

<b>Title:</b> Age of Sale - Nicotine Inhaling Products <b>IA No:</b> 3132  <b>Lead department or agency:</b> The Department of Health  <b>Other departments or agencies:</b>	<b>Impact Assessment (IA)</b>		
	<b>Date:</b> 18/02/2015		
	<b>Stage:</b> Final		
	<b>Source of intervention:</b> Domestic		
	<b>Type of measure:</b> Secondary Legislation		
	<b>Contact for enquiries:</b> Policy Lead - Andrew Black Analytical Lead - Rob Unsworth		

**Summary: Intervention and Options** **RPC Opinion:** RPC Opinion Status

Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Two-Out? <span style="float: right;">Measure qualifies as</span>
-£2.1m	-£2.31m	£0.20m	Yes <span style="float: right;">IN</span>

**What is the problem under consideration? Why is government intervention necessary?**  
Nicotine is a potent pharmacological agent, is highly addictive and can permanently affect the development of the adolescent brain. The Government has concerns about young people becoming addicted to any substance before they are able to make informed, adult decisions. Also, as nicotine inhaling products (NIPs), such as electronic cigarettes, are currently legally available to under 18's, there is a risk that they could act as a gateway into tobacco smoking if young non-smokers become addicted to nicotine. While the evidence-base regarding gateway effect remains limited, there is not sufficient evidence to rule out e-cigarettes acting as a gateway into smoking tobacco.

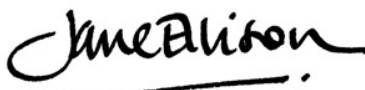
**What are the policy objectives and the intended effects?**  
The policy objective of the regulations is to limit the sale of nicotine inhaling products, such as electronic cigarettes (and related products including refill cartridges and nicotine liquids) to adults only, with certain limited exceptions for medicinal products. The intended effect is to limit the availability of nicotine inhaling products to young people and therefore restrict the scope for young people to become addicted to nicotine and any potential gateway effect into smoking tobacco.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**  
Option 1: Do Nothing  
Option 2: (preferred option): The option of (a) introducing an age of sale of 18 years for nicotine inhaling products together with (b) an offence of proxy purchasing nicotine inhaling products by adults for children is preferred. This is the preferred option as it is considered to be the most effective, proportionate and practical option.  
Option 3 (non regulatory): Introducing a voluntary agreement with retailers that they will not sell these products to under 18's.

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** Oct/2020

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	<b>Micro</b> Yes	<b>&lt; 20</b> Yes	<b>Small</b> Yes	<b>Medium</b> Yes	<b>Large</b> Yes
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)			<b>Traded:</b>		<b>Non-traded:</b>

*I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.*

**Signed by the responsible Minister:**  **Date** 24/02/15

# Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing

## FULL ECONOMIC ASSESSMENT

Price Base Year 2015	PV Base Year 2015	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

### Description and scale of key monetised costs by 'main affected groups'

This is the baseline against which other options are assessed and is by definition 0.

### Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

### Description and scale of key monetised benefits by 'main affected groups'

This is the baseline against which other options are assessed and is by definition 0.

### Other key non-monetised benefits by 'main affected groups'

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
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## BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	In scope of OITO?	Measure qualifies as
Costs: 0	N/A	N/A
Benefits: 0		
Net: 0		

# Summary: Analysis & Evidence

# Policy Option 2

**Description:** a) Introducing an age of sale of 18 years for nicotine inhaling products and b) Introducing an offence of proxy purchasing nicotine inhaling products by adults for children

## FULL ECONOMIC ASSESSMENT

Price Base Year 2015	PV Base Year 2015	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£2.1m	High:	Best Estimate:

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	£0.52m	£0.16m	£3.4m

### Description and scale of key monetised costs by 'main affected groups'

Direct cost to retailers (£170,000 per year), distributors (£20,000 per year) and manufacturers (£10,000 per year) of Nicotine Inhaling Products (NIPs) who can no longer sell to the under 18 market.

Costs to the justice system of £5,000 per year.

Costs to enforcement bodies of £600,000 in year one, and ongoing costs of £70,000 per year.

These costs are reduced by redirecting spending on other goods and services of around £170,000 per year

### Other key non-monetised costs by 'main affected groups'

The potential prevention of a 'gateway out of smoking' effect whereby under-18s who presently smoke tobacco find it more difficult to utilise NIPs as a way of quitting tobacco smoking.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate			£1.4m

### Description and scale of key monetised benefits by 'main affected groups'

Increased profits for other industries from redirected consumer spending. Classified as an indirect impact.

### Other key non-monetised benefits by 'main affected groups'

Children do not start a life of nicotine addiction leading to them to buy NIPs in the future which, given a fully informed decision as an adult they would not have chosen, but did choose when they were a child.

Preventing a gateway into tobacco smoking saving 1 QALY per person not taking up tobacco smoking.

By preventing 4 children per year (net of gateway effects in and out of smoking) from taking up tobacco smoking the policy generates a positive net present value.

### Key assumptions/sensitivities/risks

The EANCB calculation assumes the policy stops all sales to under-18s.

The probability that an under-18 will use a NIP will grow by 10% per year.

NIP use will grow more slowly with declining tobacco prevalence amongst children.

Retail profit margins will fall from 40% in year 1 to 10% in year 3, manufacturer margins from 18% to 11% - both more in line with returns from established and mature goods.

Price and NPV base is 2015, apart from EANCB and business NPV (on front page) which is 2009 prices, 2010 NPV.

Discount rate (%)

3.5

## BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0.20	Benefits: 0	Net: 0.20	Yes	IN

## **Evidence Base (for summary sheets)**

### **Rationale for intervention and intended effects**

1. Given the emergence of e-cigarettes in recent years, coupled with concerns about their use by children and young people, the Government took the opportunity offered by the Children and Families Act to introduce regulation making powers to set a minimum age of sale for these products. Section 92 of the Act 2014 therefore includes regulation-making powers for a prohibition of sale of nicotine products to persons under 18 years of age. Health ministers have undertaken a public consultation regarding the use of these regulation-making powers to inform decision-making. The public consultation included draft regulations and a consultation-stage IA.

### ***Policy objective***

2. The policy objective of the regulations is to limit the sale of nicotine inhaling products, such as electronic cigarettes (and related products including refill cartridges and nicotine liquids) to adults only, with certain limited exceptions. The intended effect is to limit the availability of nicotine for young people and prevent young people becoming addicted to nicotine before they are able to make informed, adult decisions. The regulations do not apply to tobacco products which are already covered by age of sale laws.
3. An electronic cigarette licensed as a medicine by the Medicines and Healthcare Products Regulatory Agency (MHRA), for example as a smoking cessation device, would be available to be sold to children under the age of 18 years if (a) prescribed by a relevant health professional or (b) the product's medicine marketing authorisation provides that it is indicated for use by under 18s.

