

EXPLANATORY MEMORANDUM TO
THE NICOTINE INHALING PRODUCTS (AGE OF SALE AND PROXY
PURCHASING) REGULATIONS 2015

2015 No. [XXXX]

THE PROXY PURCHASING OF TOBACCO, NICOTINE PRODUCTS ETC.
(FIXED PENALTY AMOUNT) REGULATIONS 2015

2015 No. [XXXX]

1. This explanatory memorandum has been prepared by the Department of Health (DH) and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Purpose of the instruments**

- 2.1 This Explanatory Memorandum provides information on two Statutory Instruments:

- the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015, referred to here as the “Age of Sale Regulations”, and
- the Proxy Purchasing of Tobacco, Nicotine Products etc. (Fixed Penalty Amount) Regulations 2015, referred to here as “Proxy Purchasing Fixed Penalty Amount Regulations”.

- 2.2 The Age of Sale Regulations introduce a minimum age of sale of 18 years for nicotine inhaling products, also known as electronic cigarettes, and certain related parts of such devices, in order to protect children from the risk and associated harms of nicotine addiction. They also set out exemptions for nicotine inhaling products licenced as medicines and set a statutory review of the Regulations within 5 years of their coming into force. For the purposes of effective enforcement, the Regulations bring the age of sale offence within the scope of Primary Authority.

- 2.3 The Regulations extend the proxy purchasing offence in the Children and Families Act 2014 to cover nicotine inhaling products. Enforcement officers may issue a fixed penalty notice to someone committing a proxy purchasing offence and the Proxy Purchasing Fixed Penalty Amount Regulations set the amount of the fine at £90. These enforcement arrangements for e-cigarettes mirror legislation already in place to stop the sale of tobacco to young people under the age of 18 years.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 If approved, Regulations 1 and 2 of the Age of Sale Regulations will come into force one day after the day on which the Regulations are made.

3.2 Regulation 2 amends section 91 of the Children and Families Act 2014 (purchase of tobacco etc. on behalf of persons under 18) to add references to “nicotine products” and a definition of a “relevant nicotine product” to make it an offence for a person aged 18 or over to purchase a nicotine product on behalf of a person under 18.

3.3 Section 91 of the Children and Families Act 2014 has so far been commenced for the purposes of making regulations only. It is intended that the section will be commenced for all other purposes on 1 October 2015. Guidance and public information about the new offences of proxy purchasing of tobacco or nicotine products and the prohibition on the sale of nicotine products to under 18s will be published before they come into force. People will be able to familiarise themselves with the provisions and make any necessary changes to their practices and behaviours before 1 October 2015, when the section comes fully into force.

3.4 The amendment to section 91 of the Children and Families Act 2014 made by regulation 2 enlarges the enabling powers at paragraphs 5 and 8 of Schedule 1 to the Health Act 2006 (as applied to section 91(5) of the Children and Families Act 2014), which relate to issuing fixed penalty notices. This has no substantive impact on people until those powers are exercised in the Proxy Purchasing Fixed Penalty Amount Regulations, which do not come into force until 1 October 2015.

3.5 Regulations 1 and 2 of the Age of Sale Regulations will therefore come into force the day after the Regulations are made, which is contrary to the 21 day statutory assumption referred to in the JCSI Report on the draft S.I. “Openness of Local Government Bodies” (1st Report of 2014/15 session). However, the offence of proxy purchasing of tobacco and nicotine inhaling products and the related fixed penalty notice regime themselves will not be brought into force until 1 October 2015 which allows adequate time for people to be informed about the offences.

4. Legislative Context

4.1 Section 91 (1) of the Children and Families Act 2014 makes it an offence for an adult to buy tobacco on behalf of someone under the age of 18. This is often referred to as proxy purchasing. Section 92 (6) of that Act (prohibition of sale of nicotine products to persons under 18) contains a Henry VIII power to amend section 91 so as to apply section 91 to nicotine products. Regulation 2 of the Age of Sale Regulations amends section 91 to insert references to nicotine products for the purpose of making the proxy purchasing of nicotine products an offence.

4.2 The Proxy Purchasing Fixed Penalty Amount Regulations set the amounts for fixed penalty notices given for alleged offences under s91(1) Children and Families Act. Fixed penalty notices can be issued for the proxy purchasing of either tobacco or nicotine inhaling products (following the amendment to that section). The fixed penalty notice and enforcement regime from the Health Act 2006 are used for to the proxy purchasing offence and so the powers used to fix the amounts for the fixed penalty notices are from Schedule 1 the Health Act 2006.

