVPs or they are using a combination of tobacco and NVPs.

84. This was important to the ASA as it considered that if it made it too hard for NVPs to be advertised then the public health prize of reducing smoking may be damaged. The ASA highlighted that "the evidence and arguments seem to show that successful marketing of e-cigarettes equals people switching from tobacco."⁴⁴

85. The ASA highlighted three potential negative consequences of banning advertising of NVPs:

- it would then restrict the ability of manufacturers and marketers to responsibly advertise products that, according to the evidence, are helping people to switch away from tobacco;
- it sends the message that NVPs are as bad as tobacco (a view found in 21-22 % of people surveyed by ASH Scotland);
- it would restrict the ability of companies to compete, preserving the market share of the incumbent operators (including tobacco companies).⁴⁵

86. The Scottish Grocers Federation⁴⁶ explained that—



"the explanatory notes that accompany the bill suggest that the Scottish Government would not ban advertising at the point of sale but that is not made explicit within the Bill as introduced. We hope that the Scottish Government will address that matter at Stage 2."⁴⁷

87. The DISPLAY Research Team argued that the results from its sample of 1404 Scottish school pupils, suggested that e-cigarette use by adolescents may be influenced by point of sale displays of e-cigarettes. It therefore concluded that e-cigarette marketing at point of sale should also be prohibited to protect young people from experimenting.⁴⁸

88. Fast Forward highlighted their concerns that NVPs were currently being actively marketed towards young people with flavours such as bubblegum and candy floss.⁴⁹
89. In summarising the Scottish Government's approach in the Bill, the Minister for Public Health explained that it was seeking regulation making powers to restrict advertising to point of sale as it is important that current smokers are able to ask questions and have consultations about which products might be right for them.⁵⁰ However—

” “There is a fine balance to be struck with NVPs...We would not want them to be advertised to the extent that people who would not even thinking of smoking were encouraged to start using NVPs.”⁵¹


90. We support the precautionary approach adopted by the Scottish Government in relation to advertising of NVPs given the need to balance encouraging smokers to switch to NVPs as an aid to smoking cessation whilst also not attracting new “never smoked” NVP users.
91. We are therefore content that the Bill's proposals in relation to the advertising of NVPs are appropriate given that the evidence on the long-term health impact of NVP use is still developing. We recommend that the Scottish Government works with the ASA to ensure harmonisation of advertising restrictions wherever possible.
92. However we request a response from the Scottish Government to the concerns of some witnesses that restricting advertising of NVPs in Scotland to point of sale only will offer a competitive advantage to those already established NVP retailers.
93. We are concerned at the responses we received that highlighted the potential of NVPs to be made more attractive to young people through flavourings or point of sale advertising and therefore recommend that the Scottish Government monitors these potential risks.

Part 1 - Smoking outside hospitals

94. At the moment, the NHS in Scotland operates a smoke free policy across all of its grounds including GP surgeries, health centres, NHS car parks or gardens. The use of NVPs such as e-cigarettes is also not permitted, either inside or outside NHS premises.
95. The PM to the Bill reports that this approach is having a positive impact in reducing smoking but that health boards have reported difficulties in enforcing the ban. This is because there is no sanction that can be applied if someone refuses

to comply with the policy other than to ask the person smoking to stop or to leave the grounds. There is no data collected on breaches of the policy.

The Bill's provisions

96. The Bill would make it an offence to smoke within a designated no-smoking area around buildings in NHS hospital grounds. The area will be immediately outside of buildings on hospital sites, with a perimeter of a specified distance (to be confirmed in regulations). The Bill would require that no-smoking notices are conspicuously displayed at the entrance to hospital grounds and at every entrance to hospital buildings.
97. Those caught smoking within the designated no-smoking zone will be liable, on summary conviction, to a fine not exceeding level 3 on the standard scale (up to £1000). NVPs are not included in these provisions. The restrictions would be enforced by local authority officers.
98. Out-with the designated zone, NHS boards would have the discretion to continue operating a no-smoking policy, although it would not be an offence to smoke in these areas if they chose to apply such a policy.
99. The Scottish Government explains that its approach effectively extends the indoor smoking ban to those areas where i) there is the highest footfall of people leaving and entering the hospital and ii) where there is a risk of smoke entering hospital buildings as a result of people smoking close to the building, in particular at entrances. It will also prevent or reduce public, patients and staff from being exposed to second-hand smoke around entrances and near windows and vents through which smoke could drift into hospital buildings. Such concerns were also raised by other witnesses such as NHS Grampian in its written submission.⁵²
100. The majority of the written responses we received (including almost all those received from NHS boards and Local Authorities) supported the proposed restrictions on smoking in hospital grounds. ASH Scotland also highlighted You Gov research it commissioned in 2014 which showed that 73% of Scottish adults supported the proposal that smoking on hospital grounds should end.⁵³
101. ASH Scotland endorsed the Scottish Government's approach to restricting smoking in hospital grounds explaining that—
 “the aim in Scotland is to put tobacco out of sight, out of mind and out of fashion. As part of that, we have to be compassionate with people who are used to smoking and might have a physical addiction. The NHS is very good at offering all forms of support to people to manage that, which is important as part of any proposed restrictions.”⁵⁴
102. Professor Bauld agreed that this was the main aim of restricting smoking in hospital grounds, highlighting that it would be complex and challenging to determine the perimeter within which the ban on smoking would be enforceable—

” “Those of us who work in this field would agree that allowing smoking - even slightly away from the building- in the very place where people go to get well is not compatible with our spending millions of pounds in the NHS on treating smoking-related diseases.”⁵⁵

103. We heard that key to making smoke-free policies work is good policy, good enforcement and good communication with the public about what the policy is for and why it is happening.⁵⁶ In that regard Professor Bauld considered that—

” “by having at least some of the hospital grounds covered by a smoke-free policy that is enforceable and has penalties associated with it, we can successfully implement that.”⁵⁷

104. FOREST considered it totally wrong to ban smoking in all hospital grounds calling it “inhumane” especially for visitors, staff and patients who may be experiencing stressful situations. FOREST also highlighted safety concerns for staff and others who would have to leave NHS premises in order to smoke.

105. FOREST called for the decision on where to restrict smoking to be left to the Chief Executive of each hospital rather than a “one-size-fits all” approach imposed from central Government.⁵⁸ A number of other organisations also argued that it should be left to each health board to decide the extent and boundaries of the non-smoking area designated under the Bill.⁵⁹ Some highlighted that the ban may cause increased issues relating to littering and discarded cigarette stubs at the boundary of hospital grounds.⁶⁰

106. NHS Ayrshire and Arran explained its experiences of using a “stepped approach” to banning smoking in its hospital grounds.⁶¹ In 2006 it initially introduced a 15 metre perimeter rule to try and get people away from hospital entrances.

107. They explained that this approach was however totally impracticable given the overlap between hospital building perimeters and that people didn’t know where 15 metres from the building started. As a result, people ended up just smoking where they wished, which in turn led to a large number of complaints from people coming and going through hospital doors. NHS Ayrshire and Arran then allowed smoking in one designated area before moving to smoke-free grounds.

108. At each level they found that the number of people who complied increased, with only a small number now who do not comply. NHS Ayrshire and Arran welcomed legislation that supports smoke free grounds as reinforcing the message that smoking is harmful.

109. NHS Ayrshire and Arran also highlighted the support it provides to smokers in its hospitals, who are all offered an intervention by the smoking cessation service to help them manage their smoking. Patients are followed up when they leave hospital with telephone support and encouragement to attend support groups.⁶²

110. We heard of a similar experience in relation to the High Court in Livingston where an area of 15m from the door is designated as no-smoking. COSLA explained that—

” “What happens is that people gather from the 15m mark for the next 20m. Now we are going to extend that area to the perimeter, where the footpath is.”⁶³

111. NHS Ayrshire Health and Social Care Partnership considered that reintroducing a set perimeter would be a "backwards step" as it risks the focus on any measures to address smoking on NHS premises to be perceived as a matter of distance.⁶⁴ A number of organisations⁶⁵ supported banning smoking in all NHS grounds under this Bill to avoid any confusion and ambiguity about where people cannot smoke. Some argued that the ban should be extended to also apply to primary care sites and jointly managed sites given the integration of health and social care (and in some cases to all public buildings) to provide consistency of message and approach.⁶⁶

112. The Scottish Government states in its PM that it considered measures to make it an offence to smoke anywhere within all NHS grounds (with and without exempted zones where smoking would be permissible) but it does not believe that this is a proportionate response to the current situation given the wide range of hospital grounds that exist. It considers that its proposed approach will be easier to enforce given the size of some hospital grounds and that it reflects the NHS's direct but compassionate approach while being an important contribution to the progressive denormalisation of smoking.

113. In evidence the Minister for Public Health explained that it would be for regulations to determine at what distance the perimeter is set but that—

” “Something like 10 to 15m is roughly what we have in mind for the perimeter.”

114. That perimeter distance would apply across all NHS sites with hospital buildings regardless of their size.⁶⁷ health boards will be consulted as to what the most appropriate perimeter distance is having considered the function and layouts of their estates. The perimeter within hospital grounds where smoking will be an offence will then be set out in affirmative regulations.

115. The Minister commented that it would then be for each health board to determine whether smoking was permitted in those parts of the hospital grounds beyond the enforceable areas set within the Bill. In that regard "different health boards are at different points along the journey."⁶⁸

116. We note that all hospital grounds are currently no-smoking areas and in this regard the Bill will simply allow a part of those current no-smoking areas to be enforceable by local authorities.