### ***Regulatory proposal (Preferred Option)***

4. The Department of Health proposes to introduce an age of sale requirement for "nicotine inhaling devices", which would include nicotine inhaling products such as electronic cigarettes (the term "e-cigarette" used throughout this document is intended to encompass all nicotine inhaling products). The age of sale requirement will apply to disposable and rechargeable devices and their refills (such as pre-filled refill cartridges and nicotine liquids).
5. The regulation-making powers in the Children and Families Act 2014 require that any age of sale requirement for nicotine inhaling products be introduced for persons under the age of 18 years.
6. Any nicotine inhaling product that is licensed as a medicine by the MHRA would be regulated under medicines legislation and would only be available to children these limited circumstances - (a) prescribed by a relevant health professional or (b) the product's medicine marketing authorisation provides that it is indicated for use by under 18s.
7. The regulations make it an offence for a retailer to sell nicotine inhaling devices (and related products) as defined by the regulations to anyone under the age of 18 years, consistent with existing legislation on the sale of tobacco products.
8. A retailer convicted of selling a nicotine inhaling device to a person under the age of 18 years would be liable on summary conviction to a fine not exceeding level 4 on the standard scale (currently up to £2,500 but due to increase to £10,000 later in 2014). This level of fine is consistent with the corresponding tobacco age of sale offence. In addition, Restricted Premises Orders and Restricted Sales Orders that are currently issued by the court to retailers found to be persistently selling tobacco to people under the age of 18 years will be extended to include the sale of nicotine inhaling devices. Such an Order, if granted by the court, prohibits a named individual, or a named retail outlet, from selling nicotine inhaling products or tobacco to anyone for a period of up to one year.
9. The government also proposes to extend new "proxy purchasing" laws at Section 92 of the Children and Families Act to also cover nicotine inhaling devices, meaning that adults will not be permitted to buy products covered by these regulations, or tobacco, on behalf of children.

10. Subject to consent being provided by Welsh Ministers, the regulations would apply to England and Wales.

### **What are e-cigarettes?**

11. Over the past 5-10 years, the market for electronic cigarettes (also known as e-cigarettes) has developed rapidly. A wide range of different types and brands of e-cigarettes are on the market. According to a report on e-cigarettes commissioned by Public Health England (PHE), e-cigarettes were invented in China in 2003 and designed to provide inhaled doses of vaporized nicotine. Electronic cigarettes were first introduced to Europe in about 2005 and become increasingly popular since. The products have evolved and improved considerably.<sup>1</sup> Action on Smoking and Health (ASH) has provided the following description of electronic cigarettes:

*Electronic cigarettes, also known as vapourisers or electronic nicotine delivery systems (ENDS), are often, although not always, designed to look and feel like cigarettes. They have been marketed as less harmful alternatives to cigarettes and for use in places where smoking is not permitted since they do not produce smoke.*

*There are three main types of electronic cigarettes or vapourisers:*

- *Disposable products (non-rechargeable)*
- *An electronic cigarette kit that is rechargeable with replaceable pre-filled cartridges*
- *An electronic cigarette that is rechargeable and has a tank or reservoir which has to be filled with liquid nicotine*

*The first two types of electronic cigarette are often known as “cigalike” products as they resemble cigarettes and often have a light at the end that glows when the user draws on the device to resemble a lit cigarette. The liquid in the devices usually contains nicotine suspended in propylene glycol and glycerine. The level of nicotine in the cartridges may vary and most also contain flavourings. When a user sucks on the device, a sensor detects air flow and heats the liquid in the cartridge so that it evaporates. The vapour delivers the nicotine to the user. There is no side-stream smoke but some nicotine vapour is released into the air as the smoker exhales.<sup>2</sup>*

12. Electronic cigarettes are often designed to look and feel like conventional lit cigarettes. Broadly, they can mimic the physical and social aspects of tobacco smoking. They have been marketed as cheaper and healthier alternatives to cigarettes and for use in places where smoking is not permitted since they are not lit and therefore do not produce smoke.

13. Most e-cigarettes on the market are flavoured. A huge variety of flavours for e-cigarettes are available, some of which may be appealing to children (such as cherry cola, white chocolate, bubble gum, vanilla ice cream, energy drink and gummy bear flavours).

14. E-cigarettes must not be sold as a smoking cessation aid unless they are regulated as a medicine by the MHRA. A number of e-cigarette companies have said publicly that they have submitted an application for a medicines licence for their product. At the time of writing, a license has been granted to only two products that would meet the definition of nicotine inhaling products: Voke and the Nicorette Inhalator. An e-cigarette that is regulated as a medicine, such as a nicotine replacement therapy, could still be made available to children under the age of 18 but by way of prescription only. Licensed medicines are subject to separate regulatory rules that cover aspects including advertising, product presentation, to whom medicines can be supplied and requirements relating to the sale and supply of medicines.

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<sup>1</sup> Britton, J. and Bogdanovica, I. (2014). *Electronic cigarettes: A report commissioned by Public Health England*. Available at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/311887/Ecigarettes\\_report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf)

<sup>2</sup> Action on Smoking and Health (2014). *ASH briefing: E-cigarettes*. Available at: [http://www.ash.org.uk/files/documents/ASH\\_715.pdf](http://www.ash.org.uk/files/documents/ASH_715.pdf)

## **Use and awareness of e-cigarettes among children**

15. E-cigarettes are becoming increasingly popular and are now widely promoted. ASH estimates that there are currently around 2.1 million adults in Great Britain using electronic cigarettes, up from an estimated 700,000 users in 2012.<sup>3</sup> While use of these products by people under the age of 18 is presently limited, international evidence suggests that it is plausible that usage of e-cigarettes by young people will increase.
16. Another report was commissioned by PHE on e-cigarette uptake and marketing, which provided information on the current situation regarding the use of e-cigarettes by children:

*“Only one published nationally representative survey of e-cigarette use in children in the UK currently exists. This was conducted in March 2013 and did not include children in Northern Ireland but involved a sample of 2,178 11 to 18-year olds from Great Britain weighted to be representative of the population. It found that two-thirds (66%) had heard of e-cigarettes. Taking this group of children as the base (804 11 to 15-year-olds, 624 16 to 18-year olds), ever use, current use and dual use (with conventional tobacco cigarettes) was measured.*

