

## **CONSULTATION QUESTIONS**

*Please note that we have responded only to those parts of the consultation that are relevant to our business.*

*We have answered in anticipation that in future there will be some e-cigarette products which have been licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) and which hold Marketing Authorisations (MAs) as non-prescription medicines licensed for use as nicotine replacement therapy (NRT) products for existing tobacco cigarette users to use as an aid to reducing and/or stopping cigarette smoking.*

*The MHRA has said that it intends to start licensing selected e-cigarettes in this way once the EU Directive on Tobacco Products comes in to effect in 2016.*

*It is our belief that such licensed products should be exempt from the proposed controls on the promotion and sale of e-cigarettes, so long as they are being promoted, sold and used within the terms of their Marketing Authorisation licence and the sale is made from appropriate premises (for example, community pharmacies).*

*We also believe that there should be a period of grace regarding e-cigarettes where the manufacturer has indicated that they are applying, or intend to apply, for a MA as a medicinal product if there is a difference in the timing of changes to Scottish legislation and UK medicines legislation.*

*We note that since this consultation started, the Department of Health and Welsh Government have jointly launched a consultation on introducing age of sale restrictions for nicotine inhaling products. Within this consultation, it is proposed to exempt any nicotine inhaling products, including e-cigarettes, that are licensed by the MHRA. Such products could be supplied to under-18s either on prescription or by permitting the sale of non-prescription medicines that include an indication for use in people aged under 18 years old. We suggest that the Scottish Government should consider adopting this legislative approach.*

*(<https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>)*

*While we generally agree that e-cigarettes should be restricted to customers who are aged 18 years and over, we also strongly defend the right of our pharmacists to act in the best interests of patients. So, for example, an individual pharmacist might use his or her professional judgement to assess the risks and benefits of supplying an e-cigarette product to a person aged under 18 – in particular comparing the risks against continued smoking of tobacco cigarettes – and might decide to make a supply. We do not advocate this approach, but we always support the ability of pharmacists to make clinically based professional judgements that put the interests of patients first and foremost.*

### **Age restriction for e-cigarettes**

**1. Should the minimum age of sale for e-cigarette devices, refills (e-liquids) be set at 18?**

Yes ☒ No ☐

*But see also our comments on professional judgement (above).*

**2. Should age of sale regulations apply to:**

**a. only e-cigarette devices and refills (e-liquids) that contain nicotine or are capable of containing nicotine, or**

**b. all devices / refills (e-liquids) regardless of whether they contain or are capable of containing nicotine?**

a ☐ b ☐

**3. Whom should the offence apply to:**

**a. the retailer selling the e-cigarette**

a ☐

**b. the young person attempting to purchase the e-cigarette**

b ☐

**c. both**

c ☐

**4. Should sales of e -cigarettes devices and refills (e-liquids) from self-service vending machines be banned?**

Yes ☐ No ☐

**5. Should a restriction be in place for other e-cigarette accessories?**

Yes ☐ No ☐

6. If you answered “ yes” to question 5, which products should have restrictions applied to them?

Comments

**Proxy purchase for e-cigarettes**

7. Should the Scottish Government introduce legislation to make it an offence to proxy purchase e-cigarettes?

Yes ☐ No ☐

**Domestic advertising and promotion of e-cigarettes**

8. Should young people and adult non-smokers be protected from any form of advertising and promotion of e-cigarettes?

Yes ☐ No ☒

9. In addition to the regulations that will be introduced by the Tobacco Products Directive do you believe that the Scottish Government should take further steps to regulate domestic advertising and promotion of e-cigarettes?

Yes ☒ No ☐

10. If you believe that regulations are required, what types of domestic advertising and promotion should be regulated?

- |  |                                       |
|--|---------------------------------------|
| a. Bill boards   | a <input checked="" type="checkbox"/> |
| b. Leafleting  | b <input checked="" type="checkbox"/> |
| c. Brand-stretching (the process of using an existing brand name for new products or services that may not seem related) | c <input checked="" type="checkbox"/> |
| d. Free distribution (marketing a product by giving it away free)  | d <input checked="" type="checkbox"/> |
| e. Nominal pricing (marketing a product by selling at a low price)   | e <input checked="" type="checkbox"/> |
| f. Point of sale advertising (advertising for products and services at the places where they were bought)                | f <input checked="" type="checkbox"/> |
| g. Events sponsorship with a domestic setting  | g <input checked="" type="checkbox"/> |

11. If you believe that domestic advertising and promotion should be regulated, what, if any, exemptions should apply?

*Any e-cigarette products which have been licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) and which hold Marketing Authorisations (MAs) as non-prescription medicines licensed for use as nicotine replacement therapy (NRT) products for existing tobacco cigarette users to use as an aid to reducing and/ or stopping cigarette smoking should be exempted from the proposed controls on the promotion and sale*