4.3 Regulation 3 of the Age of Sale Regulations prohibits the sale of nicotine inhaling products to persons under the age of 18 subject to exceptions for medicinal products indicated for the treatment of person under 18. Regulation 4 provides an exemption for products that are prescription only medicinal products under the Human Medicines Regulations 2012 or medicinal devices under the Medical Devices Regulations 2002; regulation 5 provides an exemption for authorised medicinal products that are indicated for use by someone of the age specified.

4.4 The Proxy Purchasing Fixed Penalty Amount Regulations set the amounts for fixed penalty notices for the offences of proxy purchasing of tobacco and nicotine inhaling products under section 91(1) of the Children and Families Act as amended by regulation 2. Section 9 of and Schedule 1 to the Health Act 2006 provides for the issue of fixed penalty notices for smoking offences.

4.5 The provisions of these two sets of Regulations could not be combined because the amendment to section 91 of the Children and Families Act by regulation 2 of the Age of Sale Regulations needs to take effect before the Proxy Purchasing Fixed Penalty Amount Regulations can be made.

4.6 These two sets of Regulations are interrelated and so have been laid together but they will be made sequentially. The Age of Sale Regulations are to be made on day 1; regulations 1 and 2 of the Age of Sale Regulations are to come into force on day 2 for the reasons set out in paragraph 3; the Proxy Purchasing Fixed Penalty Amount Regulations are to be made on day 3. The Proxy Purchasing Fixed Penalty Amount Regulations and regulations 3 to 6 of the Age of Sale Regulations will come into force on 1 October 2015.

4.7 Two further Statutory Instruments are to be made to allow enforcement of the regimes for the age of sale of nicotine inhaling products and the proxy purchase of tobacco and nicotine inhaling products. They are subject to negative resolution. The first provides the form to be used for the fixed penalty notice for the proxy purchasing offences. The second amends 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. These two SIs are attached at Annex A for information. They will be made after the two affirmative SIs, if approved, are made and will come into force on 1 October 2015.

5. Territorial Extent and Application

5.1 These instruments apply to England and Wales.

5.2 Welsh Ministers have provided consent to the Age of Sale Regulations to the extent that those Regulations would be within the legislative competence of the Welsh Assembly, in accordance with section 92(8) Children and Families Act.

6. European Convention on Human Rights

6.1 The Secretary of State for Health has made the following statement regarding Human Rights:

In my view the provisions of the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 and the Proxy Purchasing of Tobacco, Nicotine Products etc. (Fixed Penalty Amount) Regulations 2015 are compatible with the Convention rights.

7. Policy background

Electronic cigarettes

7.1 In recent years, the market for nicotine inhaling products, such as electronic cigarettes (also known as e-cigarettes), has developed rapidly. According to a report commissioned by Public Health England (PHE), e-cigarettes were first introduced to Europe in about 2005.¹ There are a wide range of different types and brands of e-cigarettes available and their use is increasing. Some are designed to look and feel like conventional cigarettes and often have a light at the end that glows when the user draws on it, others are not. There are three main types of electronic cigarettes:

- Disposable products that are not rechargeable
- Rechargeable electronic cigarettes that have replaceable pre-filled cartridges
- Rechargeable electronic cigarettes that have a tank or reservoir which is filled and refilled with liquid nicotine

7.2 Most e-cigarettes on the market are flavoured with a huge variety of flavours available. Some of these may be appealing to children such as vanilla ice cream and gummy bear flavours.

7.3 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.

¹ Britton, J. and Bogdanovica, I. (2014). *Electronic cigarettes: A report commissioned by Public Health England*. Available at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf

Use of e-cigarettes

7.4 Action on Smoking and Health (ASH) estimates that there are currently around 2.1 million adults in Great Britain using e-cigarettes, up from an estimated 700,000 users in 2012.² While use of these products by people under the age of 18 is not widespread in England and Wales, international evidence suggests that it is plausible that usage of e-cigarettes by young people in this country may increase.

7.5 Emerging evidence suggests that awareness of e-cigarettes by British children is high. A PHE report found that two-thirds (66%) of 11 to 18-year olds had heard of e-cigarettes. Some 7% had tried e-cigarettes at least once and 2% reported using them sometimes or often.

7.6 E-cigarettes are sold in a wide range of retail outlets, including supermarkets, newsagents, specialist shops and pharmacies, and are often prominently displayed and promoted in store. E-cigarette companies compete on price and invest in marketing and promotion, including through social media.

Association with tobacco smoking

7.7 While e-cigarette use by children is currently associated with existing tobacco smoking, research published by the Welsh Government provides tentative evidence that e-cigarette use may represent a new form of childhood experimentation with nicotine.³ The Chief Medical Officer for England raised concern about e-cigarette use by children.⁴ The World Health Organization has recently recommended that e-cigarettes should not be sold to minors. More research is needed to determine whether e-cigarettes serve as a gateway to tobacco use.