*In terms of prevalence, 7% of 11 to 18-year olds reported they had tried e-cigarettes at least once and 2% reported using them sometimes (more than once a month) or often (more than once a week). Within the sample of those who had ever used e-cigarettes, 28% had used e-cigarettes within the last month. When prevalence was examined by age, 95% of 11 to 15-year olds and 90% 16 to 18-year olds stated they had never used e-cigarettes. Use was higher among the older teenagers: 11% of 16 to 18-year olds had tried e-cigarettes at least once; 8% reported using them sometimes (more than once a month); and 1% using them often (more than once a week). Among the younger age group, just 4% of 11 to 15-year olds had tried them at least once and 1% reported using them sometimes; none reported more frequent use...Among those 11 to 18-year olds reporting they had never smoked, 99% reported never using e-cigarettes and 1% reported they had tried them once or twice. Less than 1% of never smokers reported using e-cigarettes ‘often’ (<1% illustrates that the number was negligible but included at least one person). There were no ‘sometimes’ users. Among children who had tried smoking at least once, 8% had used an e-cigarette but none reported using them more often. The sample of current weekly 11 to 18-year old smokers (smoking between one and six cigarettes per week) in the survey was very small (22 weekly smokers); 59% had never used e-cigarettes, 37% reported having tried them once or twice, 7% reported use more than once a month and 5% reported (1 person) use more than once a week”.*<sup>4</sup>

17. Emerging evidence suggests that awareness of e-cigarettes by British children is high, with over two-thirds of children in Wales reporting that they have heard of e-cigarettes.<sup>5</sup> In a study conducted among children in Cheshire and Merseyside, there were no children that had not heard of e-cigarettes or did not know what they are. This study also found:

*There was an overwhelming sense across all groups that the majority of young people who do use e-cigarettes do so not for the benefits proposed by those who produce and market these products (e.g. for health benefits, to save money, to allow users to intake nicotine in locations where tobacco smoking is prohibited), but simply “for the sake of it”, to fit in with or impress their peers, or to portray a certain desired image of themselves. Although participants did not indicate that their friends put any direct pressure on them to try the devices, it was certainly the case that they felt that a young person would be more likely to want to try an e-cigarette if they had friends*

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<sup>3</sup> Action on Smoking and Health (2014). ASH briefing: Use of electronic cigarettes in Great Britain. Available at: [http://www.ash.org.uk/files/documents/ASH\\_891.pdf](http://www.ash.org.uk/files/documents/ASH_891.pdf)

<sup>4</sup> Bauld, L., Angus, K. and de Andrade, M. (2014). *E-cigarette uptake and marketing: A report commissioned by Public Health England*. Available at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/311491/Ecigarette\\_uptake\\_and\\_marketing.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311491/Ecigarette_uptake_and_marketing.pdf)

<sup>5</sup> 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*.

that were using them. Friendship groups were considered very likely to share e-cigarettes and have collective experiences of their use.<sup>6</sup>

18. According to the PHE-commissioned report on e-cigarettes, there is evidence that in the US, use of electronic cigarettes has become more popular among young people with 'ever use' doubling between 2011 and 2012 from 3.3% to 6.8%, and current use increasing from 1.1% to 2.1%. Most of this increase has occurred as a result of use by people who already use some form of tobacco product.<sup>1</sup> However, another study of 11-17 year old males in the US found that while fewer than 1% of respondents indicated that they had previously tried e-cigarettes, 18% suggested that they would be willing to if offered one by a close friend.<sup>7</sup> Research also suggests that e-cigarettes have achieved 'substantial penetration' into the young market in South Korea, where rather than using e-cigarettes as an alternative to conventional tobacco cigarettes, most Korean adolescent e-cigarettes users are dual users with tobacco cigarettes.<sup>8</sup> Based on this international evidence, it is plausible that e-cigarette use by children in Britain could continue to grow.

### ***E-cigarette promotion and young people***

19. The promotion of e-cigarettes is likely to be a key reason why awareness of these products is high among children. E-cigarettes are now available for sale, and are often prominently displayed, in a variety of different shops. E-cigarette companies compete on price and invest significantly in marketing and promotion, including through social media such as Twitter.<sup>9</sup> E-cigarettes are also widely advertised, which has become a cause of concern for some. For example, the Faculty of Public Health says it is 'deeply concerned by the aggressive marketing and promotion of electronic cigarettes to young people'.<sup>10</sup>
20. We have no reason to believe that e-cigarette makers are specifically advertising to children. The PHE-commissioned report on e-cigarette uptake and marketing states:

*One of the reasons that e-cigarettes have become increasingly popular is the marketing of these products, which is currently difficult to regulate and has prompted calls for a consultation by the Advertising Standards Authority (ASA) in the UK. This marketing may appeal to children as well as adults.*

21. While recognising that responsible e-cigarette manufacturers would not seek to specifically market e-cigarettes to children, there is a risk that some may be designing advertising and promotion for the young adult market. A Cancer Research UK report examined the marketing of e-cigarettes (including interviewing marketing experts) and found that 'independent e-cigarette companies appear to be actively targeting younger non-smokers or social smokers and promoting the e-cigarette as lifestyle products'.<sup>11</sup> Nevertheless, while e-cigarette companies may design their promotional activity to reach out to young adults, it is possible that this promotion may also resonate with young people. In April 2014, Sir Cyril Chantler published his independent review into standardised packaging of tobacco products, and described how promotional activity with respect to tobacco which is designed to reach out to young adults may also engage teenagers:

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<sup>6</sup> Hardcastle, K. and Bennett, A. (2014). "Most people I know have got one": Young people's perceptions and experiences of electronic cigarettes. Centre for Public Health at Liverpool John Moores University, Liverpool.

<sup>7</sup> Pepper, J. et al. (2013). "Adolescent males' awareness of and willingness to try electronic cigarettes" in *Journal of Adolescent Health* 2013; 52(2), pp.144-50.

<sup>8</sup> Lee, S. et al. (2014). "Electronic cigarette use among Korean adolescents: A cross-sectional study of market penetration, dual use and relationship to quit attempts and former smoking" in *Journal of Adolescent Health* 2014; 54(6), pp.684-90.

<sup>9</sup> Juang, J. et al. (2014). "A cross-sectional examination of marketing of electronic cigarettes on Twitter" in *Tobacco Control* 2014; 23, pp.iii26-iii30.