117. We agree with the proposal to make smoking outside hospital doors and around buildings an offence given the high foot fall in these areas and the concerns regarding drifting second hand smoke. However, by distinguishing between a legally enforceable no-smoking area and those areas of no-smoking set by NHS policy, the unintended consequence could be that compliance with the NHS designated no-smoking areas deteriorates as smokers will be now more aware that there are no penalties for smoking in those areas.
118. We do have concerns about the feasibility of the proposed approach of setting the same set distance from hospital buildings for all hospital grounds given the experiences of NHS Ayrshire and Arran and Livingston High Court. We question whether identifying the same set distance is achievable given the diversity of purposes of hospitals (such as outpatient, inpatient, secure etc) and the differing sizes and layout of hospital grounds.
119. We therefore recommend that the Scottish Government reviews its proposal to set out, in regulations, the same set distance from hospital buildings for all hospital grounds within which no-smoking will be legally enforceable. We recommend that the Scottish Government consider whether each NHS board should be able to propose its own legally enforceable perimeter in the regulations. This will enable each health board to reflect the differing topography and grounds of hospitals within each board area. It will also enable the outcome of any discussions between each health board and relevant local authorities about enforcement to be reflected in each NHS health board's agreed perimeter (see also the next section).
120. With health and social care becoming more integrated, we would welcome clarification from the Scottish Government of whether it proposes to legislate for enforceable no-smoking areas outside other health facilities such as Community Treatment Centres and primary care premises or even more widely to all public buildings.

Enforcement

121. FOREST also highlighted concerns with the costs of enforcing the no-smoking areas identified in regulations including whether tobacco control wardens and closed-circuit television cameras would be needed. Also highlighted was what the consequences might be for a visitor or patient being caught smoking and whether it was practicable to either enforce it physically or appropriate to order them from the grounds.⁶⁹
122. COSLA expressed concern about the practicalities of its enforcement officers, sited out-with hospital grounds, not being able to quickly respond to requests to enforce a no smoking area designated under the Bill. UNISON also expressed

concerns about the capacity of environmental health officers to enforce the no-smoking areas in hospital grounds designated under the Bill⁷⁰ given—

” “they have abandoned whole areas of legislation that they are supposed to enforce-including legislation on health and safety issues and food inspection - because of a lack of resources.”⁷¹

123. In evidence the Minister for Public Health explained that—

” “We do not expect a local authority officer to travel say, a mile to a hospital to issue a fine, but the Bill requires local authorities to get involved in cases of persistent breaches.”⁷²

124. The Scottish Government confirmed that it expected compliance by the public, patients and staff with the enforceable no-smoking areas to be as high as with previous smoke-free legislation but that it was discussing its implementation and enforcement with local authorities, COSLA and environmental health officers (who already have a role in enforcing the current smoke-free legislation).⁷³ In the run up to implementing the legislation the Minister for Public Health confirmed that there will be more advertising and leaflets to make people aware of it.

125. The Scottish Government will be responsible for providing signage to health boards to ensure that staff, visitors and patients are aware that they may not smoke in designated areas of hospital grounds. Total national costs are estimated to be in the range of £99,000 to £198,000.⁷⁴

126. The Scottish Government also highlighted that NHS boards do and can require staff to challenge smoking on NHS grounds to promote compliance, and the Bill permits this to continue, though there is flexibility if boards wish to take an alternative approach - such as employing staff just for compliance purposes or writing it into the contract of other roles.⁷⁵

127. We recognise that most patients, visitors and staff will abide by the legally enforceable no-smoking area and each NHS board's policy in relation to smoking in NHS grounds. As such this Bill is intended to address those people who currently persistently smoke in no-smoking areas in hospital grounds despite being asked to stop.

128. We are reassured by the Minister's evidence that local authority officers are not expected to enforce every infringement within the no-smoking area designated under this Bill. Rather the local authority's role is to provide an enforcement mechanism for those who persistently smoke within the legally enforceable no-smoking areas in hospital grounds.

129. Given this we are content with the proposals for local authority enforcement of such areas. We recognise that local authorities already undertake a similar role in relation to other smoke-free legislation.

130. We also welcome the provision of a defence within the Bill whereby the person committing the offence would also be allowed the defence that they did not know - and could not reasonably be expected to know - that they were smoking in the no-smoking area. We acknowledge the Scottish Government's intention to advertise the change in the law prior to any legally enforceable no-smoking areas coming into force.
131. The Finance Committee reported that the Scottish Government provides £2.5 million for enforcement of smoke-free legislation by local authority environmental health officers and as such enforcing no-smoking areas in hospital grounds will need some reprioritisation of duties and resources. We therefore welcome the Government's commitment to consider any breakdown of costs provided by COSLA should there be a short term increase in enforcement costs.⁷⁶

The offence of permitting others to smoke

132. The Bill would also make it an offence for someone with management and control of the no-smoking zone to knowingly permit someone to smoke there. The Bill allows a person a defence that they took all reasonable precautions to prevent the person from smoking or that there was no lawful or reasonably practicable means by which they could prevent the other person from smoking.
133. West Dunbartonshire Health and Social Care Partnership questioned whether the proposed "offence of permitting others to smoke outside hospital grounds" would be fair or would make enforcement easier.⁷⁷ The Royal College of Psychiatrists in Scotland contended that it is difficult enough to nurse and treat mentally ill patients who do not wish to stop smoking without staff facing the prospect of prosecution as well.⁷⁸
134. UNISON highlighted concerns about who might be defined in the Bill as "having the management and control of the no-smoking areas" especially as some staff such security staff, porters and others are currently the staff that might first have to deal with people smoking in hospital grounds. That said, UNISON indicated that the term "knowingly permits" might give some comfort to its members.⁷⁹
135. The Minister for Public Health explained that in relation to patients who need to smoke but may require staff assistance to facilitate their smoking (such as those with mobility issues) —
- ” “In each individual circumstance, it will be up to the nurses or doctors, in consultation with the patient to decide, and there will be areas set aside outside the perimeter.”⁸⁰
136. NHS Health Scotland has already published guidance to support the implementation of smoke-free grounds across all NHS sites which sets out the

standards for boards, including what the roles and responsibilities of staff are. In evidence the Scottish Government confirmed that—

” “No staff member would be criminalised for assisting somebody to go out and smoke although that would be a matter for the NHS board.”⁸¹

137. The Scottish Government confirmed that the offence of “knowingly permitting” smoking will apply to health boards and other organisations rather than individuals.⁸²

138. Given the offence will apply to health boards rather than individuals we are content with the Bill’s proposed offence of knowingly permitting others to smoke. We welcome the Minister’s reassurance that it is for each health board to decide its staff policy but that discussions between patients and medical staff will enable a compassionate approach to be taken with patients who consider they need to smoke.

Exemptions

139. The Bill also includes a power to exempt certain buildings or grounds. The PM cites psychiatric hospitals, the State Hospital and hospices as examples of possible exemptions.

140. The Royal College of Psychiatrists in Scotland explained that although it had successfully introduced no smoking in hospital grounds, a blanket ban raised particular issues for some psychiatric units. This was due in part to patients recommencing smoking after leaving hospital (which can also then impact on effective prescribing e.g. smoking can impact on metabolising pharmacokinetics⁸³). Other issues included patients refusing to stay voluntarily if they are not permitted to smoke and respecting the individual autonomy of patients particularly those detained for long periods (given smoking is not illegal).⁸⁴

141. The Scottish Directors of Public Health’s submission contends that all hospital grounds should be smoke-free including mental health and long-stay premises.⁸⁵ They explain that there is no clinical justification for maintaining an exemption given:

- a. the significant proportion of patients who wish to stop;
- b. that smoking compensates for lack of purposeful and therapeutic activity among inpatients;
- c. the avoidable burden of smoking-related physical health problems this patient group experiences; and
- d. the adverse impact of smoking on symptom control and drug levels.⁸⁶

142. The Minister for Public Health explained that in the case of people who are going in for an operation—

“we are trying to make sure that they are made aware of the smoking policies at the initial appointment with their consultants and are offered smoking cessation services before they go for their operation. Areas will be set aside for people who have mental health issues to smoke. However the overarching policy will be to encourage people to stop smoking because smoking does not contribute anything towards mental health and wellbeing. It actually does the opposite.”⁸⁷

143. The Scottish Government explained that the starting point for exemptions would likely be those set out in the Smoking, Health and Social Care (Scotland) Act 2005. Where, following consultation, any exemptions are applied to the enforceable no-smoking area, they will apply uniformly across all establishments.⁸⁸

144. We agree with the Bill's proposals to provide for exemptions to the legally enforceable no-smoking area. However we recognise that despite any exemption, it could still be the case that smoking is banned as a result of the health board's policy (albeit it won't be legally enforceable).

145. Whilst we recognise the intention that any exemptions should apply uniformly across all relevant hospitals we question how such exemptions might be practically applied given the different types of hospital buildings that could be sited within hospital grounds (could an exemption for the grounds of an adult hospice be clearly identified where the same grounds are shared with or are in close proximity to other hospital types?).

146. Under our recommendation at paragraph 119, NHS boards would be able to take cognisance of how any exemptions might be applied based on their own site layouts before each NHS board recommends its own legally enforceable perimeter for inclusion within the regulations.

Banning the use of NVPs in hospital grounds

147. Some witnesses such as Professor Bauld expressed concern that NVPs were also banned from hospital grounds although this is not a proposal in this Bill. She called for the ban on using NVPs in hospital grounds to be reversed given it sends the wrong message that NVPs are as harmful as smoking tobacco. Professor Bauld also highlighted that by allowing NVPs to be used on hospital grounds staff members who smoke have an alternative to smoking cigarettes in addition to using nicotine patches.⁸⁹

148. NHS Ayrshire and Arran also called for a national approach on the use of NVPs in hospital grounds should evidence support their use as a smoking cessation tool and to avoid variation in local practices.⁹⁰
149. The Minister for Public Health explained that whether NVPs are banned or not would be for each health board to decide.⁹¹ The Scottish Government confirmed that it continues to work with boards to understand the emerging evidence around NVPs and how services can engage with people who are using these devices.⁹²

150. We agree that it should be for each NHS board to decide whether to ban the use of NVPs in hospital grounds. We recognise that banning NVPs from hospital grounds risks conflating the harm of tobacco with the lesser harm of NVPs (based on current evidence).