*of e-cigarettes, so long as they are being promoted, sold and used within the terms of their Marketing Authorisation licence and the sale is made from appropriate premises (for example, community pharmacies).*

*Thus, for example, community pharmacies would be able to stock, sell and promote (using point of sale materials and other advertising) licensed e-cigarettes as NRT to help customers stop smoking, alongside existing NRT products (patches, gums, etc), as long as they were complying with the restrictions set out within the Marketing Authorisation. This would be in line with the approach proposed by the Department of Health and Welsh Government in their joint consultation on nicotine inhaling products.*

*In addition, trade advertising by manufacturers of licensed products should be permitted towards retailers, as long as this was through media channels that were not aimed at or freely available to members of the public and the purpose of the advertising was to encourage retailers to stock licensed e-cigarette products for use as NRT within the terms of relevant Marketing Authorisations.*

**12. Are you aware of any information or evidence that you think the Scottish Government should consider in relation to regulating domestic advertising in relation to impacts on children and adults (including smokers and non-smokers)?**

Comments

**13. Are you aware of any information or evidence that you think the Scottish Government should consider in relation to regulating domestic advertising in relation to impacts on business, including retailers, distributors and manufacturers?**

*Assuming that licensed e-cigarette products are introduced, and that medicines licensing remains a reserved activity, there is likely to be a small amount of cross-border advertising of licensed products in media that is not restricted, controlled or produced in Scotland (eg, print magazines).*

*Retailers who operate internet sites that are available on a UK-wide basis may not be able to restrict the display of certain products to customers (assuming there is a difference in retailing restriction across the UK) but they would be able to restrict sales, such as by blocking delivery to addresses in Scotland.*

#### **Inclusion of electronic cigarettes on the Scottish Tobacco Retailer Register**

**14. Do you agree that retailers selling e-cigarettes and refills should be required to register on the Scottish Tobacco Retailers Register?**

Yes ☐ No ☒

**15. Do you agree that the offences and penalties should reflect those already in place for the Scottish Tobacco Retailers Register?**

Yes ☐ No ☒

**16. If you answered 'no', to question 15, what offences and penalties should be applied?**

*We believe that there is a major difference between products which are predominantly made from or contain tobacco (cigarettes, cigars, etc) and those which only contain nicotine extracted from tobacco (ie, e-cigarettes). The majority of licensed NRT products also contain nicotine and these are not subject to a requirement for the retailers to be on the Scottish Tobacco Retailers Register.*

*Retailers should be exempt from registering with the Scottish Tobacco Retailers Register, and from any associated offences and penalties, so long as the only e-cigarette products they stock are ones that hold MHRA licenses as non-prescription medicines for use as NRT to help customers reduce or stop using tobacco cigarettes.*

*Thus, for example, community pharmacies would not be required to be registered, so long as they were only stocking licensed e-cigarettes for sale alongside other forms of NRT.*

**E-cigarettes – use in enclosed public spaces**

**17. Do you believe that the Scottish Government should take action on the use of e-cigarettes in enclosed public spaces?**

Yes ☐ No ☐

**18. If you answered 'yes' to Question 17, what action do you think the Scottish Government should take and what are your reasons for this?**

Comments

**19. If you answered, 'no' to Question 17, please give reasons for your answer.**

Comments

**20. Are you aware of any evidence, relevant to the use of e-cigarettes in enclosed spaces, that you think the Scottish Government should consider?**

Comments

**Smoking in cars carrying children aged under 18**

**21. Do you agree that it should be an offence for an adult to smoke in a vehicle carrying someone under the age of 18?**

Yes ☐ No ☐

**22. Do you agree that the offence should only apply to adults aged 18 and over?**

Yes ☐ No ☐

**23. If you answered 'no' to Question 22, to whom should the offence apply?**

Comments

**24. Do you agree that Police Scotland should enforce this measure?**

Yes ☐ No ☐

**25. If you answered 'no' to Question 24, who should be responsible for enforcing this measure?**

Comments

**26. Do you agree that there should be an exemption for vehicles which are also people's homes?**

Yes ☐ No ☐

**27. If you think there are other categories of vehicle which should be exempted, please specify these?**

Comments

**28. If you believe that a defence should be permitted, what would a reasonable defence be?**

Comments

### **Smoke-free (tobacco) NHS grounds**

**29. Should national legislation be introduced to make it an offence to smoke or allow smoking on NHS grounds?**

Yes ☐ No ☒

**30. If you support national legislation to make it an offence to smoke on NHS grounds, where should this apply?**

- a. All NHS grounds (including NHS offices, dentists, GP practices) a ☐  
b. Only hospital grounds b ☐  
c. Only within a designated perimeter around NHS buildings c ☐  
d Other suggestions, including reasons, in the box below