<sup>10</sup> Faculty of Public Health of the Colleges of Physicians of the United Kingdom (2014). *UK Faculty of Public Health Policy Statement on Electronic Cigarettes*. FPH, London. Available at: <http://bit.ly/1j5HDAX>

<sup>11</sup> de Andrade et al. (2013). *The Marketing of Electronic Cigarettes in the UK*. Cancer Research UK, London. Available at: [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/cr\\_115991.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/cr_115991.pdf)

*I have seen considerable evidence of tobacco companies carrying out market research on all aspects of packaging (e.g. colour, size, shape and opening) to make it appeal to various target groups of young adults. In my opinion a “spill over effect” (as described by tobacco control experts) is extremely plausible, whereby packages that are meticulously designed to appeal to, say, an 18 year old, are highly likely to appeal to a 16 year old. Because 16 year olds look up to 18 year olds and want to emulate them, in my view it is not possible to design packages in such a way as to appeal solely to one group without also appealing to the other. Research looking at the link between branded and innovative packaging and childhood and young adulthood smoking susceptibility bears this out, describing an “inevitable knock on effect” of targeting product design at young adults.<sup>12</sup>*

22. The Cancer Research UK report concluded that particular marketing techniques can increase the prospects of e-cigarette advertising and promotion also appealing to youth, including through:

*Independent e-cigarette companies present their products using a) cosmetic appeals (their attractiveness, coolness, colours and innovative packaging) and b) flavour variations across e-cigarette and e-shisha brands.*

*Social media platforms display attractive price incentives and promotional discounts.*

*Celebrities, their endorsements, and celebrity-inspired styling are common promotional tools in PR and advertising.*

*Online promotions use contests, sales apps and group discount vouchers for e-cigarettes.*

*Sponsorship for a range of sports is a prominent promotional strategy used by a number of independent e-cigarette companies.*

*E-cigarettes are described as being for sale at exclusive events, popular venues, on company and group voucher websites, via social media platforms, specialist shops, concessions and e-lounges.*

*For young non-smokers and social smokers, e-cigarettes are positioned as socially attractive and part of a rapidly growing trend.<sup>11</sup>*

23. Research undertaken in June-July 2013<sup>13</sup> into the retail availability and in-store marketing of e-cigarettes in London found the following:

*Our results show a high availability of e-cigarettes in small and large stores, with an overall availability of 57% (95% CI 48% to 67%) in our study sample. This is significantly higher than the 34% rate we found in an unpublished 2012 national study conducted in the USA, in the only other audit of e-cigarette availability. Given the recent increased investment in e-cigarettes by the tobacco industry, continued growth in e-cigarette availability is to be expected. Small stores had a noteworthy amount of e-cigarette marketing materials in the form of point-of-sale movable displays but not advertisements. Many of these point-of-sale movable displays engaged consumers directly by inviting them to try the product. We also noticed after beginning data collection that some small and large stores had e-cigarette brochures available at the point-of-sale, which can be included as a measure of the presence of marketing materials in future studies...*

24. This study covered 128 stores across London (both inner and outer London boroughs). Audits were completed in 108 of the 128 stores identified. 57% of the 108 shops audited sold e-cigarettes. The distribution of e-cigarette sales in small and large stores was not significantly different.

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<sup>12</sup> Chantler, C. (2014). *Standardised Packaging of Tobacco: report of the independent review undertaken by Sir Cyril Chantler*. Available at: <http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF>

<sup>13</sup> Hsu, R et al. (2013). “An observational study of retail availability and in-store marketing of e-cigarettes in London: potential to undermine recent tobacco control gains?” in *BMJ Open*; 2013; 3.



25. According to the Government's *Tobacco Control Plan for England*, there is 'evidence that the display of tobacco products in shops can promote smoking by young people and undermine the resolve of adult smokers who are trying to quit. The Health Act 2009 ends the display of tobacco in shops'.<sup>14</sup> However, the 2009 legislation only extends to tobacco products and does not apply to e-cigarettes (and related products) which can still be displayed openly and prominently in shops. Therefore, it is plausible that the increasing prominence of e-cigarettes in shops may increase the appeal for these products among children.
26. Research undertaken in Cheshire and Merseyside found that although some older adolescents appeared to associate e-cigarette use with smoking cessation, generally young people viewed e-cigarettes as a product in their own right, suggesting that many young people use them simply for the sake of it, for fun, or to try something new. According to this research, the main focus for young people was on the different flavours and designs of e-cigarettes and the opportunity for users to customise their devices and show individuality. The authors suggested that with their colourful designs and variety of flavours, e-cigarettes may provide a more accessible and appealing way for young people who may not like the taste or sensation of tobacco cigarettes to experiment with nicotine.<sup>6</sup>
27. A study among 11-12 year old girls in North Wales suggested that girls were very knowledgeable about the different flavours of e-cigarettes that are available and where they can be bought. For example, in two focus groups in Wrexham, girls talked about a pizza shop that sells e-cigarettes to children aged seven or older. The research also found that teachers at a local school in Wrexham confiscate e-cigarettes on a daily basis.<sup>15</sup>

### ***The Potential for E-cigarettes to act as a gateway into tobacco smoking***

28. E-cigarette use by children is strongly associated with tobacco smoking; those children who smoke more are more likely to also use e-cigarettes (and vice versa). Survey-based evidence from the UK suggests regular e-cigarette use by children who have never smoked or have only tried smoking once is rare, the wider evidence-based regarding gateway effect remains limited. Nevertheless, there is not sufficient evidence to rule out e-cigarettes acting as a gateway into smoking tobacco for children, and further research is necessary to establish what role, if any, e-cigarettes have in encouraging the take up of tobacco use.
29. E-cigarette vapour is less irritating than tobacco smoke, making it easier for inexperienced smokers to inhale. Flavourings can also make the use of e-cigarettes more pleasurable for novice users compared to smoking conventional cigarettes, and a huge variety of flavours for e-cigarettes are available.
30. In her 2013 Annual Report, the Chief Medical Officer for England 'raises concern that there may be young people for whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes'.<sup>16</sup> On whether e-cigarettes are a gateway into smoking, the UK Faculty of Public Health (FPH) says:
- No longitudinal studies in the UK have examined whether electronic cigarettes serve as 'gateways' to future tobacco use. These data are urgently required. Until then, the precautionary principle suggests that it would be rash to dismiss the worrying trends in US children.*
31. Based on current evidence, we cannot be sure that there is a "gateway" effect where e-cigarettes lead to tobacco smoking in children. Further research is needed to answer this question definitively.

<sup>14</sup> HM Government (2011). *Healthy Lives, Healthy People: A tobacco control plan for England*. Department of Health, London.

<sup>15</sup> Evans, K. (2014). *Smoking in girls aged 11-12 years in North Wales*. Social Change UK and Public Health Wales.

<sup>16</sup> Davies, S. (2013). *Annual Report of the Chief Medical Officer 2012 - Our Children Deserve Better: Prevention Pays*. Department of Health, London.