Part 2 - Duty of Candour

151. Following a number of reviews into poor care and patient safety such as the Francis report⁹³, the Dalton Williams review⁹⁴ and the Berwick report⁹⁵, there have been calls for greater candour amongst health and care organisations when things go wrong.
152. As a consequence, this Bill proposes to give health, social care and social work organisations a “duty of candour”. What this would mean is that, in the event that a person experiences (or could have experienced) an unintended or unexpected harm from their care, which is unrelated to their illness or condition, the organisation would have a duty to tell that individual. The Bill specifies that any apology given as a result of the duty of candour procedure would not in itself amount to an admission of negligence or a breach of a statutory duty. The Bill does not, however, provide exemption from disciplinary action when someone reports an unintended or unexpected incident, if indeed disciplinary action is required.⁹⁶
153. The Bill does not set out what the procedure should be but instead gives Scottish Ministers the power to set this out in regulations. The Bill at section 22 explains that such regulations may include provisions about (among other things); the notification procedure; the apology to be provided, and the actions which must be taken and will emphasise learning, change and improvement.
154. The Bill applies to a range of 'responsible person[s]' including NHS boards, anyone (other than an individual) contracted by a health service such as GP practices, independent health care providers, local authorities or anyone (other than an individual) who provides a care service or social work service.
155. The Scottish Government confirmed that although the duty in the Bill and the procedure to be followed is placed on organisations, it is not intended to usurp the role of individuals.⁹⁷

The need for legislation

156. The majority of those who responded to the Committee's call for views supported the duty of candour. In oral evidence there was almost unanimous support for candour in health and social care settings when unintended harm arises. However, we heard a range of views as to whether setting out a duty of candour in legislation was necessary.
157. One of the main arguments cited by witnesses as to why a duty of candour did not require to be legislated for was that there are already long standing professional and ethical duties which require candour or disclosure of harm. This includes through the national framework 'Learning from adverse events through reporting and review'⁹⁸ as well as a joint statement on the professional duty of candour signed by the regulators of health care professionals (such as the General Pharmaceutical Council).⁹⁹ Some regulators also already have explicit candour requirements in their standards (e.g. General Medical Council and the Nursing and Midwifery Council).
158. The Law Society of Scotland and others¹⁰⁰ also highlighted that, although the duty of candour was aimed at organisations,—
- “It will be almost impossible for those organisations to discharge the obligations in the bill, or even to try and implement the processes in the bill, without involving individuals.”
159. In that regard they considered that it would be challenging for employees to be compassionate on the one hand but, on the other hand, to also discharge their duties in terms of compliance with the procedures, processes and parameters required by the duty.¹⁰¹
160. The Medical Protection Society and others¹⁰² expressed concerns about whether the legislation would add to the culture of openness that should be supported through education and training or whether "it will simply add a bureaucratic burden and become a box-ticking exercise".¹⁰³ COSLA questioned whether a new duty of candour on providers of health or social care is "the best way or only way of securing a culture of openness and transparency across the newly integrated health and social care systems."¹⁰⁴ BMA Scotland and the Medical Protection Society highlighted concerns that the duty could adversely impact on clinical decision making leading to risk avoidance at the margins of clinical practice or defensive behaviours focussed on self-preservation.¹⁰⁵
161. Some witnesses also questioned whether the duty of candour could address entrenched organisational issues such as lack of resources and the historical lack of investment in social care.¹⁰⁶
162. Marie Curie, UNISON and others supported legislating for a duty of candour as driving culture change and helping to ensure organisational shift towards a supportive culture of learning and improvement.

163. Action against Medical Accidents (AvMA) also welcomed the duty of candour —

“What is exciting and different about the statutory duty of candour is that it applies to organisations collectively and corporately and it deals with situations when things have gone wrong....the bill is the final piece of legislation that will complete the Scottish approach to patient safety by filling in a missing segment. It says unequivocally that a lack of openness and honesty when harm has been caused or is suspected to have been caused, is not tolerable.”¹⁰⁷

164. AvMA considered that the organisational focus of the duty of candour should give staff confidence that their organisation has to provide “the necessary environment and support the culture that is required for them to safely and humanely fulfil what, for most people, is a professional obligation”. In that regard it will drive improvements in patient safety as the requirement for candour will enable organisations to learn from incidents of harm or potential harm where some may not have previously.¹⁰⁸

165. Citizens Advice Scotland supported the duty of candour given their experiences of the inconsistent way that health boards currently respond to complaints.¹⁰⁹ However, the Law Society of Scotland questioned whether consistency in applying the duty of candour could be achieved given it is an 'amorphous' concept where there may be different views on whether staff have met it. As a result they considered that finding a "one-size-fits-all" approach will be a challenge.¹¹⁰

166. The Scottish Public Sector Ombudsman (SPSO) suggested some practical steps to help ensure that the duty of candour is successful. This includes involving other stakeholders such as patients, families and the wider community in not only contributing their views and experiences but also actively involving those stakeholders in identifying i) the causes of incidents and ii) future improvements to the service.¹¹¹

167. Representatives of Haemophilia Scotland, the Scottish Infected Blood Forum and the Hepatitis C Trust recommended to us that the duty of candour procedure should enable patients and their families to challenge the details about an incident where they consider these to be incorrect.

168. The PM to the Bill explains that the overarching aim of the duty of candour provisions are to support the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm, that is not related to the course of the conditions for which the person is receiving care.¹¹²

169. The Minister for Public Health explained that although the duty of candour is part of existing professional arrangements of several health professions—

“...we want to extend the duty to cover all health and social care professionals, which is not the case now.”¹¹³

170. The Minister added that the duty of candour is being introduced as there is “wide variation across Scotland in health and social care organisations' response to incidents of unintended or unexpected harm”.¹¹⁴
171. The Scottish Government hopes that the Bill will encourage cultural change whereby even if a particular incident does not fall within the duty of candour procedure, over time the Bill might encourage organisations to be more open even in relation to smaller incidents.¹¹⁵
172. To address concerns regarding the potential for the duty of candour to become administratively burdensome, the PM explains that clear guidance will be provided to support integration of the duty of candour with existing responses to complaints, adverse events and incident reporting.¹¹⁶ A development group will, as part of its remit, consider how information should be disclosed to people who have or may have experienced harm (as well as those who do not wish to know) when the Scottish Government considers the formulation of the guidance.¹¹⁷
173. In addition guidance based on the work of the National Patient Safety Agency Incident Decision Tree will inform implementation guidance to ensure that all elements of a 'just culture' inform organisational decision making after incidents involving death or harm.¹¹⁸

174. We agree with witnesses that being open and honest with people about their care is a key part of building trust especially when things go unexpectedly wrong. We recognise that for many health and care professionals a duty of candour already exists and in that regard including it within this Bill will to some extent build on the good practice already demonstrated by many hardworking and dedicated professionals.

175. However we also recognise that not all health and care professionals are currently subject to a duty of candour and that the different professional requirements can lead to inconsistencies in the way in which such a duty is applied in health and social care organisations.

176. We therefore are content with the inclusion of a duty of candour within this Bill. We also welcome the Bill's proposal that the duty of candour applies to organisations. This is important if health and social care organisations are to learn from incidents of unintentional harm and improve their care so that such harm does not arise in future.

177. Whilst the Bill sets out the range of provisions that the duty of candour procedure should include (such as the role of the responsible person, the actions they should take and when as well as how information should be made available) much of the detail of the duty of candour procedure will be set out in regulations later on. As such these regulations will play a

significant part in ensuring that the duty of candour procedure is able to be implemented effectively across a wide range of health and care settings.

178. Given this we agree with the Delegated Powers and Law Reform Committee that the Bill should be amended at Stage 2 to provide for these regulations to be subject to affirmative procedure.

179. We note that the guidance on the duty of candour procedure will build on existing candour procedures and processes. This should allay some of the concerns of witnesses that the duty may create an additional administrative burden.

180. In relation to witness comments that the duty of candour in the Bill might lead to a 'box ticking exercise' or risk avoidance behaviour in clinical practice we recommend that a wide range of health and care staff should be involved in drawing up the regulations. This should encourage greater staff ownership of the duty of candour procedure.

181. We seek the Scottish Government's views on whether the duty of candour procedure will enable patients and their families to challenge the details about an incident where they consider these to be incorrect. We also request clarification of the extent that patients and their families would be involved in identifying the causes of incidents as well as in identifying any future service improvements.

182. We support the definition in the Bill of who a responsible person is as it encapsulates the wide range of health and social care providers. However given the complexity with which health and social care is delivered we would seek clarification from the Scottish Government as to the extent to which the duty of candour would apply to:

- local authorities when they commission, contract or fund health or care services to be provided externally;
- specialist educational schools (as suggested by ENABLE Scotland);
- providers of healthcare and assistive technology (who may be part of a multidisciplinary team).

183. We also seek the Scottish Government's response to the concerns of the Care Inspectorate that some providers of care services may choose to establish their business in a way that means they would be exempt from the duty of candour.

Training and education

184. A number of witnesses including the BMA Scotland highlighted the importance of education, training and support for staff to support change, and oversight. This is particularly the case for less experienced or more junior staff who may be anxious

about breaching the statutory obligations, given it will be for individuals to implement the bill's provisions.

185. AvMA explained that it was fundamental that by the time the bill comes into force, there is a co-ordinated, planned and resourced programme of awareness raising, training and support for the staff who will be responsible for implementing the policy.¹¹⁹

186. Citizens Advice Scotland highlighted the important role of supporting patients and their families through independent advocacy and the patient advice and support service. It would also welcome training around complaints and early resolution for NHS staff.¹²⁰

187. The SPSO highlighted its practical experience of implementing complaint standards legislation commenting that although the training did not require significant resources it did require on-going resources to ensure that support was sustainable.¹²¹

188. The Bill requires that the training the responsible person receives as well as any training, supervision and support they provide, should be included in the duty of candour procedure. The Financial Memorandum to the Bill states that £182,000 will be provided by the Scottish Government "for use by all organisations which have to implement the duty". This will reduce to £45,000 in the 2nd year and £25,000 annually recurring costs thereafter.

189. The Minister for Public Health explained that the duty of candour was about a continuous improvement process—

” “The focus is on learning from what has happened and on the organisation providing support, training and staff development.”¹²²

190. AvMA explained that the duty of candour had the potential to also make savings through patient safety as it would drive learning from such incidents so that it is unlikely they would happen again. If the Bill changes the culture to a genuine learning culture then—

” “The payback will come in preventing extra bed days, extra treatment and extra litigation in the future.”¹²³

191. In order for the duty of candour procedure to be effectively implemented it is important staff have the skills and confidence to deliver it. We therefore welcome the provision of additional funding for training and support of organisations which will be subject to the duty of candour.