The effects of nicotine

7.8 It has long been established that nicotine is highly addictive. Nicotine is a potent and powerfully addictive drug, which is five to ten times more potent than cocaine or morphine in producing behavioural and psychic effects associated with addiction potential in humans.⁵ Research shows that adolescents are more sensitive to the rewarding effects of nicotine, which may be a reason that many people start to smoke during adolescence.⁶

² Action on Smoking and Health (2014). *ASH briefing: Use of electronic cigarettes in Great Britain*. Available at: www.ash.org.uk/files/documents/ASH_891.pdf

³ Welsh Government (2014) *Exposure to secondhand smoking in cars and e-cigarettes use among 10-11 year old children in Wales: CHETS Wales 2 key findings report*.

⁴ Davies, S. (2013). *Annual Report of the Chief Medical Officer 2012 – Our Children Deserve Better: Prevention Pays*. Department of Health, London. Available at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/255237/2901304_CM_O_complete_low_res_accessible.pdf

⁵ Royal College of Physicians. (2007). *Harm Reduction in Nicotine Addiction: Helping People who can't quit*. RCP, London.

⁶ Counotte, D. et al. (2011). "Development of the motivational system during adolescence, and its sensitivity to disruption by nicotine" in *Developmental Cognitive Neuroscience*; 2011; 1 (2011), pp.430-443.

Proxy purchasing

7.9 Proxy purchasing occurs when a person over age 18 buys an age restricted product on behalf of someone underage. Section 91 of the Children and Families Act introduced a new offence of proxy purchasing of tobacco; selling tobacco to those under 18 was already an offence.

7.10 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.⁷ The Government is extending these proxy purchasing provisions to include nicotine inhaling products.

Detail of the regulations

7.11 The aims of the Age of Sale Regulations 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.

The Age of Sale Regulations

7.12 Regulation 1 defines a ‘nicotine inhaling product’ as any device which is intended to enable nicotine to be inhaled through a mouthpiece. It encompasses e-cigarettes (including disposable and rechargeable types) and certain component parts such as nicotine refill cartridges and nicotine refill substances, often called ‘e-liquids’. These liquids may be sold separately and may or may not contain nicotine. The Regulations apply to all nicotine inhaling products, regardless of how they are powered and whether they look like a conventional cigarette or not. ‘Dual use’ refillable devices which might alternatively be filled with either nicotine or non-nicotine liquid would also be subject to the age of sale requirements. Some devices may not contain nicotine at the point of sale but they would be covered by the Regulations if they are intended to enable nicotine to be inhaled through a mouthpiece.

7.13 The scope of the definition is limited to inhaled products; it excludes products which are intended to be consumed in some other way (e.g. nicotine-containing foods or patches). The Regulations do not cover component parts such as batteries, charging devices and electrical leads for nicotine inhaling products.

7.14 The Regulations prohibit the sale of nicotine inhaling products to people under the age of 18. The regulations do not apply to tobacco products, because such age of sale laws already exist.

⁷ Health and Social Care Information Centre. *Smoking, Drinking and Drug Use Among Young People in England, 2012*. Health and Social Care Information Centre, Leeds.

7.15 The Regulations extend the proxy purchasing provision to make it an offence for an adult to buy, or attempt to buy, a nicotine inhaling product on behalf of a child aged under 18 years.

7.16 The Regulations provide exemptions for nicotine inhaling products that are licensed as medicines so that they can be made available to children and young people. Nicotine inhaling products can only be marketed as a smoking cessation aid if they have been licensed as a medicine by the Medicines and Healthcare Products Regulatory Agency (MHRA)⁸. Licensed medicines are subject to separate regulatory rules that cover aspects such as advertising, product presentation and other aspects relating to sale and supply.

7.17 The Regulations therefore exempt the sale of nicotine inhaling products that are medicines or medical devices made available in accordance with a valid prescription by a pharmacist. They also exempt the sale of any nicotine inhaling products licenced as non-prescription medicines 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.

7.18 Those under 18 years trying to quit smoking would, therefore, still be able to access 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.

7.19 Local authority trading standards officers would be responsible for enforcement of the proposed Regulations, and on request they may be assisted by the police as necessary.

7.20 The Children and Families Act sets out the penalties that are to apply to offences under sections 91 and 92 of the Act. A person guilty of an offence of proxy purchasing tobacco or a nicotine inhaling product may be issued with a Fixed Penalty Notice. A person who refuses or does not otherwise pay a Fixed Penalty Notice, may also be referred to court and is liable on summary conviction to a fine not exceeding level 4 of the standard scale (currently up to £2,500). As with the offence for tobacco, the adult making the purchase would be committing the offence, not the retailer.

7.21 A person guilty of an offence of selling nicotine inhaline products to someone under the age of 18 is liable on summary conviction to a fine not exceeding level 4 on the standard scale.