E-cigarettes may facilitate the continued use of nicotine. A study of over 75,000 Korean adolescents found that e-cigarette use was strongly associated with current and heavier cigarette smoking, and that rather than being used as an alternative to conventional cigarettes, most e-cigarette users were dual users with cigarettes. This dual use may have negative implications for individual and public health because even low levels of cigarette smoking confers nearly the same risk of cardiovascular disease as heavy smoking and duration of smoking (as well as intensity) determines the risk of lung cancer. The researchers concluded that:

*Despite the e-cigarette industry's claims that it markets only to adults, e-cigarettes have achieved substantial penetration into the youth market. As elsewhere with youth and adults, most Korean adolescent e-cigarette users are dual users with conventional cigarettes... Use of e-cigarettes is associated with heavier use of conventional cigarettes, which raises the likelihood that, like smokeless tobacco, actual use of e-cigarettes may increase harm by creating a new pathway for youth to become addicted to nicotine and by reducing the odds that an adolescent will stop smoking conventional cigarettes.<sup>17</sup>*

A study of 40,000 young people in the US found that e-cigarette use among middle and high school students doubled between 2011 and 2012, from 3.1% to 6.5%. The researchers found that dual use of e-cigarettes and conventional cigarettes is high among adolescents. While the study was not able to identify whether most youths are initiating smoking with conventional cigarettes and then moving on to (usually dual use of) e-cigarettes or vice-versa, it suggested that e-cigarettes do not discourage the use of conventional cigarettes. The researchers concluded that '*e-cigarettes may contribute to nicotine addiction and are unlikely to discourage conventional cigarette smoking among youths*'.<sup>18</sup>

32. Many e-cigarettes are manufactured to look identical to cigarettes. E-cigarettes mirror smoking behaviours and may normalise smoking among children, particularly in places where smoking tobacco is no longer permitted by smokefree legislation introduced in 2007. E-cigarettes provide some of the additional behavioural cues that are known to be important in tobacco dependence, including the "hand to mouth" action. The potential role of behavioural cues and imagery associated with e-cigarettes in smoking initiation or smoking maintenance needs further research. Research in the US suggests that "passive" exposure to both e-cigarettes and to combustible cigarettes may evoke smoking urges in young adult daily smokers.<sup>19</sup>

33. While current technology e-cigarettes do not deliver nicotine as efficiently as cigarettes, the potential for these products to cause addiction to nicotine remains high. The German Cancer Research Centre says that:

Evidence in 2013:

*Some young, non-smoking people might start using e-cigarettes, because they believe this to be less harmful than smoking cigarettes. Since most e-cigarettes contain nicotine, which is addictive, there is concern for young non-smokers who start using e-cigarettes developing nicotine dependence or, because of using e-cigarettes, becoming more familiar with smoking and eventually taking up cigarette smoking. Even though only a comparatively small proportion of adolescent non-smokers takes up using e-cigarettes, this still means that a new market of nicotine use and dependence opens and develops – with unpredictable consequences.<sup>20</sup>*

34. Research conducted with Welsh children in year 6 (10-11 year olds) found that:

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<sup>17</sup> Lee, S. et al. (2014). "Electronic cigarette use among Korean adolescents: a cross-sectional study of market penetration, dual use, and relationship to quit attempts and former smoking" in *Journal of Adolescent Health* 2014; 54(6), pp.684-690.

<sup>18</sup> Dutra, L. and Glantz, S. (2014). "Electronic Cigarettes and Conventional Cigarette Use Among US Adolescents A Cross-sectional Study" in *JAMA Pediatrics* 2014; 168(7), pp.610-617.

<sup>19</sup> King, A. et al. (2014). "Passive exposure to electronic cigarette (e-cigarette) use increases desire for combustible and e-cigarettes in young adult smokers" in *Tobacco Control*. Published online first, 21 May 2014.

<sup>20</sup> German Cancer Research Centre (2014). *Electronic Cigarettes: An overview – supplement March 2014*. DKFZ, Heidelberg.

*E-cigarettes represent a new form of childhood experimentation with nicotine. Findings are consistent with a hypothesis that children use e-cigarettes to imitate parental and peer smoking behaviours, and that e-cigarette use is associated with weaker antismoking intentions.*<sup>21</sup>

35. The European Commission says that:

*E-cigarettes simulate smoking behaviour and can lead to further experimentation with other nicotine-containing products. Recent studies suggest that e-cigarettes are increasingly used by non-smokers and young people. For example a French study of 2013 revealed that the number of Parisian students experimenting with e-cigarettes has doubled in one year reaching 18%.*<sup>22</sup>

### **Protecting children from addiction and the impact of nicotine on the developing adolescent brain**

36. Nicotine is a potent pharmacological agent with established effects on the cardiovascular system and the central nervous system. Nicotine is highly addictive. The government has legitimate concerns about young people becoming addicted to any substance before they are able to make informed, adult decisions.

37. The chemistry and pharmacology of nicotine alone qualifies it as 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, including measures of pleasure and liking.<sup>23</sup> Nicotine fulfils all the criteria required for a drug of dependence.<sup>24</sup>

38. Young people can rapidly develop nicotine dependence. With respect to nicotine from smoking conventional tobacco, symptoms can develop soon after a young person's first puff on a cigarette. Novice smokers often do not recognize the symptoms they experience as related to nicotine dependence.<sup>25</sup> A four-year cohort study of 1,246 students in the United States found that the most susceptible youths lose autonomy over tobacco within a day or two of first inhaling from a cigarette.<sup>26</sup> While it is clear that e-cigarettes deliver nicotine to users, we are not aware of any research into how addictive e-cigarettes might be to users that are children (and it is likely to be differences in addictiveness between products, depending on how efficiently nicotine is delivered).

39. The brain continues to develop during adolescence, and exposure to exogenous substances such as nicotine can exert long-lasting adaptations during this vulnerable period. Research by Counotte et al. concluded:

*..the brain and specifically the prefrontal cortex continue to develop during adolescence, making the adolescent brain uniquely different from the adult brain. One of the differences is that adolescents are more sensitive to the rewarding effects of nicotine, which may be a reason that many people start to smoke during adolescence. Both prospective and longitudinal human studies suggest that adolescent exposure to nicotine has long-term effects, among which are 1) the risk to develop substance use disorder and 2) various mental health problems, the most prevalent ones relating to affective disorders such as anxiety and depression. In addition, inasmuch our animal studies can be extrapolated to humans, adolescent exposure to nicotine may lead to decreased attention performance and increased impulsivity on the long-term. The*

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<sup>21</sup> Moore, G. et al.. (2004). "E-cigarette use and intentions to smoke among 10-11-year-old never-smokers in Wales" in *Tobacco Control*. Published online 22 December 2014.

<sup>22</sup> European Commission (2014). *E-cigarettes Myth Buster*. Available at: [http://ec.europa.eu/health/tobacco/docs/tobacco\\_mythbuster\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/tobacco_mythbuster_en.pdf)

<sup>23</sup> Royal College of Physicians (2007). *Harm Reduction in Nicotine Addiction: Helping people who can't quit*. RCP, London.

<sup>24</sup> Gourlay, S. and McNeil, J. (1990). "Antismoking products" in *Medical Journal of Australia*. 153, pp.699-707.

<sup>25</sup> Gervais, A., et al. (2006). "Milestones in the natural course of onset of cigarette use among adolescents" in *Canadian Medical Association Journal*. 175(3), pp.255-261.