192. We seek further information from the Scottish Government on the extent to which it will provide additional information and funding to support patients and families through the duty of candour process.

Saying sorry

193. Concerns were raised about whether a statutory duty to apologise would devalue the apology given especially if families or patients felt they only got an apology because it was required by statute. Professor Britton from the Law Society of Scotland observed that—

” “I do not think that any piece of legislation can ever be drafted that enhances the value of a personal and sincerely given apology...The best that legislation or policy or regulation can do is look at the processes that accompany that so that an apology is given and, importantly, we review what happened, to identify whether we can prevent it from happening again.”¹²⁴

194. We also heard from representatives of Haemophilia Scotland, the Scottish Infected blood Forum and the Hepatitis C Trust that the apology is more meaningful when it comes from someone who has been involved in their care or who has caused the harm.

195. The BMA also observed that a meaningful apology can help repair damaged relationships and build trust. However they questioned how the Bill would work in practice with the UK wide GMC standards and investigatory process especially given professional regulation is a reserved matter. As such, the Scottish Government has no direct authority over the GMC. BMA Scotland had concerns that—

” “irrespective of the status of such an apology in Scottish law, that the GMC as a UK-wide regulatory body, might consider one as an admission of fault or evidence of poor performance in the course of their pursuance of individual cases.”¹²⁵

196. The Bill specifies that any apology given as a result of the duty of candour procedure would not in itself amount to an admission of negligence or a breach of a statutory duty. The Scottish Government explained that it was important to health and social care professionals that an apology is part of the duty of candour procedure. However—

” “any decisions that might be made in the legal process, for example, on negligence and liability, are completely separate procedures.”¹²⁶

197. The Apologies (Scotland) Bill is currently also being considered by the Scottish Parliament which effectively proposes the same as the apology proposals in this Bill with the exception that it would apply to all public sector organisations.

198. The Scottish Public Services Ombudsman, in written evidence, called for the apology provision in the Health (Tobacco, Nicotine etc. and Care)(Scotland) Bill to be removed altogether and included in broader legislation or to be extended to the whole public sector.

199. We welcome the Scottish Government's evidence that the apology proposals in the Bill will not replace the role of individual professionals in apologising for any harm caused or potentially caused.
200. We support the provision which makes clear that steps taken under the duty of candour procedure do not amount to an admission of negligence. We note that, to some extent, this reflects guidance and legislation already in place (such as in the Compensation Act 2006).
201. Given this, we recommend that the Scottish Government works with health and care regulators, such as the General Medical Council, to ensure the duty of candour procedure clearly sets out how it relates to other processes already in place.
202. We welcome the clarification provided by the Scottish Government¹²⁷ that the need for apologies offered as part of the duty of candour procedure should be exempt from the Apologies (Scotland) Bill. We will therefore monitor Stage 2 of the Apologies (Scotland) Bill to confirm that this is the case.
203. We seek clarification from the Scottish Government of whether any procedure for apologising, and the duty of candour more generally will recognise the range of patients' communication skills and needs (as recommended by ENABLE Scotland in written evidence).
204. We also seek a response from the Scottish Government to COSLA's concerns, in written evidence, that employer's liability insurance and personal indemnity insurance could be affected by apologising.

Triggers for the duty of candour

205. The types of harm which would trigger the procedure are set out in section 21 in the Bill as outcomes which could result in:
 - Death
 - Severe harm
 - Harm which is not severe but requires further treatment, changes the structure of the person's body, shortens life expectancy or impairs sensory, motor or intellectual functions for at least 28 continuous days,
 - Pain or psychological harm lasting at least 28 continuous days, or
 - The person requires treatment by a doctor to prevent their death or any of the other outcomes above.

206. There was a range of views on whether the harms or potential harms listed in the Bill which could trigger the duty of candour were appropriate. The Law Society of Scotland explained that the harms outlined in the Bill will—

“change thresholds in relation to the definitions of harm and possible outcomes of harm. The bill changes or lowers some thresholds and it will be important that everyone who is involved understands that.”¹²⁸

207. In its written submission it also highlighted that the inclusion of the term “could have caused harm” is particularly difficult because this requires a professional to make a decision about causation. This is a notoriously difficult area in medicine. It also highlighted that as the duty of candour is activated “as soon as reasonably practicable” after becoming aware of the incident, this could, in some instances, still be some considerable time later (potentially years later in cases where life expectancy is shortened).

208. We heard a range of views on whether all patients would wish to know that harm (or the potential for harm) had arisen particularly when it would not significantly alter their health outcome. Ardgowan Hospital staff highlighted to members that some 10-20% of patients do not want to receive information about any unintended harm caused especially where this may cause them further distress.

209. AvMA explained that each individual's wishes must be respected and that in England the duty of candour requires that the patient, service user or their family are told that there is something to report and to discuss. However—

“...they can simply say; “thanks, but I don’t want to know....That is their absolute right but it is not the right of any individual health professional or organisation to decide for them that they do not need the opportunity to know.”¹²⁹

210. COSLA expressed concerns about the triggers of “pain or psychological harm lasting at least 28 continuous days” in that it can be difficult to define, particularly where the person lacks capacity. Similar views were expressed by Social Work Scotland in relation to young people as well as the challenge of dissociating ‘psychological harm’ from other social/psychological factors in peoples’ lives.¹³⁰ COSLA also questioned whether some other incidents such as delayed discharge could trigger the duty of candour given the Bill's definition of harm.¹³¹

211. In considering the harm or potential harm that would trigger the duty of candour AvMA stressed that it is important that patients and families are involved early in any investigations—

“It should not be the case that the NHS or the nursing home conducts its own investigation and that it is only when, as a result of a rigorous investigation, it is found that harm has been caused or there was an unintended harmful incident that the patient or their family is spoken to.

They should be involved at the very first stage when it is suspected...so that they can be involved, if they want to be, in the investigation.”¹³²

212. AvMA supported the policy intention, as they understood it, to include omissions such as a failure to diagnose or a delayed diagnosis as an incident.¹³³ Other witnesses highlighted concern about the practicalities of extending harm to omissions. The Medical Protection Society explained that GPs will sometimes see patients two or three times before reaching a diagnosis and that—

”the nature of practice is that people do not necessarily get everything right first time. If every patient who potentially had a serious diagnosis was immediately referred for investigation or treatment, there would be gross overinvestigation and the secondary care system would be brought to its knees.”¹³⁴

213. Some who opposed a statutory duty of candour commented that the range of harm identified as triggering the candour procedure was so wide that it could result in a significant drain on staffing and resources.¹³⁵

214. AvMA highlighted their concerns about how unintended harmful incidents might come to the attention of patients when it may be another medical professional or provider such as a GP that recognises that harm or the potential for harm has arisen. They recommended that with such incidents the duty of candour should endure so that the original provider is notified.¹³⁶

215. The Minister for Public Health stressed that the duty of candour was intended to ensure that people learnt from incidents of harm or potential harm but that—

”We acknowledge that it might not always be in the best interests of the individual for them to be told about something that happened to them but the organisation will be required to consider the issue carefully and to ensure that they do not have a one-size-fits-all approach to disclosing information.”¹³⁷

216. The Scottish Government explained that some people would know of the harm caused, such as where there is a change in the body's structure or the wrong procedure performed. In other cases, the Bill proposes that it would be at an initial meeting when the person would be asked—

”how often they wanted an update, whether they wanted to be involved in the review and what information they might require.”¹³⁸

217. We note that the PM is clear that the harm or potential harm must be unrelated to the course of the condition for which the person is receiving care. It also focuses on unintended harm either caused or potentially caused.

218. Whilst we are content that the harms listed as triggering the duty of candour are comprehensive, we note witnesses concerns about the potential for relatively minor incidents to trigger the duty of candour. We therefore invite the Scottish Government to consider amending the Bill to reflect the magnitude of the harm or potential harm (such as 'significant' harm) which would trigger the duty of candour.

219. We acknowledge the evidence of some witnesses¹³⁹ that the harms listed in the Bill differ from those used by other inspection regimes such as the Care Inspectorate. As such there is the potential for confusion or misinterpretation amongst staff.

220. We therefore recommend that the Scottish Government also considers including within its duty of candour procedure clear guidance on how the triggers for the duty of candour differ from other regulatory regimes but also case studies setting out the thresholds for activation of the duty of candour procedure (as suggested by Healthcare Improvement Scotland).

Independent Registered Health Professional (IRHP)

221. In the event that a person in receipt of health, social care or social work services experiences an unintended or unexpected incident which, in the opinion of a registered health professional, results (or could have resulted) in death or harm, the Bill would require the responsible person to implement the duty of candour procedure. The registered health professional would need to be someone who was not involved in the incident - an independent registered health professional.

222. The Law Society of Scotland questioned the resource implications of requiring an IRHP to give an opinion on an incident such as in the case of a busy hospital when a patient might be treated by a whole chain of professionals from the moment they attend the hospital. RCN Scotland and others¹⁴⁰ also questioned how duty of candour disclosure would work given the boundaries between healthcare and social care are becoming increasingly blurred through health and social care integration.¹⁴¹

223. We heard differing views on how IRHP involvement might work in practice in a care setting (when a health professional might not be on site). UNISON and COSLA questioned whether it would be appropriate to use an IRHP every time. COSLA also highlighted the role of integrated teams in delivering care and whether the focus in the Bill on the healthcare aspect would be difficult. In that regard they consider it better to deal with such issues with a culture of openness and transparency rather than legislate to deal with it.

