



Government response to the consultation on an age of sale for nicotine inhaling products

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Government response to the consultation on an age of sale for nicotine inhaling products

Prepared by

Department of Health Tobacco Programme

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Executive summary

Given the emergence of electronic cigarettes (also known as e-cigarettes) in recent years, coupled with concerns about the increased awareness and use of these products by children, the Government has committed to setting an age of sale requirement for these products. Section 92 of the Children and Families Act 2014 ('the Act') gives the Secretary of State the powers to make regulations to introduce a minimum age of sale for nicotine products in England and Wales.

The Government has decided to proceed with the introduction of a minimum age of sale of 18 years for nicotine inhaling products and related parts such as nicotine refill cartridges and liquids. There will be exemptions for nicotine inhaling products licensed as medicines or medical devices and sold by prescription. We will also extend the tobacco 'proxy purchasing' offence in the Act to cover nicotine inhaling products such as e-cigarettes, so it will be an offence for an adult to buy such products on behalf of a person under 18 years.

The purpose of the consultation was to seek views on the draft Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations. This report has been prepared and published by the Department of Health, in agreement with the Welsh Government, to provide an overview of the responses received and a summary of the main themes that emerged in response to the specific questions asked in the consultation document. It also sets out how the regulations have been amended to reflect the information gathered during the consultation.

1. Overview of the consultation

Purpose of consultation

- 1.1. The Department of Health has responsibility for improving public health, including reducing tobacco use through the implementation of comprehensive tobacco control strategies.
- 1.2. The aims of the regulations on an age of sale for nicotine inhaling products are to:
 - limit the sale of nicotine inhaling products such as e-cigarettes to adults only,
 with certain limited exceptions for medicinal products
 - protect children from the risk of nicotine addiction and the impact that nicotine can have on the developing adolescent brain
 - protect children and young people from any potential 'gateway' effect into smoking tobacco that might come from the use of nicotine inhaling products.
- 1.3. The regulations make it an offence to sell nicotine inhaling products (such as ecigarettes) and related products to anyone under the age of 18 years. The regulations apply to all nicotine inhaling products, regardless of how they are powered and whether they look like a conventional cigarette or not. They extend the tobacco proxy purchasing offence in section 91 of the Act to also cover e-cigarettes, so it will also be an offence for an adult to buy a nicotine inhaling products on behalf of a person under 18 years.
- 1.4. The regulations exempt the sale of any nicotine inhaling product that is licensed as a medicine or a medical device, where it has been prescribed to the child or where the medicine is indicated for use by children. The regulations will apply to England and Wales, as the necessary consent has been provided by Welsh Ministers.
- 1.5. The purpose of the consultation was to seek the views of interested people, organisations and businesses on the draft regulations and also to seek views on the initial assessment of the impact on business and the equality analysis which were published alongside the consultation document. The consultation document, which includes the draft regulations, is available on the Department of Health's website.¹

Consultation exercise

1.6. On 17 December 2014, the Department of Health launched a six-week public consultation on draft on an age of sale for nicotine inhaling products. Consultation respondents were invited to answer nine questions (listed at Appendix A).

Purpose of report

1.7. This report has been prepared and published by the Department of Health. It gives an overview of the consultation responses received and summarises the main

¹ https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale

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themes which emerged. It also sets out the Government's response to the points raised and how the regulations will be amended.

2. Overview of responses

2.1. This chapter provides an overview of the responses received to this consultation.

Collation, analysis and interpretation of consultation responses

- 2.2. The Department of Health engaged TONIC Consultants Ltd to assist with collating and undertaking initial analysis of consultation responses. The Department of Health has undertaken further detailed analysis and consideration of the issues raised in consultation responses.
- 2.3. This report provides an overview of all the responses received and reflects the main themes that emerged in response to the specific questions asked in the consultation document.