<sup>26</sup> Di Franza, et al. (2007). "Symptoms of tobacco dependence after brief intermittent use: The development and assessment of nicotine dependence in Youth-2 study" in *Archives of Pediatrics and Adolescent Medicine*. 161(7), pp.704-710.

*latter observation in turn might promote the maintenance of smoking behaviour. Based on studies in human subjects, it is difficult to determine whether adolescent smoking underlies these problems, or whether smoking and mental health disorders have a common origin that predisposes an enhanced risk to the development thereof. In order to understand the effects of drugs of abuse on motivational systems, it is important to gain a better understanding of their development in the adolescent brain.<sup>27</sup>*

40. The impact of nicotine on the developing adolescent brain, as delivered by e-cigarettes, is also described by Dutra et al.:

*Although e-cigarettes deliver many fewer toxins and at much lower levels than conventional cigarettes, they contain nicotine, a highly addictive substance, in doses designed to mimic cigarettes. Animal models suggest that, through its effect on cholinergic pathways, nicotine may have permanent effects on the brain and behaviour such as dysregulation of the limbic system, which can lead to long-term difficulties with behavioural regulation, attention, memory, and motivation, among other functions. The adolescent human brain may be particularly vulnerable to the effects of nicotine because it is still developing.<sup>20</sup>*

### **Uncertainty about whether e-cigarettes are safe for children to use**

41. We do not know about the effect of e-cigarette emissions on the developing lungs of young people. We are not aware of any long-term studies that suggest the use of e-cigarettes is safe, particularly for young people. The FPH says that nicotine, whether inhaled, ingested or in direct contact with the skin, can be particularly hazardous to the health and safety of certain populations – such as children, young people, pregnant women, breastfeeding mothers, people with heart conditions and older people.<sup>10</sup>
42. The PHE-commissioned report on e-cigarettes says that evidence on the content and emission of electronic cigarettes is limited. Different electronic cigarette products are highly variable in the amount of nicotine they deliver in vapour and that the nicotine content indicated on a cartridge is not a reliable guide to likely nicotine delivery. The report also described how the risks between smoked tobacco cigarettes and e-cigarettes differ:

*Cigarettes deliver nicotine in conjunction with a wide range of carcinogens and other toxins contained in tar, including nitrosamines, acetone, acetylene, DDT, lead, radioactive polonium, hydrogen cyanide, methanol, arsenic and cadmium, and vapour phase toxins such as carbon monoxide. In contrast, electronic cigarettes do not burn tobacco, so any toxins in vapour arise either from constituents and contaminants of the nicotine solution, and products of heating to generate vapour. The principal component other than nicotine is usually propylene glycol, which is not known to have adverse effects on the lung but has not to our knowledge been tested in models that approximate the repeated inhalation, sustained over many years, that electronic cigarettes involve. We are aware of two cases of lipoid pneumonia attributed to inhalation of electronic cigarette vapour, one in the peer-review literature the other a news report.*

*Despite some manufacturers' claims that electronic cigarettes are harmless there is also evidence that electronic cigarettes contain toxic substances, including small amounts of formaldehyde and acetaldehyde, which are carcinogenic to humans, and that in some cases vapour contains traces of carcinogenic nitrosamines, and some toxic metals such as cadmium, nickel and lead. Although levels of these substances are much lower than those in conventional cigarettes, regular exposure over many years is likely to present some degree of health hazard, though the magnitude of this effect is difficult to estimate.<sup>1</sup>*

43. Research indicates that young people may not be aware that e-cigarettes contain nicotine and can, therefore, be addictive. There is likely to be a general lack of understanding among young people about the safety of using e-cigarettes. Research undertaken in Cheshire and Merseyside found that

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<sup>27</sup> 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.

young people aged 13-17 in that area 'showed a real uncertainty and lack of awareness of the potential risks and harms associated with e-cigarettes, current and proposed future regulation in the UK, and the actual chemical content and functional components of these devices'.<sup>6</sup>

44. Nicotine is classified as a poison and e-cigarette fluids for refilling certain types of e-cigarettes are toxic. In 2013, 139 calls were made to the National Poisons Information Service (NPIS) by health professionals seeking expert advice on how to treat members of the public suspected of nicotine poisoning. This is a sharp increase from the 29 reported cases in 2012 and 36 cases in the five years before that. The Director of the NPIS was reported as saying:

*E-cigarette usage has increased significantly in recent years. The liquid found in e-cigarettes can be very harmful and I would urge anyone who uses e-cigarettes to make sure that the liquids are stored safely, and in particular away from children.*<sup>28</sup>

45. The European Commission says:

*Nicotine is an addictive and toxic substance. The Commission has received notifications concerning the safety of e-cigarettes, i.e. there are significant differences between what is on the label and the true levels of nicotine inside. The long term effects of e-cigarettes on public health are not yet known.*<sup>23</sup>

### **Age of sale restrictions will support the position of the e-cigarette industry and retailers**

46. Responses to the consultation confirmed that many responsible manufacturers recommend that their products are for use by adults only and responsible retailers already voluntarily restrict children from accessing e-cigarettes. However, there are some that do not. The impact of these regulations will be primarily on those businesses that currently sell nicotine inhaling products to people under the age of 18. Research by the Trading Standards Institute, conducted across England in March 2014, showed that young people are most easily able to get e-cigarettes from market stalls and car boot sales, independent pharmacists and specialist e-cigarette suppliers. Sales of e-cigarettes were least frequently made from national newsagents and large retailers, which are stores that are already familiar with applying age of sale restrictions, including the sale of tobacco.<sup>29</sup>
47. The government has responded to calls from a number of manufacturers and retailers of e-cigarettes for a minimum age of sale. Age of sale restrictions that are consistent with the sale of tobacco and other age restricted products will support retailers in the operation of their business. The Electronic Cigarette Industry Trade Association has told the Department of Health that they support the introduction of age of sale controls for e-cigarettes.
48. There remains a need for clarity for how e-cigarettes should be sold, and many retailers are confused as to whether a minimum age of sale for e-cigarettes already exists. A recent study by the Trading Standards Institute of "test purchasing" of e-cigarettes by children showed that children were able to buy e-cigarettes in four out of every ten attempts. There were similar findings in July 2014 when an ITV investigation also found that a 17 year old was able to purchase e-cigarettes from a range of different types of shop, including pharmacies and supermarkets, with a third of outlets testing making a sale. In response to the investigation, the Sainsbury's, Waitrose and Co-Op supermarket chains each confirmed that they have policies to not sell e-cigarettes to children.<sup>30</sup>

### **Supporting adolescents who want to quit smoking**

49. Adolescents who are currently smoking tobacco and wish to quit are likely to require support that combines a range of approaches. There is evidence to conclude that stop smoking medicines such

<sup>28</sup> Meikle, J. (2014). "E-cigarette poisoning figures soar as vaping habit spreads across UK" in *The Guardian*; 14 April 2014.