7.22 The Regulations bring the age of sale offence for nicotine inhaling products within the scope of Primary Authority. The arrangements 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.⁹

⁸ The Stationery Office (2012). The Human Medicines Regulations 2012 (SI 2012/1916)

⁹ Further information on the Primary Authority arrangements can be found here:

7.23 The Regulations will come into force on 1 October 2015. The October rather than April common commencement date was chosen to allow time for training of enforcement officers and to raise retailer and public awareness. The April date would also fall in the pre-election purdah period and so the Government would be limited in its public communications activities.

The Proxy Purchase Fixed Penalty Amount Regulations

7.24 The Regulations set the amount of the fixed penalty notice for the proxy purchase provisions at £90, reduced to £60 if it is paid within 15 days. This brings the purchase of tobacco and nicotine inhaling products in line with the equivalent offence for alcohol, which provides consistency for retailers and enforcement officers.

7.25 There will be two further negative SIs relating to enforcement. One will set out the fixed penalty notice form for the proxy purchase of tobacco and nicotine inhaling products. The other adds the age of sale and proxy purchasing offences to the offences for which enforcement officers can carry out directed surveillance, subject to existing safeguards. As is the case now when enforcing the age of sale for tobacco, enforcement officers need to be able to carry out test purchasing operations which involve children attempting to buy age restricted products from a retailer. Enforcement officers may also need to observe adults handing tobacco or nicotine inhaling products to someone under age 18 in order to enforce the proxy purchase offence.

8. Consultation outcome

8.1 On 17 December 2014, the Department of Health launched a six-week public consultation on draft Regulations to introduce a minimum age of sale of 18 years for the sale of nicotine inhaling products. There were 81 responses to the consultation, with the majority of those coming from organisations.

8.2 The majority of respondents supported the policy aims and the specific proposals set out in the Regulations. Support came from all sectors – health organisations, e-cigarette manufacturers, tobacco companies, retailers and their trade associations, trading standards and local authorities, with all agreeing about the need to protect children.

8.3 Many respondents emphasised that this is fast moving market in terms of product development and patterns of consumer use and that research evidence into their effectiveness in smoking cessation and potential long-term health harms is still emerging. All of these aspects were suggested as reasons to include a duty to review the Regulations. The Government agrees it is important to evaluate these Regulations to consider their effectiveness and amended them to include a requirement to review the Regulations within five years of them coming into force.

8.4 There were a number of comments on the definition of nicotine inhaling products. Whilst there was a general agreement that the definition was correct and sufficiently future-proofed to cope with expected innovations

in the market, some offered extensions to, or alternatives for, the definition. Having considered the points made the Government decided that the definition did not need to be amended.

8.5 The Responses also suggested areas in which more information would assist in complying with and implementing the Regulations, which will be helpful when preparing information about the Regulations including for the public and when preparing guidance for retailers and enforcement officers. The Government response to the consultation will be available on the DH web page¹⁰.

9. Guidance

9.1 Guidance will be made available for enforcement officers and retailers, which will be developed with relevant bodies responsible for training enforcement officers and trade associations.

9.2 There were many suggestions for areas for guidance which came out of the consultation including providing more information on:

- 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 have traditionally worked with retailers rather than the public.

which are helpful in identifying aspects to be covered in guidance.

9.3 These Regulations are part of a package of tobacco measures due to come into force on 1 October and the Department of Health will publicise the new offences so members of the public aware of them.

10. Impact

10.1 The Government has considered any impact on business, charities or voluntary bodies and an Impact Assessment (IA) is attached to this memorandum at Annex B, which will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

10.2 There are some direct cost to e-cigarette retailers, manufacturers and distributors from reduced profits as a result of removing the under 18 market. The impact on the public sector falls on enforcement bodies and the justice system. There will be health benefits to individuals prevented from developing an addiction to nicotine and, potentially, tobacco use. Further detail can be found in the IA.

¹⁰ Available at: <https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

11. Regulating small business

11.1 The IA includes a Small and Micro Business Assessment as a number of the retail outlets potentially affected will be small businesses. Enforcement agencies are expected to continue to take a compliance building approach with retailers, at they do with tobacco control legislation now, so that retailers are fully aware that nicotine inhaling products are no longer available for purchase by children and young people. Further detail can be found in the IA.

12. Monitoring & review

12.1 The Government monitors tobacco legislation on an ongoing basis. Officials will talk to enforcement authorities as the legislation comes into force to see how enforcement is working and a formal requirement to review in the Regulations within 5 years has been included.

13. Contact

13.1 Andrew Black at the Department of Health – Tel: 020 7972 4843 or email: andrew.black@dh.gsi.gov.uk can answer any queries regarding the instrument.