Number of responses received

- 2.4. There were a total of 81 responses to the consultation, with the majority coming from organisations, including health organisations and local authorities. The breakdown of the responses is as follows:
 - 42 from organisations (52%)
 - 21 from members of the public (26%)
 - 11 from businesses (14%)
 - 5 from health or social care professionals (6%)
 - 2 from regulatory services professionals (2%)
- 2.5. Responses were received via Citizenspace, the Government's consultation portal and via email. Appendix B sets out details of the organisations who responded to the consultation with the exception of any who wished to remain anonymous.
- 2.6. Action on Smoking and Health (ASH) and Fresh North East each submitted a list of organisations (39 and 19 respectively) that endorsed their responses to the consultation. These lists can be seen at Appendix C.
- 2.7. To meet our obligations under the World Health Organization's Framework Convention on Tobacco Control (FCTC), we asked all respondents to our consultations to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry and 9 respondents declared that they had such links.

Comments on the policy

2.8. Chapter 3 sets out the responses to the consultation questions. The consultation questions focussed on the detail of the regulations but respondent's general views on the policy intention were also set out in many of the resposes. Of the responses we received, 79% supported the draft regulations, 7% did not and the remaining responses were unclear.

- 2.9. The majority of respondents supported the policy aim and agreed with the proposals for regulation. This support covered all sectors health organisations, retailers and their trade associations, e-cigarette manufacturers, tobacco companies, local authorities including trading standards departments. Many respondents emphasised that this was a fast moving market in terms of product development, and that further research was needed on patterns of consumer use, effectiveness in smoking cessation and potential long-term health harms.
- 2.10. There was widespread support from business and organisations for the introduction of regulations that were consistent with existing provisions for age restricted products. The 7% who were opposed to the policy were all members of the public.
- 2.11. Most respondents supported the inclusion of an exemption for licensed medicines or medical devices in the regulations to ensure the safety and quality of products available to under 18s. A few respondents expressed the view that nicotine inhaling products should not be classified as medicines, citing legal decisions in the US and Sweden.
- 2.12. There was general agreement among all respondents that the definition of nicotine inhaling products was broad enough to future-proof the regulations against future innovation in the market. A small number of respondents suggested that the regulations should be widened to include all e-cigarettes and liquids including those that do not contain nicotine.
- 2.13. There was no consensus of opinion among the responses as to whether use of nicotine inhaling products is a gateway in or out of smoking for under 18s or whether there is any gateway at all. Many respondents referred to the limited available evidence and urged caution until further long term studies on e-cigarettes were concluded.
- 2.14. Most respondents agreed that the enforcement proposals were proportionate and that the consistency of the penalties with similar offences for tobacco products was appropriate.
- 2.15. There were a range of views expressed on costs, with some responses expressing concern that there would be an increase in costs for trading standards organisations. Other respondents suggested that the majority of retailers did not sell to under 18s voluntarily and that the regulations would provide consistency with other age restricted products resulting in few additional costs.

Limitations to elicit representative samples of public opinion

- 2.16. The consultation process was not intended or designed to elicit representative samples of public opinion, instead it sought information, comments and views on the draft regulation, impact assessment and equality analysis.
- 2.17. It is in the nature of open consultation exercises that, generally, it is only those who already have an interest in the subject who respond to the questions. The nature of consultation exercises means that respondents are self-selecting, and cannot therefore be considered to be a representative sample of public opinion.

3. Responses to the consultation

3.1. People were invited to respond to nine consultation questions in the consultation document and this chapter summarises the key themes that emerged from each of these questions.

Question 1

- 1. Do you have any comments regarding the definition of nicotine inhaling products proposed in the regulations?
- 3.2. Most respondents agreed that the definition of nicotine inhaling products in the draft regulations was appropriate. Some said they considered that the definition was sufficiently broad enough to future-proof it against expected innovations in the market. Some gave general support for the definition but also suggested how it could be added to or expanded, for example by specifying products that enable nicotine to be inhaled through the nose or other novel products.
- 3.3. Some responses proposed that the definition should be wider. For example it was suggested that the regulations should cover all e-cigarettes including non-nicotine containing products or paraphernalia, such as batteries and chargers, primarily designed for use with e-cigarettes. Others suggested using definitions set out in other legislation or documents, for example the UK Advertising Codes, the British Standards Institute PAS 54115 or the revised EU Tobacco Products Directive.
- 3.4. A few responses supported wider action on e-cigarettes such as banning their marketing to under 18s, regulating the quality of nicotine products or an awareness campaign about the comparative levels of harm from smoking and using e-cigarettes.
- 3.5. There were also requests for clarification about which devices and products were covered by the regulations such as all refills and e-liquids, dual use refillable devices, e-shisha and shisha pens and what "intended" to enable nicotine to be inhaled means in practice.