224. The Medical Protection Society questioned how the role would work for GPs who might see a patient two or three times before diagnosis. If it turned out that the

patient has a more serious diagnosis which the GP could have diagnosed a week or two earlier—

” “would I need to get an independent doctor to critique my care and give feedback? From a GP perspective, I suggest that would be unnecessarily or unworkably burdensome.”¹⁴²

225. The Law Society of Scotland highlighted that in a small GP practice, it might be difficult to identify an IRHP as easily as in a care setting where it could be costly to bring in an IRHP. It recommended that in relation to the Bill—

” “When we are looking at the definitions the idea of the extent of involvement could be usefully reviewed to make better use of the resources and of the expertise and knowledge of the person who is dealing with a case.”¹⁴³

226. The Law Society of Scotland also highlighted the difficulties in identifying a suitable "uninvolved" person on site in specialised areas of medicine or surgery.¹⁴⁴

227. The AvMA explained that it understood that an IRHP would not be involved in every incident that it might be subject to the duty of candour procedures given that would be costly and unnecessary. More importantly it considered that it would delay health professionals from getting on with providing patients with explanations of what had happened. However, if there was a doubt then the AvMA considered that a second independent opinion would be a good idea.

228. UNISON supported training and supporting people to a high level to undertake the IRHP role so that they could look at an incident objectively and describe it properly for the board. This was considered to be important so that decisions about it can be taken but that it should not require IRHP involvement with every incident.

229. The Scottish Government explained that the Bill requires a different health professional to make a judgement about an incident that has caused an outcome listed in the Bill but—

” “that does not mean that the professionals close to the incident cannot be involved in the information giving. That is something that we can look at in relation to the regulations and when we set out the detail of the procedure to be followed.”¹⁴⁵

230. As to why a health professional requires to be involved in the duty of candour procedure even in care settings, the Scottish Government explained that as some of the outcomes are health related—

” “The bill contains a requirement for the decision to be made that the outcomes are not directly related to the course of the person's illness or their condition and we propose that such a judgement be made by a health professional.”¹⁴⁶

231. They provided the example where a social care professional might consider that the harm outcomes in the Bill have occurred. In that circumstance it would be for the organisation responsible for the duty of candour procedure, in deciding whether to report it, to have it confirmed by an IRHP that the outcome was not related to the course of the person's illness or their condition.¹⁴⁷

232. We welcome the provision of an IRHP in the Bill. This will provide not only an independent perspective in those cases where organisations are not clear whether the duty of candour is engaged but also an important check and balance that the procedure is being initiated as intended.

233. Under the Bill in order for the duty of candour procedure to be invoked an unintended or unexpected incident must arise (or could have arisen) 'and' an IRHP must consider that the incident triggered (or could have triggered) the harm and is unrelated to the person's illness or underlying condition. Given this and witness concerns about the practical challenges of involving an IRHP in small or specialised organisations, we request clarification from the Scottish Government of the extent to which the duty of candour procedure can be invoked prior to receiving the views of the IRHP particularly in those cases where the cause of the harm is clear.

234. We note that under the Bill the duty of candour procedure must set out the training to be provided to the responsible person. In view of the importance of the IRHP in triggering the duty of candour procedure we recommend that the Bill be amended to include a specific requirement to provide training and support on the IRHP role.

235. We would also welcome clarification from the Scottish Government of as to whether the duty of candour procedure will include:

- a dispute resolution procedure should the IRHP and the organisation disagree about whether the duty of candour procedure is engaged¹⁴⁸; and
- guidance on the order of priority of notification of an IRHP as compared with other regulatory requirements once an unintended incident has occurred.

Monitoring, Reporting and Enforcement

236. The Bill would also require that the responsible person must report annually on the duty of candour. This report would set out information on the number and nature of incidents in which the duty was invoked and any changes to policies and procedures that resulted from the incidents. The Bill also provides for Scottish Ministers, Healthcare Improvement Scotland and Social Care and Social Work Improvement Scotland to publish a report on compliance by responsible persons should they wish.
237. The Committee heard that key to consistency in applying the duty of candour is monitoring. AvMA commented that, if the Bill is to be meaningful having adverse consequences for health boards or GPs who do not comply with the duty of candour is important. They therefore welcomed the provisions in the Bill which enable Ministers and others to report on compliance.¹⁴⁹ They did however recommend that training provided to staff on compliance and good practice should be a mandatory part of that report.
238. Age Scotland called for a high degree of consistency with the approach adopted for England and Wales. They explained that the collection of statistics across the UK would allow for easier analysis about the approaches to safety and adverse events taken in different jurisdictions. This, in turn would support a greater evidence-based approach to policy and practice.¹⁵⁰
239. The Law Society suggested that it might be more efficient if health boards and other responsible persons could adapt and utilise existing mechanisms to monitor and record these incidents.¹⁵¹
240. In written evidence to the Finance Committee, Healthcare Improvement Scotland (HIS) explains that, under the Bill it will be required to monitor the implementation of the duty of candour procedure in relation to independent healthcare services (which are defined in the National Health Service (Scotland) Act 1978). HIS state that of the services listed (such as independent hospitals and hospices, independent clinics, independent medical agencies etc) only the provisions of the Act that relate to independent hospitals and private psychiatric hospitals have commenced. As a result those services defined by the National Health Service (Scotland) Act 1978 which have not yet come into force would not currently fall within the duty of candour.
241. We support the provisions of the Bill on reporting compliance with the duty of candour. This will demonstrate how organisations have learned from the unintentional incidents that may have occurred and will also support wider learning across health and care providers. We agree that such reports should only contain anonymised information about the incident or accident.

242. We have some sympathy with witnesses who called for such annual reports to be aligned with or consolidated within other annual reporting functions in order to reduce the administrative burden on organisations. Given the Scottish Government's intention that the duty of candour procedure will build on existing candour processes, we seek clarification of whether it will consider building on organisations existing annual reporting mechanisms.
243. We are content with the Bill's provisions that Scottish Ministers and others can report on compliance by responsible persons. We agree with the Care Inspectorate and others that this represents a proportionate approach to securing compliance as opposed to the creation of an offence in relation to non-compliance.
244. We note that Healthcare Improvement Scotland (HIS) proposes that the Bill be amended to clarify that it is the monitoring body for those independent healthcare services it regulates "and where the legislative powers for regulation have been commenced." We seek the Scottish Government views on this proposed amendment.
245. Finally we invite the Scottish Government to consider whether there would be merit in working with the UK Government and Welsh Assembly to develop UK-wide statistics on the effectiveness of patient safety programmes and responses to adverse incidents to better inform policy making.

Part 3- Ill-treatment and wilful neglect

246. The Bill proposes to create new offences of ill-treatment or wilful neglect. There is one offence that would apply to adult health and social care workers and another that would apply to adult health and social care providers.

The need for legislation

247. The PM to the Bill explains that whilst offences of wilful neglect and ill-treatment already exist for mental health patients in Scotland under the Mental Health (Care and Treatment) (Scotland) Act 2003, the Bill will extend those offences to all health and social care patients in Scotland.
248. The majority (60%) of respondents supported the proposed offences. For those who didn't the most common reason was that they considered there was no need for the legislation given the existing avenues for redress. The RCN Scotland considered that there was enough legislation in place already to deal with wilful neglect such as the offence of common law assault, the Protection of Vulnerable Groups (Scotland) Act 2007 and mental health legislation. They and others¹⁵² also highlighted the role of regulatory bodies such as the GMC and NMC who hold professionals to account for their behaviours and where they can, if appropriate, end the careers of healthcare professionals.

249. COSLA questioned whether the issue was lack of legislation or rather a lack of investment in social care. In that regard they considered that adding another layer of legislation on top of what already exists would not deliver better leadership, better training or a culture shift.¹⁵³
250. Some witnesses¹⁵⁴ highlighted the current low usage of existing legislation as a reason why further legislation is not required, whilst others¹⁵⁵ questioned whether there were any people currently “getting away” with wilful neglect who would not with this Bill. As an example RCN Scotland highlighted that of the 600 cases before the RCN only two related to conduct in which someone had been accused of neglect.¹⁵⁶
251. Some witnesses, such as COSLA questioned whether the creation of offences of wilful neglect and ill-treatment would address more systemic problems such as pressure on resources, staffing ratios, and low pay in the sector particularly in the social care sector.¹⁵⁷
252. In contrast Age Scotland supported the proposed offences as empowering patients, service users and their representatives to complain, providing justice in individual cases and as providing consistency with other legislation such as the Adult Support and Protection (Scotland) Act 2007.¹⁵⁸
253. In written evidence the Scottish Government explained that the policy intention is to provide the criminal justice system with offences which could properly address any similar type of conduct to that which was revealed by the Francis report on the serious failings of care at Mid Staffordshire NHS Foundation Trust.
254. In the FM to the Bill the Scottish Government estimated that there will be no more than 100 potential prosecutions for the new offences per annum. This is however likely to be a high estimate given it is based on prosecutions for the existing mental health offence where 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.

255. We acknowledge that the vast majority of health and social care professionals provide high quality care and that the new offences of wilful neglect and ill-treatment may therefore be engaged in only a small number of instances.

256. We note that these offences already exist for some patients and that as such the new offence proposed in the Bill will extend it to all health and social care service users thereby recognising a wider range of circumstances when people may be vulnerable to ill-treatment or neglect.

257. Given this, we are content with the Bill's proposal to create a new offence of wilful neglect or ill-treatment.

258. Given the number of regulatory bodies and existing legislation which may also be engaged by an incident of alleged wilful neglect or ill-treatment we recommend that the Scottish Government provides guidance as to how these new offences will sit alongside existing process and procedures.

The definition of wilful neglect and ill-treatment

259. The Committee heard concerns that the bill does not define what wilful neglect and ill-treatment is. The RCN Scotland expressed concern that people might be criminalised for simple errors, and therefore stressed that wilful neglect should be seen as where people have taken premeditated decisions to act cruelly.¹⁵⁹ COSLA agreed that a tight definition was needed for wilful neglect to avoid criminalising behaviours which otherwise would have resulted in censure for poor practice.¹⁶⁰

260. Professor Britton explained that under current Scottish and English Law, neglect or negligence in a health-care setting is regarded as an unintentional act of omission. Where “wilful” is used, it is a criminal concept that means an act with premeditated, intentional or exercised with such a degree of recklessness that it is considered to be within the criminal sphere—

” “My personal observation is that what the Bill proposes could mean somebody would be criminally investigated for a crime that might have not occurred, which takes us back to the idea of a near miss.”¹⁶¹

261. The Minister for Public Health explained that the terms “wilful neglect” and “ill-treatment” already exist in legislation but that the wilful neglect and ill-treatment offence will cover “intentional acts or omissions and are not intended to catch incidents of mistake.”¹⁶²

262. The Scottish Government confirmed that the Mental Health (Scotland) Act 1984 and the Adults with Incapacity (Scotland) Act 2000 both use the terms of wilful neglect and ill-treatment without further definition. Given this, the terms are already familiar to the courts and police. It is then a matter for the criminal justice system to determine whether or not they have arisen based on the circumstances in each case. In that regard the courts have interpreted the term “wilful” as requiring a high level of intention and therefore not something that can be done as a result of mistake or accident. They indicate that defining these terms within the Bill may cast doubt on their meaning in existing legislation.¹⁶³

263. We are content that the Bill does not define wilful neglect and ill-treatment given these terms are already established in Scottish law.