<sup>29</sup> MacGregor, J. (2014). *Youth access to e-cigarettes and associated products: A report commissioned by Public Health England*. Available at: <http://www.tradingstandards.gov.uk/templates/asset-relay.cfm?frmAssetFileID=75751>

<sup>30</sup> ITV (2014). "Third of outlets ITV News tested sold e-cigarette to 17-year-old" on *ITV News*, 16 July 2017. Available at: <http://www.itv.com/news/2014-07-16/third-of-outlets-itv-news-tested-sold-e-cigarette-to-17-year-old/>

as nicotine replacement therapies (NRT) used without behavioural support are not as effective in supporting adolescents to stop smoking as structured cessation services.

50. A Cochrane Review of evidence regarding tobacco cessation interventions for young people was published in 2010, which set out:

*We identified 24 good quality studies (>5000 participants) that researched ways of helping teenagers to quit. Programmes that combine a variety of approaches, including taking into account the young person's preparation for quitting, support behavioural change and enhance motivation show promise. The number of trials and participants are beginning to be adequate to provide evidence to judge effectiveness. Medications such as nicotine replacement and bupropion have not yet been shown to be successful with adolescents.*<sup>31</sup>

51. There is not sufficient evidence to conclude that e-cigarettes can assist children who want to stop smoking to quit. Children who want to quit smoking with the support of stop smoking medicines can continue to access existing forms of NRT, such as gums or patches. These NRT products are licensed for stop smoking by people down to the age of 12 years, and as they have been in use for a longer period than e-cigarettes, more is known about their safety profile.
52. Research suggests that children are not using e-cigarettes to quit smoking. The children that use e-cigarettes are most likely to be smokers, and that e-cigarette use is 'consistent with experimental behaviour or "poly-nicotine" use among current smokers'.<sup>32</sup>
53. In the future, e-cigarettes that are licensed as a stop smoking medicine could be made available to children under the age of 18 years on prescription, but as a prescription only medicine.

#### **Age of sale of e-cigarettes in other countries**

54. The sale of e-cigarettes to minors has been banned in more than half of US states and there are proposals to set a federal minimum age of 18 years to use e-cigarettes in the US.<sup>33</sup> Within the EU, Croatia, Slovakia, Spain, Italy and Latvia have set age of sale requirement for e-cigarettes.
55. The WHO recommends that retailers should be prohibited from selling electronic nicotine delivery system products such as e-cigarettes to minors.<sup>34</sup>

#### **Consultation outcome**

56. 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.
57. The following reactions were reported on the publication of the consultation in the trade magazine *Better Retailing*:

*ACS [Association of Convenience Stores] chief executive James Lowman said: "E-cigarettes are a growing product category in convenience stores, providing a viable alternative to smoking for thousands of people".*

*"The vast majority of our members already have a voluntary age restriction on these products in place, but this consultation will provide important clarity for all responsible retailers who sell these*

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<sup>31</sup> Grimshaw G. and Stanton A. (2010). *Tobacco cessation interventions for young people (Review)*. Cochrane Collection. Available at: <http://www.thecochranelibrary.com/userfiles/ccoch/file/World%20No%20Tobacco%20Day/CD003289.pdf>

<sup>32</sup> Lippert, A. (2014). "Do adolescent smokers use e-cigarettes to quit?" in *American Journal of Health Promotion*. In print (online first edition, accepted for publication on 15 March 2014).

<sup>33</sup> Gostin, L and Glasner, A. (2014). "E-cigarettes, vaping and youth" in *JAMA*; 30 June 2014.

<sup>34</sup> WHO (2014). *Electronic Nicotine Delivery Systems: Report by WHO*. Available at: [http://apps.who.int/gb/fctc/PDF/cop6/FCTC\\_COP6\\_10Rev1-en.pdf](http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf)

*products and ensure that they have the support of legislation.”*

*E-cigarette manufacturer, Vype, said it was pleased the Government had “finally acknowledged what many in the industry are already practising”.*

*A spokesperson for Vype, said: “We support appropriate regulation and welcome the Government’s proposal to restrict sales of e-cigarettes to those aged over 18. Like many others in the category, our e-cigarette products and marketing materials already contain clear over-18 statements.”<sup>35</sup>*

58. There were 81 responses to the consultation, with the majority of those coming from organisations. 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.
59. Many respondents emphasised that this is fast moving market in terms of product development and patterns of consumer use and that research evidence into 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.
60. 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.
61. 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 page.
62. Some responses from businesses and organisations to the consultation included:

**National Federation of Retail Newsagents:**

*“We support these changes being made by regulation, as the support of the law will help our members to effectively enforce age of sale restrictions, whilst ensuring they are not at a competitive disadvantage”*

**Association of Convenience stores:**

*“ACS supports the proposed age restriction of 18 years of age for nicotine inhaling products. We believe that an age restriction will provide retailers with clarity on the sale of e-cigarettes. ACS supports the proposed regulation to extend the current proxy purchase offence for tobacco to also cover nicotine inhaling products.”*

**Electronic Cigarette Industry Trade Association:**

*“ECITA fully supports the introduction of mandated age restrictions for all electronic cigarettes”*

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<sup>35</sup> “Industry welcomes talks to ban e-cigarettes to under 18s” in *Better Retail*. Available at: <http://www.betterretailing.com/ecigarette-under-18s-ban-government/>

*“We welcome the UK Government’s intention to force all retailers of electronic cigarettes and vaping products to abide by the standards ECITA set for its members in 2010.”*

**The Co-operative Group:**

*“We support the introduction of statutory age restrictions for nicotine inhaling products”*

**Totally Wicked (e-cigarette company):**

*“We publicly welcomed the Department of Health’s and the Welsh Government’s announcements to ban sales of electronic cigarettes to those under 18 years of age in England and Wales, something we ourselves have been doing for the past six years.”*



## Options Considered at Consultation

63. The following policy options to achieve the objective of preventing individuals under the age of 18 years from accessing Nicotine Inhaling Products (NIPs) were considered at consultation.

### **Option 1: Do Nothing**

64. The Do Nothing option is the baseline against which other options are assessed.

65. Details of the current situation (which would remain under option 1) are detailed in the 'problem under consideration' summary at the front of this impact assessment.

### **Option 2: Introduce a minimum age of sale of 18 years for nicotine inhaling products and introduce an offence of proxy purchasing nicotine inhaling products by adults for children (PREFERRED OPTION)**

66. The preferred option is detailed in paragraphs 4 to 10 and is for England and Wales, coming into effect on 1<sup>st</sup> October 2015. Costs and benefits are set out in the section below.

### **Option 3: Introducing a voluntary agreement with retailers that they will not sell to under 18's**

67. This option involves introducing a voluntary agreement by retailers that they will not sell NIPs to under-18s.

68. The strength of this option is that it is a non-regulatory proposal and therefore does not impose a direct cost to business.