Government response

3.6. The power to make regulations under section 92 of the Children and Families Act 2014 relates to a device which is intended to enable nicotine to be consumed (including devices that are also intended to enable any other substance to be consumed). We have considered the comments and suggestions in relation to the definition of nicotine inhaling products in the regulations. It is important that the definition is broad enough to provide a degree of future-proofing as we know this is a fast developing market. It is equally important that we do not make the definition so

- wide that we inadvertently capture products containing nicotine that we do not mean to capture.
- 3.7. We consider that the definition captures devices intended to be used for inhaling nicotine such as e-cigarettes and dual use products where the device also enables any other substance to be consumed and does not need to be amended. The regulation-making powers enable the Government to make provision in the future for other nicotine delivery products which may emerge in time and we will keep the definition under review as the market develops.

Question 2

- 2. Do you have any comments regarding the proposals for nicotine inhaling products that are medicines or medical devices? Do you have any comments regarding the definition of nicotine inhaling products proposed in the regulations?
- 3.8. Most respondents supported the exemption of medicines and medical devices set out in the regulations. Respondents felt that this would allow pharmacists to sell or supply licensed products and continue to allow the sale or supply of existing inhalation products
- 3.9. Some felt that by continuing to allow under 18 year olds access to licenced nicotine replacement therapy, the regulations would not create a barrier to assisting under 18s from giving up smoking. Others were concerned that limiting access to only products licenced as medicines could be a barrier to under 18s who currently smoke using what are seen as healthier options compared to tobacco.
- 3.10. Some wanted this provision to go further, wanting to see quality controls or product standardization or for all nicotine containing products to be regulated as medicines. Others felt that it had been established that nicotine inhaling products are not medicines.
- 3.11. A few respondents suggested potential unintended consequences such as additional costs associated with licensing which could be passed on to consumers, acting as a deterrent to switching from smoking. A few suggested a potential confusion for retailers in differentiating between medicinal and non-medicinal products or a reputational risk if the retailer was seen to be selling products to an under 18.
- 3.12. There were also requests for clarification about the interface between the age of sale regulations and medicines legislation and the position for General Sales List medicines.
- 3.13. Some suggested that long-term studies on the health risks should be conducted to inform this aspect of the regulations, including the impact on adolescent brain development and the efficacy of e-cigarettes as smoking cessation tools, and that the interface with medicines legislation should be reviewed.

Government response

- 3.14. The regulations provide exemptions from the age of sale requirement for nicotine inhaling products that are licensed as medicines as the Government agrees that such products should be made available to children and young people. Licensed medicines are subject to separate regulatory rules that cover aspects such as advertising, product presentation and other aspects relating to sale and supply.
- 3.15. We will exempt the sale of nicotine inhaling products that are medicines or medical devices made available in accordance with a valid prescription by a pharmacist. We will also exempt the sale of any nicotine inhaling products licenced as non-prescription medicines and indicated for use by under 18s. In such cases, the seller may not be a pharmacist as such medicines can be sold in any type of shop, subject to certain conditions being met. We will keep this aspect under review as products are licenced as medicines in the future.
- 3.16. We feel it is important that those under 18 years trying to quit smoking can still have access to nicotine inhaling products that are licensed as medicines as well as other nicotine replacement therapy (NRT), such as nicotine patches or gum, which is not covered by the regulations.