Impact on the duty of candour

264. A number of respondents and witnesses expressed concern that part 3 of the Bill although well meaning, would be counterproductive and would work against the openness, honesty and candour that part 2 of the Bill seeks to build.¹⁶⁴

265. The RCN Scotland explained that—

” “There is no evidence that individuals or organisations are not being held to account when there are failings in health or social care delivery. We are concerned that the threat of criminal proceedings being taken against individuals will run counter to the building of a culture of transparency, learning and improvement within and out with the NHS.”¹⁶⁵

266. They expressed concern that staff who are not confident to challenge organisational decisions, such as inadequate staffing levels could end up being held accountable under part 3 of the Bill, rather than the manager who initially made the decision. This risk could be greater for agency or bank staff given the different clinical structures across boards in Scotland.¹⁶⁶

267. COSLA also highlighted concerns about how parts 2 and 3 of the Bill might operate in practice questioning whether a social care worker would be open about their own actions or another's action which may have caused harm, if in disclosing that information the consequences could lead to criminal charges.¹⁶⁷

268. The Medical Protection Society highlighted that someone could go to work and try to do the right thing but end up being in the criminal justice system even if the case didn't go to trial—

” “That would need to happen only once for it to have a devastating effect on the healthcare and social care community.”¹⁶⁸

269. They explained that this could then have a disproportionate impact on attracting people into the social care and medical sectors, areas where recruitment is already challenging.¹⁶⁹ Similar concerns were expressed by the Scottish Ambulance Service in relation to the potential of the new offence to deter individuals from volunteering to be first responders.¹⁷⁰

270. The Minister for Public Health emphasised the difference between parts 2 and 3 with the duty of candour being triggered by incidents which are unintended or unexpected whilst wilful neglect offences are intended to relate to very deliberate acts or omissions.¹⁷¹ In that regard whilst the duty of candour looks to foster a culture of openness and transparency in the health service, any decisions that might be made about negligence and liability are completely separate procedures.¹⁷²

271. We note the clarification of the Minister given above and that the triggers for engaging the duty of candour (unintended or unexpected) and the offence of wilful neglect and ill-treatment (deliberate and with a high level of intention) are separate and distinct.

272. We are also reassured that given both the duty of candour and the offence of wilful neglect or ill-treatment currently existing in some form for some patients, the concerns of witnesses that parts 2 and 3 will work against each other will not materialise.

273. Nevertheless, we seek further information from the Scottish Government on what training, support and education it will provide health and social care workers and providers on the new offences.

Care Worker Offence

274. A care worker offence would apply to any individual who provides care to another individual and who ill-treats or wilfully neglects that individual. Workers covered by the provisions include employees and volunteers providing health and social care, as well as supervisors, managers and directors of provider organisations. It would not cover unpaid/informal carers such as family members. The Bill does not define what constitutes either ill-treatment or wilful neglect. In addition, it does not set a threshold of harm at which point an offence has been committed.

275. If found guilty of such an offence, the individual would be liable, on summary conviction, to imprisonment for not more than 12 months and/or a fine up to the statutory maximum (currently set at £10,000). Where an individual is convicted on indictment, they would be liable to imprisonment for up to five years and/or an unlimited fine.

276. Some¹⁷³ questioned whether there should be summary conviction¹⁷⁴ for a care worker offence given conviction would likely be career ending. Simpson and Marwick suggested that the offence should be triable on indictment only.

277. COSLA and others¹⁷⁵ questioned whether the Bill should apply to familial carers given they can provide significant amounts of care. UNISON and others also noted that with the growth of personalisation and self-directed care the provisions need to be clear.¹⁷⁶

278. We agree that the new offences in part three should extend to individual care workers. However we also recognise the comments of witnesses that the way health and social care is delivered is becoming increasingly complex and much more multidisciplinary. As such we seek the Scottish Government's views on whether the definition of care worker includes:

- care workers employed by an individual or family member under self-directed support¹⁷⁷;

- personal assistants employed by a carer on behalf of a cared for person who lacks capacity¹⁷⁸.

Care Provider Offence

279. The care provider offence would cover providers of adult health and social care services, including both statutory providers such as the NHS and local authorities, as well as contractors and voluntary services.

280. A care provider would commit an offence if:

- An individual providing care on behalf of the provider ill-treats or wilfully neglects someone in their care
- The provider organises its service in such a way that it amounts to a gross breach of its duty of care to the individual who has been ill-treated or neglected and, in the absence of that breach, the ill-treatment or neglect would not or would have been less likely to have occurred.

281. If found guilty of the offence, a court may make, in addition to any other legal remedies, a remedial order and/or a publicity order.

282. A remedial order would require the care provider to undertake specified actions to remedy any breach of its duties of care, or any deficiency in its policies, systems or practices which have contributed to the breach.

283. A publicity order would require the care provider to publicise that it had been convicted of such an offence, the details of the case and any sanctions imposed.

284. UNISON welcomed the emphasis on organisations as well as individuals, which if backed up in guidance, training and regulations, will help change the culture to what it believes it needs to be. They also considered the provisions in the Bill to provide for the courts to make a remedial publicity order as being particularly important—

“Those provisions focus the controlling voices of organisations on the fact that they are not exempt - they cannot just pass the buck every time- and that, if there are failings in an organisation, that organisation could be found criminally responsible as well.”¹⁷⁹

285. Age Scotland also welcomed the proposals for the new offences to extend to organisations. However, they questioned whether the offence requiring a 'gross' breach of the relevant duty of care would place the burden of proof too high.¹⁸⁰ They suggested that, instead, the duty should be on the care provider to demonstrate that their conduct was reasonable.¹⁸¹

286. We also heard from representatives of Haemophilia Scotland, the Scottish Infected Blood Forum and the Hepatitis C Trust that the burden of proof in proving wilful neglect and ill-treatment should not be set too high as this could lead to disillusionment as the offence becomes meaningless. They provided an example of a recent case where this had happened which has resulted in service users feeling let down by the NHS and the police.

287. The Scottish Social Services Council and others¹⁸² proposed that, in relation to the care providers found guilty of the proposed offence, other sanctions should also be considered, such as disqualification from providing care services or preventing them from moving onto or opening another service.¹⁸³ Victim Support Scotland also proposed that compensation orders would be an appropriate penalty for the courts in relation to individuals and organisations found guilty of the new offence.¹⁸⁴

288. We welcome the extension of the offence of wilful neglect or ill-treatment to organisations as assisting organisations to learn from their failings. It will also challenge organisations to ensure that their procedures and resourcing are robust and support high quality health and social care given they could be held accountable for any serious failings.

289. We recommend that, in order to ensure that the implementation of the new offence is effective, the Scottish Government provides guidance to health and social care organisations on the new offence and in particular on their role and responsibilities.

290. We support the use of remedial orders for organisations found guilty of the proposed offence as this will facilitate service improvement. We request further information on how the Scottish Government envisages that publicity orders might work, and in what circumstances.

291. We have some sympathy with those who questioned whether the burden of proof is too high for organisations to be found guilty of wilful neglect given it requires a 'gross' breach of their duties of care. We therefore recommend that the Scottish Government reviews the matter.

292. Finally we seek clarification of some concerns raised in written evidence as to whether:

- the care provider offence will extend to agencies who provide care workers (raised in the written submission of the Coalition of Care and Support Providers and the Workforce Development Network);
- Speech and Language Therapists and Allied Health Professionals whose services are geared to supporting independent living for people with disability (but who are not 'ill') should be included within the Bill.¹⁸⁵

Proposed Stage 2 amendments

293. If the general principles of the Bill are agreed to at Stage 1 the Scottish Government has indicated it will include further provisions within the Bill by way of amendment at Stage 2.

Extending wilful neglect or ill-treatment offences to children

294. At present, the proposed offences under part 3 of the Bill would not cover children's services. However, the Scottish Government has recently consulted on whether the provisions should also apply to children's services with a view to introducing an amendment at stage 2 of the Bill.

295. A number of the respondents indicated that they would support such an amendment.¹⁸⁶

Voice Equipment

296. On 1 September 2015, the First Minister confirmed the Scottish Government's intention to amend the Bill at Stage 2 to provide "a right to voice equipment when required." The Minister for Public Health wrote to the Committee on 6 October providing more detail on these amendments which will—

” "require health boards to secure the provision of voice equipment for children and adults who find speaking difficult, are at risk of losing their voice or have no voice. As part of this, Ministers will be given the power to issue guidance to support the provision of this equipment on a multi-partner basis."¹⁸⁷

297. Given the Committee has not taken evidence on either of these proposed amendments, should the Bill proceed to Stage 2 then we anticipate taking evidence on these proposed amendments prior to Stage 2 commencing.

298. We therefore seek a commitment from the Scottish Government to provide the Committee with the draft amendments as well as their purpose and effect, as soon as possible (and no later than early December 2015) to enable the Committee to take oral evidence in a timely manner.

¹ We received 845 responses to the online survey. As respondents were self-selecting and due to the way in which the survey was promoted, responses are not necessarily representative of the Scottish population as a whole.

² Scottish Parliament Finance Committee. 2015 (Session 4). *Report on the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill's Financial Memorandum* (published 1 October 2015, Web only).

³ Delegated Powers and Law Reform Committee, 56th Report, 2015 (Session 4). *Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill at Stage 1* (SP Paper 802).