*We are concerned that the term “NHS grounds” is not well defined. For example, the majority of dental surgeries, GP practices and community pharmacies are privately owned premises operated by independent contractors to the NHS. We believe it should be for the premises owners to set their own policies in regard of cigarette smoking and/or e-cigarette use in or around the property their own, drawing on the wishes of their own staff, customers and patients receiving NHS services.*

**31. If you support national legislation, what exemptions, if any, should apply (for example, grounds of mental health facilities and / or facilities where there are long-stay patients)?**

Comments

**32. If you support national legislation, who should enforce it?**

Comments

**33. If you support national legislation, what should the penalty be for non-compliance?**

Comments

**34. If you do not support national legislation, what non-legislative measures could be taken to support enforcement of, and compliance with, the existing smoke-free grounds policies?**

Comments

**Smoke-free (tobacco) children and family areas**

**35. Do you think more action needs to be taken to make children's outdoor areas tobacco free?**

Yes ☐ No ☐

**36. If you answered 'yes' to Question 35, what action do you think is required:**

- a. Further voluntary measures at a local level to increase the number of smoke-free areas** a ☐
- b. Introducing national legislation that defines smoke-free areas across Scotland** b ☐
- c. That the Scottish Government ensures sufficient local powers to allow decisions at a local level as to what grounds should be smoke-free** c ☐
- d. Other actions. Please specify in the box below**

Comments

**37. If you think action is required to make children's outdoor areas tobacco-free, what outdoor areas should that apply to?**

Comments

**Age verification policy 'Challenge 25' for the sale of tobacco and electronic cigarettes**

**38. Do you agree that retailers selling e-cigarettes, refills and tobacco should be required by law to challenge the age of anyone they believe to be under the age of 25?**

Yes ☐ No ☐

**39. Do you agree that the penalties should be the same as those which are already in place for selling tobacco to someone under the age of 18?**

Yes ☐ No ☐



### **Unauthorised sales by under 18 year olds for tobacco and electronic cigarettes**

**40. Do you agree that young people under the age of 18 should be prohibited from selling tobacco and non-medical e-cigarettes and refills unless authorised by an adult?**

Yes ☐ No ☐

**41. Who should be able to authorise an under 18 year old to make the sale, for example, the person who has registered the premises, manager or another adult working in the store?**

Comments

**42. Do you agree with the anticipated offence, in regard to:**

**a. the penalty**

a ☐

**b. the enforcement arrangements**

b ☐

### **Equality Considerations**

**43. What issues or opportunities do the proposed changes raise for people with protected characteristics (age; disability; gender reassignment; race; religion or belief; sex; pregnancy and maternity; and sexual orientation)?**

Comments

**44. If the proposed measures are likely to have a substantial negative implication for equality, how might this be minimised or avoided?**

Comments

**45. Do you have any other comments on or suggestions relevant to the proposals in regard to equality considerations?**

Comments

### **Business and Regulatory Impacts Considerations**

**46. What is your assessment of the likely financial implications, or other impacts (if any), of the introduction of each of these proposals on you or your organisation?**

*The main financial cost would be any need for our business to register approximately 200 community pharmacies with the Scottish Tobacco Retailers Register. We consider this to be an unnecessary bureaucratic burden and we would wish the Scottish Government to exempt pharmacies and other retailers from the need to register, so long as the only e-cigarette products they stock are ones that hold MHRA licenses as non-prescription medicines for use as NRT to help customers reduce or stop using tobacco cigarettes.*

*We are also concerned that if there is a major difference in retail or advertising policy between Scotland and the rest of the UK, then this would lead to additional business costs in terms of designing, approving and distributing materials, promotions or magazines which could only be used in Scotland.*

**47. What (if any) other significant financial implications are likely to arise?**

Comments

**48. What lead-in time should be allowed prior to implementation of these measures and how should the public be informed?**

Comments

**49. Do you have any other comments on or suggestions relevant to the proposals in regard to business and regulatory impacts?**

Comments

As a party to the World Health Organization's Framework Convention on Tobacco Control (FCTC), Scotland has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To meet this obligation, we ask all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. We will still carefully consider all consultation responses from the tobacco industry and from those with links to the tobacco industry and include them in the published summary of consultation responses.

*Boots UK pharmacies currently stock the Puritane brand of e-cigarettes. These are manufactured by Fontem Ventures, which is a wholly-owned subsidiary of Imperial Tobacco. Boots pharmacies also stock a wide range of non-prescription nicotine replacement therapy products.*