Question 3

- 3. Do you have any comments regarding the enforcement arrangements proposed in the regulations, or any views or evidence on enforcement costs?
- 3.17. Most responses supported the enforcement and penalty proposals set out in the consultation document. There was support for making local authority trading standards departments responsible for the enforcement as this is consistent with enforcement for the age of sale of tobacco in particular and many other age restricted products. The proposed level of fine for the age of sale offence was also considered appropriate. Some felt that the fine for the proxy purchasing offence was too low; others felt it should be lower and not set at the same level as for tobacco. Maintaining consistency with the existing enforcement regimes was considered helpful for businesses and the general pubic.
- 3.18. Some responses suggested extending the scope of the offence, for example to apply to the child attempting to buy the product, or that the fine should apply to whoever authorized the sale if the retailer were under 18. Some respondents commented that the existing age of sale provisions did not completely prevent young people accessing alcohol and tobacco so effective enforcement was important.
- 3.19. Some felt that the new regulations would incur additional costs for trading standards services in training, in delivering their role in educating retailers (especially small businesses) and in taking enforcement action across a range of retail outlets.
- 3.20. Others felt that enforcement would bring no, or low, additional costs, commenting that many retailers were already complying voluntarily. Some suggested that there

- may be cost benefits to retailers as it brings a level playing field for those not currently selling e-cigarettes to under 18s. The manufacturers who responded suggest that there will be no cost to them from the regulations. There were suggestions that enforcement costs should be paid for by the industry through a levy or through a tax on nicotine inhaling products.
- 3.21. It was suggested that retailers and enforcement officers promote the Challenge 21 / 25 schemes already in existence to assist with enforcement of these regulations. Specific guidance on the interface between these regulations and medicines legislation was suggested as helpful for businesses and enforcement agencies.

- 3.22. Effective compliance building and enforcement is important and we consider that local authority trading standards officers are best placed to enforce the regulations. We agree with the importance of maintaining consistency with the existing enforcement regimes that businesses are familiar with. The Children and Families Act sets out the penalty on summary conviction and provides for the fixed penalty notice regime to apply. The penalty for selling nicotine inhaling products to someone under the age of 18 will be the same as that for the sale for tobacco to under 18s. The fixed penalty amount of £90 (with a discount amount of £60) for an offence of proxy purchasing tobacco or a nicotine inhaling product is the same as that for the proxy purchasing of alcohol. The offence will apply to on-line sales.
- 3.23. For the purposes of effective enforcement, the regulations bring the age of sale offence within the scope of Primary Authority. This arrangement allows businesses to form a statutory partnership with one local authority, which then provides advice for other local regulators to take into account when carrying out inspections or addressing non-compliance.
- 3.24. There will be further Statutory Instruments to complete the enforcement regimes for the age of sale of nicotine inhaling products and the proxy purchase of tobacco and nicotine inhaling products. Those regulations will provide for the amount of the fixed penalty and specify the form to be used for the fixed penalty notice for the proxy purchasing offences, with separate regulations for Wales as appropriate. They will also amend the Regulation of Investigatory Powers (Directed Surveillance and Covert Human Intelligence Sources) Order 2010 to allow authorisations for direct surveillance to be given in respect of investigations into the age of sale and proxy purchasing offences under section 91 and section 92 of the Children and Families Act.
- 3.25. As with tobacco control legislation, we anticipate that enforcement agencies will take a compliance building approach, working with local retailers to assist them in implementing the legislation. We will work with enforcement agencies and retail organisations to develop the appropriate information and guidance. We will also make information available to the public to help build awareness of the legislation before it comes into force.
- 3.26. There were many useful suggestions for areas for guidance, which we will consider as guidance is developed, such as:
 - what the term "intended to enable nicotine to be inhaled" means in practice

- how the definition relates to other smoking paraphernalia such as shisha, shisha pens and hookah pens
- the interface with licensed medicines and which products will be available to help under 18s wanting to stop smoking
- how to best enforce the proxy purchase offence as trading standards officers usually work more with retailers rather than with the public.