⁴ www.gov.scot/tobaccofreegeneration

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⁵ Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill. Policy Memorandum (SP Bill 73-PM, Session 4 (2015)), paragraph 7 to 9.

⁶ Ash Scotland Fact sheet; <http://www.ashscotland.org.uk/media/6675/E-cigarettes.pdf>

⁷ Policy Memorandum, paragraph 21.

⁸ Public Health England (2015) E-cigarettes: an evidence update. Available at:

<https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 11.

¹⁰ Scottish Parliament Information Centre. (2015) Survey: Controlling E-cigarettes and Restricting Smoking in Parts of Hospital Grounds. Available at:

http://www.scottish.parliament.uk/S4_HealthandSportCommittee/Inquiries/Health_Bill-Survey_Results.pdf

¹¹ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 37.

¹² Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 18.

¹³ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 15.

¹⁴ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 19. Also cited by NHS Greater Glasgow and Clyde. Written submission

¹⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 15.

¹⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 10.

¹⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 18.

¹⁸ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 14.

¹⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 5.

²⁰ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 18.

²¹ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 9.

²² VOKE 0.45mg Inhaler – see:

<http://www.mhra.gov.uk/spc-pil/?prodName=VOKE%200.45%20MG%20INHALER&subsName=NICOTINE&pageID=SecondLevel>

²³ Professor Bauld, New Nicotine Alliance, Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Cols 13-14. JTI UK, Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 7.

²⁴ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 10.

²⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Cols 7-8.

²⁶ Policy Memorandum, paragraph 36.

²⁷ Professor Linda Bauld. Written submission.

²⁸ World Health Organisation. (2014) Electronic nicotine delivery systems. FCTC/COP/6/10 rev.1. Paper for Conference of the Parties to the WHO Framework Convention of Tobacco Control, Sixth Session 13-18 October 2014. [Online]. Available at: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf

²⁹ Scottish Grocers Federation. Written submission.

³⁰ Fontem Ventures

³¹ Policy Memorandum, paragraph 45.

³² Policy Memorandum, paragraph 52.

³³ Such as the British Heart Foundation Scotland, New Nicotine Alliance, ECITA.

³⁴ New Nicotine Alliance, Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 16. ECITA, Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 6.

³⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 3.

³⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 5.

³⁷ Totally Wicked, Written submission.

³⁸ such as the Scottish Coalition on Tobacco.

³⁹ Policy Memorandum, paragraph 58

⁴⁰ Policy Memorandum, paragraph 61.

⁴¹ see also National Federation of Retail Newsagents, NHS Health Scotland, Scottish Coalition on Tobacco.

⁴² Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 3.

⁴³ Totally Wicked. Written submission, Vaporized (CCHG Ltd). Written submission. JTI UK, Written submission.

⁴⁴ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 12.

⁴⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 17.

⁴⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 15.

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- ⁴⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 8 September 2015, Col 24.
- ⁴⁸ the DISPLAY Research Team. Written submission.
- ⁴⁹ Fast Forward. Written submission.
- ⁵⁰ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 2.
- ⁵¹ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 8.
- ⁵² Policy Memorandum, paragraph 89.
- ⁵³ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 22.
- ⁵⁴ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 7.
- ⁵⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 12.
- ⁵⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 12.
- ⁵⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 24.
- ⁵⁸ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 12 – 13.
- ⁵⁹ such as NHS Tayside. Written submission, Environmental Health Service-Aberdeen City Council. Written submission.
- ⁶⁰ Aberdeen City Council Protective Services. Written submission.
- ⁶¹ With the exception of the mental health inpatient setting where one outside gazebo is available but only used in exceptional circumstances e.g. someone under constant observation or at risk of absconding, NHS Ayrshire and Arran. Written submission.
- ⁶² Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 38-39.
- ⁶³ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 40.
- ⁶⁴ NHS Ayrshire Health and Social Care Partnership. Written submission.
- ⁶⁵ such as Fife Health and Wellbeing Alliance, Scottish Directors of Public Health, NHS Lanarkshire and South Lanarkshire Council Environmental Services, East Dunbartonshire CHP, NHS Health Scotland.
- ⁶⁶ Scottish Directors of Public Health. Written submission. NHS Lanarkshire. Written submission.
- ⁶⁷ Scottish Government. Supplementary written submission, 6 October 2015.
- ⁶⁸ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 4.
- ⁶⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 21-22.
- ⁷⁰ See also NHS Western Isles. Written submission.
- ⁷¹ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 40-41.
- ⁷² Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 21.
- ⁷³ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 21.
- ⁷⁴ Finance Committee. 2015 (Session 4). *Report on the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill's Financial Memorandum* (published 1 October 2015, Web only). Paragraph 23.
- ⁷⁵ Scottish Government. Supplementary written submission, 6 October 2015.
- ⁷⁶ Finance Committee. 2015 (Session 4). *Report on the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill's Financial Memorandum* (published 1 October 2015, Web only). Paragraphs 34 and 36.
- ⁷⁷ West Dunbartonshire Health and Social Care Partnership. Written submission.
- ⁷⁸ The Royal College of Psychiatrists in Scotland. Written submission.
- ⁷⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 40.
- ⁸⁰ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 6.
- ⁸¹ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 6.
- ⁸² Scottish Government. Supplementary written submission, 6 October 2015.
- ⁸³ The branch of pharmacology concerned with the movement of drugs within the body.
- ⁸⁴ The Royal College and Psychiatrists in Scotland. Written submission.
- ⁸⁵ This view was also provided by some Health Boards such as NHS Tayside.
- ⁸⁶ Scottish Directors of Public Health. Written submission.
- ⁸⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 6.
- ⁸⁸ Scottish Government. Supplementary written submission, 6 October 2015.
- ⁸⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 1 September 2015, Col 25.
- ⁹⁰ NHS Ayrshire and Arran. Written submission.
- ⁹¹ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 10.
- ⁹² Scottish Government. Supplementary written submission, 6 October 2015.
- ⁹³ Mid-Staffordshire NHS Foundation Trust Public Inquiry (2013). Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry. London, the Stationary Office. Available at: <http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffspublicinquiry.com/report>
- ⁹⁴ Dalton D & Williams N (2014). Building a culture of candour: A review of the threshold for the duty of candour and of the incentives for care organisations to be candid. Available at: <https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>

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⁹⁵ National Advisory Group on the Safety of Patients in England (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

⁹⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 16.

⁹⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 15.

⁹⁸ Healthcare Improvement Scotland (2015). Learning from adverse events through reporting and review. Available at:

http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx

⁹⁹ Chief Executives of statutory regulators of healthcare professionals (2014). Joint statement on the professional duty of candour. Available at: http://www.gmc-uk.org/Joint_statement_on_the_professional_duty_of_candour_FINAL.pdf_58140142.pdf

¹⁰⁰ Medical Protection Society, Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 4.

¹⁰¹ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 3.

¹⁰² BMA Scotland. Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 20.

¹⁰³ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 3.

¹⁰⁴ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 18.

¹⁰⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 20.

¹⁰⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 42.

¹⁰⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 9.

¹⁰⁸ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 17.

¹⁰⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 6.

¹¹⁰ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 6.

¹¹¹ Scottish Public Services Ombudsman, Written submission.

¹¹² Policy Memorandum, paragraph 152.

¹¹³ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 11.

¹¹⁴ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 14.

¹¹⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 19.

¹¹⁶ Policy Memorandum, paragraph 157.

¹¹⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 13.

¹¹⁸ Policy Memorandum, paragraph 158.

¹¹⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 11.

¹²⁰ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 13.

¹²¹ Scottish Public Services Ombudsman. Written submission.

¹²² Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 15.

¹²³ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 28.

¹²⁴ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Cols 20-21.

¹²⁵ BMA Scotland. Written submission.

¹²⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 16.

¹²⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 17.

¹²⁸ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 4.

¹²⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 9.

¹³⁰ Social Work Scotland. Written submission.

¹³¹ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 26.

¹³² Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 22.

¹³³ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 22.

¹³⁴ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 23-24.

¹³⁵ Simpson and Marwick, Forum of Insurance Lawyers. Written submission.

¹³⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 23.

¹³⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 13.

¹³⁸ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 13.

¹³⁹ such as the Coalition of Care and Support Providers (CCPS) and the Workforce Development Network (WDN)

¹⁴⁰ North Ayrshire Health and Social Care Partnership. Written submission.

¹⁴¹ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 31.

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- ¹⁴² Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 24.
- ¹⁴³ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 27.
- ¹⁴⁴ Law Society of Scotland, Written submission.
- ¹⁴⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 15.
- ¹⁴⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 20.
- ¹⁴⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 20.
- ¹⁴⁸ Coalition of Care and Support Providers (CCPS) and the Workforce Development Network (WDN). Written submission.
- ¹⁴⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 11-12.
- ¹⁵⁰ Age Scotland, Written submission.
- ¹⁵¹ Law Society of Scotland, Written submission.
- ¹⁵² Such as BMA Scotland.
- ¹⁵³ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 24.
- ¹⁵⁴ such as RCN Scotland.
- ¹⁵⁵ Medical Protection Society, Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 15.
- ¹⁵⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 23.
- ¹⁵⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 42.
- ¹⁵⁸ Age Scotland. Written submission.
- ¹⁵⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 32.
- ¹⁶⁰ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 32.
- ¹⁶¹ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 15-16.
- ¹⁶² Scottish Parliament Health and Sport Committee. *Official Report*, Col 3, 6 October 2015
- ¹⁶³ Scottish Government. Supplementary written submission, 6 October 2015.
- ¹⁶⁴ such as UNISON, Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 42. Medical Protection Society, Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 15. BMA Scotland. Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 20.
- ¹⁶⁵ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 19.
- ¹⁶⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 27.
- ¹⁶⁷ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 25.
- ¹⁶⁸ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 16.
- ¹⁶⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 22 September 2015, Col 17.
- ¹⁷⁰ Scottish Ambulance Service. Written submission.
- ¹⁷¹ Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 3.
- ¹⁷² Scottish Parliament Health and Sport Committee. *Official Report*, 6 October 2015, Col 16.
- ¹⁷³ such as Simpson and Marwick, Forum of Insurance Lawyers.
- ¹⁷⁴ Summary procedure is used for less serious offences (with the charges set out in a complaint) and may ultimately lead to a trial before a sheriff or, in justice of the peace courts, before a bench of one or more lay justices. Trials under summary procedure are conducted without a jury.
- ¹⁷⁵ such as ENABLE Scotland
- ¹⁷⁶ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 33.
- Coalition of Care and Support Providers (CCPS) and the Workforce Development Group (WDN). Written submission.
- ¹⁷⁷ Coalition of Care and Support Providers (CCPS) and the Workforce Development Network (WDN), Written submission
- ¹⁷⁸ Carers Trust Scotland. Written submission.
- ¹⁷⁹ Scottish Parliament Health and Sport Committee. *Official Report*, 15 September 2015, Col 26.
- ¹⁸⁰ Similar concerns were also raised by the Care Inspectorate.
- ¹⁸¹ Age Scotland. Written submission.
- ¹⁸² WithScotland. Written submission.
- ¹⁸³ Scottish Social Services Council. Written submission.
- ¹⁸⁴ Victim Support Scotland. Written submission.
- ¹⁸⁵ Royal College of Speech and Language Therapists. Written submission.
- ¹⁸⁶ ENABLE Scotland, General Medical Council, Victim Support Scotland, UNISON, COSLA. North Ayrshire Health and Social Care Partnership
- ¹⁸⁷ Letter from the Minister for Public Health, 6 October 2015.