Question 4

- 4. Do you have any comments on the proposal to extend the current proxy purchase offence for tobacco to cover nicotine inhaling products?
- 3.27. Many respondents supported the proposal to extend the proxy purchase offence for tobacco (which will also come into force on 1 October 2015) to cover nicotine inhaling products considering that bringing them into line with other age restricted products would help with implementation and protect children. Some felt implementation of this aspect should be delayed until it was known if this was a supply route used buy under 18s in practice. A few cited data on the proxy purchase of tobacco saying that the position for e-cigarettes is not yet known and needs to be kept under review.
- 3.28. Some respondents suggested the offence could go further and apply to the retailer, adult and child involved or that under 18s should not be able to sell nicotine inhaling products. Some felt that parents should not be fined for making a proxy purchase if they were trying to help their child to quit smoking.
- 3.29. Some suggested that trading standards officers would need training in taking enforcement action with members of the public and could work in partnership with environmental health and other colleagues who had more experience in doing this. Some commented that retailers find it hard to detect attempted proxy purchases and to then challenge these.

- 3.30. Proxy purchasing occurs when a person over age 18 buys an age restricted product on behalf of someone underage and we introduced a new offence of proxy purchasing of tobacco in the Children and Families Act. Young people are known to approach strangers outside shops or ask friends, neighbours or in some cases parents to buy tobacco for them. Statistics show that among 11-15 year olds who are current smokers, some 95% have been successful at least once in the last year in having someone else buy them cigarettes in a shop.
- 3.31. Given this, the Government considers it sensible to extend the proxy purchasing provisions to include nicotine inhaling products. As set out above, those under 18

years trying to quit smoking will be able to access nicotine inhaling products that are licensed as medicines.

Question 5

5. Do you have any additional evidence on the use of e-cigarettes by under 18s as a gateway in or out of smoking? For example, how a minimum age of sale for e-cigarettes would impact on current users aged under 18?

- 3.32. A significant number of respondents felt that as nicotine inhaling products are a new product, a number of considerations should be taken into account such as changes in consumer awareness and demand, a growing supplier market, anticipated product innovations and that more research on the potential risks and benefits is likely to emege. Many respondents commented on what current information could tell us about whether e-cigarettes are acting as a gateway in or out of smoking for under 18s but there was no consensus view. Many respondents suggested therefore that the regulations should be reviewed in the light of future developments.
- 3.33. Some felt that there are no conclusive studies showing that e-cigarettes act as a gateway in to smoking; many felt that the research suggested a mixed picture and urged a precautionary approach be taken by the Government until more information is available. Some respondents felt that e-cigarette use could act as a gateway in to smoking for under 18s including by normalising nicotine use and creating nicotine addiction and because the flavours and colours used appeal to under 18s.
- 3.34. Responses provided details of a range of existing research including on the effects of nicotine, the use of e-cigarettes by under 18s, survey data and international evidence. Some encouraged the inclusion of questions on nicotine inhaling products in future surveys and statistical collections.
- 3.35. Some responses supported the introduction of regulations around the marketing of ecigarettes so that they did not appeal to under 18s and for advice for young people on the differences in risk between smoking and using nicotine inhaling products.

- 3.36. We agree that the evidence does not yet provide a clear picture about how young people use e-cigarettes and whether they act as a gateway into smoking. While use of these products by people under the age of 18 is not currently widespread in England and Wales, international evidence suggests that it is plausible that usage of e-cigarettes by young people may increase. Emerging evidence suggests that awareness of e-cigarettes by British children is high. Research published by the Welsh Government provides tentative evidence that e-cigarette use may represent a new form of childhood experimentation with nicotine.
- 3.37. We therefore consider it appropriate to introduce an age of sale provision to protect children and young people and consider that more research is needed to determine

whether e-cigarettes serve as a gateway to tobacco use. We also therefore agree with the need to consider these regulations in the light of new developments and new research and so have included a requirement to review the regulations within five years of their coming into force.

Question 6

6. Do you have any additional evidence that restricting the sale of nicotine inhaling products would contribute to reducing health inequalities and/or help us fulfil our duties under the Equality Act 2010?

- 3.38. Many respondents referred to evidence suggesting a public health benefit from the use of nicotine inhaling products when compared to smoking and some referred to their use by people trying to quit smoking. Some suggested that accurate information for health professionals and smokers would maximize these benefits and felt that there was confusion among both groups about the relative risks.
- 3.39. Some felt that the impact of the regulations would be low as levels of use of ecigarettes by under 18s are currently low.
- 3.40. A few respondents felt that any regulations which restricted access to nicotine inhaling products could lead to wider health inequalities. Some respondents raised wider concerns about the health impacts of restricting the availability of e-cigarettes for young people with serious mental illness, where rates of tobacco use are higher than in the general population.

- 3.41. We carried out an equality analysis to examine the potential impact the regulations, which we have revised after considering the consultation responses.
- 3.42. The regulations are intended to protect generation of children and young people from the risk of nicotine addiction and possible tobacco use. Overall, the Government considers that the policy will not lead to any unlawful discrimination, harassment or victimisation of any particular group by gender, race, religion, ethnicity, sexuality, sexual orientation or disability. Full details are set out in the equality analysis published alongside this report.

Question 7

7. Do you have any information or evidence that would inform the consultationstage impact assessment? We particularly welcome any evidence or information which would improve any of the assumptions or estimates we have made in terms of the impact on retailers, manufacturers and distributers, including our assessment of any loss of profits.

- 3.43. Many respondents agreed with the assumptions set out in the impact assessment or offered no further evidence to strengthen these assumptions.
- 3.44. Some respondents expressed the view that there are unlikely to be significant costs to business because most retailers already restrict the sale of e-cigarettes to under 18s, manufacturers and retailers have been calling for this legislation to be introduced and the target customer base for e-cigarettes are aged 18 and over. Some suggested reduced costs to retailers and enforcement agencies as the regulations would bring consistency with other age restricted products and some benefits for retailers as the regulations would mean a level playing field.
- 3.45. Some suggested increased costs for enforcement agencies because of their role in providing awareness and advice to retailers and in increasing the businesses they would need to engage with locally. However, they also suggest providing guidance for business could reduce these potential costs. Some felt there could be costs for businesses as many small retailers sell e-cigarettes and would need to train employees.
- 3.46. Some respondents made suggestions for the development of the impact assessment including updated prevalence data from ASH. One manufacturer supplied their own estimate for the size of the UK e-cigarette market and some responses provided some data on potential costs and numbers of staff involved.

- 3.47. We prepared a consultation-stage impact assessment for the draft regulations and have revised this in light of the information provided through the consultation. Information on costs to distributors has been included and the estimate of manufacturer profit margin has been revised. The evidence base for the estimates of market growth and retailer profit margin and loss have been strengthened.
- 3.48. The costs of the regulations will fall mainly on businesses that currently profit from selling e-cigarettes to under 18s and the final impact assessment shows that introducing an age of sale is a very low cost regulatory proposal. The final impact assessment has been given a green, fit for purpose rating by the Regulatory Policy Committee.

Question 8

- 8. Do you have any information or evidence that would improve any of the assumptions we have made in terms of the impact of these proposed regulations on small and micro businesses?
- 3.49. Most respondents did not offer any additional information on the impact on small and micro businesses. Some said they thought the impact would be minimal, commenting, as above, that retailers already operated voluntary age restrictions.
- 3.50. There was support from some for the compliance building approach set out in the impact assessment which would help small and micro businesses to be aware of the regulations and implement them. Some suggested that guidance and awareness materials for small and micro business would help with compliance. A couple of responses suggested that fines could cause the closure of specialist e-cigarette shops. One area supplied data about local independent retailer numbers.

Government response

3.51. The final impact assessment gives an estimate of the relative impact of the regulations on different business groups (manufacturers, distributors, and retailers) and quantifies what proportion of these impacts fall on small and micro business.

Question 9

Is there anything else you wish to tell us that you think would improve the draft regulations?