Annexe A

Extracts from the minutes of the Health and Sport Committee and associated written and supplementary evidence

21st Meeting, Tuesday 23 June 2015

Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (in private): The Committee agreed its approach to the scrutiny of the Bill at Stage 1.

22nd Meeting, 1 September 2015

2. Health (Tobacco, Nicotine etc. and Care)(Scotland) Bill - witness expenses: The Committee agreed to delegate to the Convener responsibility for arranging for the SPCB to pay, under Rule 12.4.3, any expenses of witnesses on the Bill.

3. Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill: The Committee took evidence on the Bill at Stage 1 from—
Sheila Duffy, Chief Executive, ASH Scotland, Scottish Coalition on Tobacco (SCOT);
Professor Linda Bauld, Professor of Health Policy, University of Stirling;
Simon Clark, Director, Freedom Organisation for the Right to Enjoy Smoking Tobacco (FOREST);
Andy Morrison, Trustee, New Nicotine Alliance.

4. Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (in private): The Committee considered the main themes arising from the oral evidence heard earlier in the meeting.

Written evidence

-  [Scottish Coalition On Tobacco \(SCOT\)](#)
-  [ASH Scotland](#)
-  [Professor Linda Bauld](#)
-  [Forest](#)
-  [New Nicotine Alliance](#)

Supplementary Written Evidence

-  [Royal Environmental Health Institute of Scotland](#)
-  [ASH Scotland](#)

23rd Meeting, Tuesday 8 September 2015

2. **Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill:** The

Committee took evidence on Part 1 of the Bill at Stage 1 from—
Mark Feeney, Policy and Development Pharmacist, Community Pharmacy Scotland;

Katherine Devlin, President, ECITA (EU) Ltd;

Guy Parker, Chief Executive, Advertising Standards Authority;

John Lee, Head of Public Affairs, Scottish Grocers Federation;






Charlie Cunningham-Reid, UK Head of Corporate Affairs and Communications, JTI UK (E-Lites);

Alan Teader, Marketing Manager, Vapourized.

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

private): The Committee considered the main themes arising from the oral evidence heard earlier in the meeting.

Written Evidence

-  Community Pharmacy Scotland
-  ECITA (EU) Ltd
-  Advertising Standards Authority
-  Scottish Grocers' Federation
-  Japan Tobacco International (JTI)
-  Vaporized

Supplementary Written Evidence

-  ECITA (EU) Ltd

24th Meeting, Tuesday 15 September 2015

2. **Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill:** The

Committee took evidence on the Bill at Stage 1 from—
Norman Provan, Associate Director, Royal College of Nursing Scotland;

Dave Watson, Head of Bargaining and Campaigns, Unison;

Councillor Peter Johnson, Health and Social Care Spokesperson, and

Beth Hall, Policy Manager, Health and Social Care Team, COSLA;

Brenda Knox, Health Improvement Lead, NHS Ayrshire and Arran;

Donald Harley, Deputy Scottish Secretary, BMA Scotland.

Rhoda Grant declared her membership of Unison.

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

private): The Committee considered the main themes arising from the oral evidence heard earlier in the meeting.

Written evidence

-  Royal College of Nursing Scotland

-  [UNISON](#)
-  [COSLA](#)
-  [NHS Ayrshire and Arran](#)
-  [BMA Scotland](#)

27th Meeting, Tuesday 6 October 2015

2. **Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill:** The Committee took evidence on the Bill at Stage 1 from—
Maureen Watt, Minister for Public Health, Claire McDermott, Bill Team Manager, Siobhan Mackay, Head of the Tobacco Control Team, Professor Craig White, Divisional Clinical Lead, and Ailsa Garland, Principal Legal Officer, Scottish Government.
3. **Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (in private):** The Committee considered the main themes arising from the oral evidence heard earlier in the meeting.

Supplementary Written Evidence

-  [Letter from Minister for Public Health](#)
-  [Scottish Government](#)







28th Meeting, Tuesday 27 October 2015

Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (in private): The Committee considered a draft of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill Stage 1 Report. Various changes were agreed to, and the Committee agreed to consider a revised draft, in private, at a future meeting.

29th Meeting, Tuesday 3 November 2015

Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (in private): The Committee considered a revised draft Stage 1 report. Various changes were agreed to, and the report was agreed for publication.






























List of other written evidence

-  [Dominic Reedman-Flint](#)
-  [Royal College of Speech and Language Therapists](#)
-  [Simpson & Marwick](#)
-  [General Pharmaceutical Council](#)
-  [Marie Curie](#)
-  [Fast Forward \(Positive Lifestyles\)](#)

-  Environmental Health Service - Aberdeen City Council
-  Under Age Sales Ltd
-  Centre for Drug Misuse Research
-  Paul Barnes
-  Social Work Scotland
-  Scottish Ambulance Service
-  YouthLink Scotland
-  Carers Trust Scotland
-  National Carer Organisations
-  Geoffrey Vann
-  Forum of Insurance Lawyers
-  West Dunbartonshire Health & Social Care Partnership
-  Linda Garcia
-  Pfizer UK
-  Cancer Research UK
-  British Heart Foundation Scotland
-  Care Inspectorate
-  North Ayrshire Health & Social Care Partnership
-  NHS Health Scotland
-  Institute of Practitioners in Advertising
-  Association of Convenience Stores Limited
-  Health and Social Care Alliance Scotland (the ALLIANCE)
-  Royal Environmental Health Institute of Scotland
-  Petrol Retailers Association
-  Scottish Social Services Council
-  Colin Robertson
-  British Healthcare Trades Association
-  Medical Protection Society (MPS)
-  Totally Wicked Ltd
-  Quarriers
-  Action against Medical Accidents (AvMA)
-  Royal College of General Practitioners
-  MRC/CSO Social and Public Health Sciences Unit, University of Glasgow
-  Citizens Advice Scotland
-  NHS Lanarkshire
-  Fontem Ventures
-  Scottish Public Services Ombudsman
-  NHS Grampian
-  Coalition of Care and Support Providers & Workforce Development Network
-  The Law Society of Scotland
-  Imperial Tobacco UK
-  Scottish Directors of Public Health

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-  NHS Lothian
-  National Federation of Retail Newsagents (NFRN)
-  Healthcare Improvement Scotland
-  British Lung Foundation
-  Philip Morris Limited
-  Victim Support Scotland
-  Scottish Wholesale Association
-  Children in Scotland
-  Advertising Association
-  The Display Research Team, School of Health Sciences, University of Stirling
-  WithScotland
-  Royal College of Psychiatrists in Scotland
-  Society of Chief Officers of Trading Standards
-  NHS Greater Glasgow and Clyde
-  NHS Highland
-  Age Scotland
-  Angus Council
-  ENABLE Scotland
-  South Lanarkshire Council
-  Nursing and Midwifery Council
-  General Medical Council
-  NHS Western Isles
-  Fife Health and Wellbeing Alliance
-  Aberdeenshire Alcohol and Drug Partnership
-  NHS Tayside
-  Aberdeen City Council Protective Services
-  East Dunbartonshire CHP
-  Aberdeen City Council
-  South Lanarkshire Council's Environmental Services
-  Royal College of Physicians of Edinburgh

Late Submissions

-  Max Cruickshank
-  Max Cruickshank

Annexe B

Summary of the results of the online survey and video blog that sought views from young people



Survey Results



Video blog


Annexe C

Note of visit to Ardgowan Hospice and meeting with Haemophilia Scotland, the Scottish Infected Blood Forum, and the Hepatitis C Trust

The note of the visit to Ardgowan Hospice can be found on the Scottish Parliament website at the following webpage:

 http://www.scottish.parliament.uk/S4_HealthandSportCommittee/Inquiries/Note_of_Visit_with_Ardgowan_Hospice.pdf

The note of the meeting with Haemophilia Scotland, the Scottish Infected Blood Forum and the Hepatitis C Trust can be found on the Scottish Parliament website at the following webpage:

 http://www.scottish.parliament.uk/S4_HealthandSportCommittee/Inquiries/Note_of_Meeting_HaemophiliaScotland_and_ScottishInfectedBloodForum.pdf

Annexe D

Report from the Delegated Powers and Law Reform Committee and Report from the Finance Committee

Report from the Delegated Powers and Law Reform Committee

The Delegated Powers and Law Reform Committee (DPLRC) report on the Health (Tobacco, Nicotine etc. and Care) (Scotland) can be found on the Scottish Parliament's website at the following webpage:

 <http://www.scottish.parliament.uk/parliamentarybusiness/CurrentCommittees/92746.aspx>

Report from the Finance Committee

Finance Committee Report on the Health (Tobacco, Nicotine etc. and Care)(Scotland)Bill's Financial Memorandum can be found on the Scottish Parliament's website at the following webpage:

 <http://www.scottish.parliament.uk/parliamentarybusiness/CurrentCommittees/92775.aspx>