- 3.52. The responses included a number of general recommendations about the regulations, including requests to pass the regulations as quickly as possible, to ensure a balance between restricting access to under 18s but not to those aged over 18, to make sure the regulations do not increase black market sales of electronic cigarettes and provide guidance and awareness information for all those involved (retailers, health professionals, consumers and enforcement agencies).
- 3.53. Some respondents set out wider points relating to nicotine inhaling products for the Government to consider, including introducing greater regulation of nicotine inhaling products and their contents to ensure quality and safety, regulate point of sale information, apply the regulations to vending machines and introduce standardised health warnings and review the impact of all tobacco and related regulations. Some

suggested that the EU Tobacco Products Directive and advertising codes of practice would help address many of the issues raised.

Government response

- 3.54. We agree with the importance of introducing the age of sale provision as soon as possible and intend that the regulations should come into force from 1 October 2015. Many of the wider points raised in the responses will be addressed by the new EU Tobacco Products Directive 2014, which the Government will transpose into UK law by May 2016. The Directive includes new product standards and information requirements for e-cigarettes alongside restrictions on advertising.
- 3.55. From May 2016 only licenced products will be able to contain nicotine in strengths greater than 20mg/ml. The Directive will establish new specific product standards and rules for the safety and quality of ingredients, presentation and advertising of consumer electronic cigarettes and refill containers. The Directive will require a range of information to be provided six months before either e-cigarettes or refills are placed on the market. We will consult widely on the proposals for transposing the Directive in due course.

4. Next steps

- 4.1. We are grateful to all who took the time to respond to the consultation. The Government recognises that responsible e-cigarette manufacturers and retailers do not currently sell e-cigarettes to children but has decided to introduce an age of sale requirement because of concerns about the increased awareness and use of these products by children. The age of sale requirement will also provide clarity for retailers and manufacturers.
- 4.2. The Government has laid the regulations and, subject to Parliamentary approval, they will come into force on 1 October 2015.

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² Directive 2014/40/EU of the European Parliament and of the Council

Appendix A – An age of sale for nicotine inhaling products – consultation questions about the proposed regulations and assessment of impact on business

- 1. Do you have any comments regarding the definition of nicotine inhaling products proposed in the regulations?
- 2. Do you have any comments regarding the proposals for nicotine inhaling products that are medicines or medical devices?
- 3. Do you have any comments regarding the enforcement arrangements proposed in the regulations, or any views or evidence on enforcement costs?
- 4. Do you have any comments on the proposal to extend the current proxy purchase offence for tobacco to cover nicotine inhaling products?
- 5. Do you have any additional evidence on the use of e-cigarettes by under 18s as a gateway in or out of smoking? For example, how a minimum age of sale for e-cigarettes would impact on current users aged under 18?
- 6. Do you have any additional evidence that restricting the sale of nicotine inhaling products would contribute to reducing health inequalities and/or help us fulfil our duties under the Equality Act 2010?
- 7. Do you have any information or evidence that would inform the consultation-stage impact assessment? We particularly welcome any evidence or information which would improve any of the assumptions or estimates we have made in terms of the impact on retailers, manufacturers and distributers, including our assessment of any loss of profits.
- 8. Do you have any information or evidence that would improve any of the assumptions we have made in terms of the impact of these proposed regulations on small and micro businesses?
- 9. Is there anything else you wish to tell us that you think would improve the draft regulations?

Appendix B – Responses to the consultation

Note: Those respondents who indicated that they wanted their response to remain anonymous are not included in this list.

Organisations

- Action on Smoking & Health (ASH)
- ASH Ireland
- ASH Wales
- Association of Convenience Stores
- Association of Directors of Public Health (ADPH)
- Association of School and College Leaders (ASCL)
- British Medical Association
- Bury Tobacco Alliances
- Camden & Islington Public Health
- Cancer Research UK
- Cheshire and Merseyside Tobacco Alliance
- Electronic Cigarette Industry Trade Association ECITA (EU) Ltd
- · Faculty of Public Health
- FRESH Smoke Free North East
- Hampshire County Council
- Health Education Yorkshire and the Humber
- Heart of Mersey
- Hywel Dda University Health Board
- Lancashire County Council
- Leicestershire Partnership NHS Trust
- Lincolnshire Community Health Services NHS Trust
- London Borough of Camden
- London Borough of Camden
- MRC/CSO Social and Public Health Sciences, University of Glasgow
- National Federation of Retail Newsagents
- New Nicotine Alliance UK
- Proprietary Association of Great Britain (PAGB)

- Quit4Life Hampshire & Surrey Stop Smoking
- Royal College of Physicians of Edinburgh
- Royal College of Psychiatrists
- Royal Pharmaceutical Society
- Save E-cigs
- Smokefree South West
- Socialist Health Association
- SWERCOTS (Trading Standards Partnership South West)
- The Chartered Institute of Environmental Health (Wales)
- The Royal College of Radiologists
- Tobacco Control Alliance Berkshire West
- Tobacco Free Buckinghamshire Alliance
- Tobacco Free Buckinghamshire Alliance
- Trading Standards Institute
- Trading Standards North West
- TSSE (Trading Standards South East)
- UK Centre for Tobacco and Alcohol Studies
- UKCRC Public Health Research Centre of Excellence, Cardiff University
- Wales Heads of Trading Standards (WHOTS)
- Welsh Medical Committee
- Wigan & Leigh Tobacco Control Alliance
- Worcestershire Tobacco Control Alliance
- Wrexham County Borough Council

Businesses

- blu (UK)
- Boots UK
- Co-Operative Group
- Fontem Ventures
- Imperial Tobacco Limited
- Japan Tobacco International
- Johnson & Johnson Limited
- Nicoventures Holding Limited
- Philip Morris Ltd

- Totally Wicked Ltd
- Under Age Sales Ltd

Appendix C – Organisations endorsing other consultation responses

Organisations that endorsed the ASH Response

- ASH Scotland
- Association of Respiratory Nurse Specialists
- Asthma UK
- Blackpool Council
- Bristol City Council
- Bristol Health & Wellbeing Board
- British Dental Health Foundation
- British Heart Foundation
- British Lung Foundation
- British Thoracic Society
- Chartered Institute of Environmental Health
- Devon County Council
- Diabetes UK
- Dudley Council
- Dudley Health & Wellbeing Board
- Hull City Council
- Liverpool Community Health NHS Trust
- London borough of Haringey
- North Lincolnshire Smokefree Alliance
- Nottinghamshire Strategic Tobacco Alliance
- Rochdale Tobacco Free Alliance
- Rotherham Tobacco Control Alliance
- Royal College of Nursing
- Royal College of Radiologists*
- Royal Society for Public Health
- Shropshire Council
- Somerset County Council
- Smokefree Devon Alliance
- Smokefree Lincs. Alliance
- Smoke Free Northumberland Alliance**

- Smokefree Yorkshire and the Humber
- Solutions4Health
- South Gloucestershire Council
- Tobacco-free Leicestershire & Rutland
- Tobacco Free Luton
- Tobacco Free Futures
- The Big Life Group
- University Hospitals of Leicester
- Warrington Borough Council Public Health Team

Organisations that endorsed the Fresh North East Response

- Association of North East Councils
- Durham County Council
- Gateshead Council
- Hartlepool Borough Council
- Hartlepool Smoke Free Alliance
- Middlesbrough Smoke Free Alliance
- Newcastle City Council
- North East Directors of Public Health Network
- North East Tobacco Control Commissioners Forum
- North East Tobacco Regulation Forum
- North East Trading Standards Association
- North Tyneside Council
- Redcar and Cleveland Borough Council
- Smoke Free Newcastle
- Smoke Free North East Network
- Smoke Free Northumberland Alliance*
- Smoke Free Redcar & Cleveland
- Stockton on Tees Borough Council
- Stockton Smoke Free Alliance

^{*} Also submitted an individual response to the consultation

^{**} Also endorsed the Fresh North East response to the consultation

^{*} Also endorsed the ASH response