69. The weakness of this option is that those retailers that sign up to the voluntary agreement are likely to be those retailers that already refuse to sell to under-18s, therefore access to NIPs will remain largely unchanged. It is likely to lead to inconsistent practice and confusion amongst retailers who would prefer the clarity that a statutory minimum age of sale would provide.

70. Retailer organisations and the Electronic Cigarette Industry Trade Association (ECITA) both support age of sale legislation and the consistency it provides with other age restricted products, notably tobacco.

71. This view was confirmed by consultation responses representing manufacturers<sup>36</sup>, distributors, retailers<sup>37</sup>, and other associated organisations<sup>38</sup>, which stated they were in favour of regulation and welcomed the clarity it would provide.

72. Consultation responses also confirmed that a number of large manufacturers, distributors, and retailers already have voluntary practices in place<sup>39</sup> as did other sources<sup>40</sup>. Despite these, there is

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<sup>36</sup> Blu eCigs (UK) 'fully endorse the objectives of the proposed regulations'; JTI 'believes... regulation of electronic cigarettes should aim to keep electronic cigarettes out of the hands of minors'; PMI 'believes that nicotine inhaling products should be for adults only and supports the proposal to restrict the sale of nicotine-inhaling products to those over 18 years of age'; Totally Wicked Ltd 'fully supports the banning of the sale of electronic cigarettes to those under the age of 18'.

<sup>37</sup> The Co-operative Group 'support the introduction of statutory age restrictions for nicotine inhaling products'.

<sup>38</sup> The Trading Standards Institute 'welcomes the inclusion of NIPs within the scope of restricted sale and restricted premises orders'; Johnson and Johnson Ltd 'fully supports the aims of these proposed regulations'; The Association of Convenience Stores (ACS) 'supports the proposed age restriction... We believe that an age restriction will provide retailers with clarity on the sale of e-cigarettes'; ECITA 'fully supports the introduction of mandated age restrictions for all electronic cigarettes...'

<sup>39</sup> Consultation responses from ACS (representative of 33,500 local shops including national chains and independent retailers) and The Co-operative Group, Blu (UK) impose contractual obligations on retailers not to sell to under-18s; Totally Wicked 'have imposed their own ban for the last six years'; Imperial Tobacco support retailer programmes to this aim. Separate to the consultation, the National Federation of Newsagents (NFNA) states 'our members are advised by us to apply the current age restrictions on tobacco to e-cigarettes'.

<sup>40</sup> Trading Standards Institute: 'Youth Access to E-Cigarettes and Associated Products' suggests that 60% of retailers already observe a voluntary age restriction

evidence of use amongst under-18s<sup>41</sup>, suggesting voluntary practices are not wholly successful in preventing sales to under-18s.

73. A voluntary agreement with retailers would therefore result in inconsistency and would not deliver the policy aim. Responsible retailers require the support of the law to effectively enforce age of sale restrictions and are supportive of a statutory minimum age of sale.<sup>42</sup>
74. Research by the Trading Standards Institute, conducted across England in March 2014, showed that there is already confusion amongst retailers regarding the age at which NIPs can be sold and this is despite the presence of age warnings on the majority (80%) of products purchased by volunteers during the study.
75. Introducing a voluntary agreement not to sell to under-18s may put the volunteer retailers at a competitive disadvantage, as they are losing out on a potential market that other retailers might be exploiting, thereby distorting the market.<sup>43</sup>
76. A voluntary agreement with retailers is not considered to be the most appropriate option to deliver a policy of reducing access of NIPs to children.
77. **Option 2 - Introducing (a) a statutory minimum age of sale of 18 years for nicotine inhaling products together with (b) an offence of proxy purchasing nicotine inhaling products by adults on behalf of children, was the preferred option.**

## Description of the consultation

78. The majority of respondents (79%) appeared to broadly welcome the proposals, supporting the aim to restrict access to NIPs to over-18s. This support covered all sectors – health NGOs, e-cig manufacturers, tobacco companies, Retailers and their Trade Associations, Trading Standards and local authorities.
79. However, many raised points to be considered and areas for further thought and dialogue as the policy, research and market develops in coming years.
80. Respondents were keen to emphasise that this was a fast moving market in terms of product development, patterns of consumer use, and emerging research evidence into effectiveness in smoking cessation and potential long-term health harms. This is also the first time that specific regulations will affect the retail of nicotine inhaling products.
81. There was widespread support from business and organisations for the introduction of regulations introducing a minimum age of sale, citing the need to protect children.
82. We have utilised both comments on our approach and data submitted as part of consultation responses to refine our estimates within this IA.

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<sup>41</sup> ASH/YouGov Survey 2013

<sup>42</sup> ACS consultation response notes that 'the introduction of a voluntary measure could only lead to inconsistency in the market place... Responsible retailers will benefit from the consistency that regulatory measures would provide.'

<sup>43</sup> ACS consultation response

## Detailed quantification of the preferred option

### Costs

83. In order to calculate the direct costs of the preferred option (for EANCB purposes), the same methodology is used as at consultation (albeit with updated data). The method seeks to:

- Estimate how under-18s use NIPs
- Estimate how many NIPs these under-18s use in any one year
- Estimate how the above values will change over the next 10 years
- Estimate the profits that are generated by NIPs to firms in the supply chain
- Calculate what proportion of these profits are made by UK-based businesses

84. The following describe these steps.

#### ***Market Estimation (Number of Users)***

85. A survey undertaken across Great Britain by YouGov for ASH in March 2013<sup>44</sup> questioned a sample of 2,178 young people aged 11-18 years on their knowledge and use of e-cigarettes, and designated those claiming to have used e-cigarettes into one of three usage categories, as below:

- 'Regular' ("more than once a week")
- 'Occasional' ("more than once a month")
- 'Experimental' ("once or twice")

86. We have been able to draw on fuller data than in the Consultation-stage IA, and consequently identify a third, intermediate usage group ('occasional') where previously only two ('regular' and 'experimental') were considered.

87. As individuals aged 18 years would be permitted to purchase NIPs under the proposed regulation, we exclude 18-year-olds from the survey results, leaving 1,895 11-17-year-olds.

88. The YouGov survey found that that of the 1,895 respondents aged 11-17 years, 0.3% currently used NIPs "more than once a week", 0.5% used them "more than once a month", and 3.1% had "tried NIPs once or twice".

89. These proportions are then applied to the England and Wales 11-17 year old projected population profiles for 2015<sup>45</sup>, giving an estimate of the number of users in the relevant population of:

- 13,368 Regular users
- 22,279 Occasional users
- 138,133 Experimental users

90. It should also be noted that the estimated number of regular NIPs users under the age of 18 in England and Wales is based a very small proportion of those surveyed who claimed to use NIPs more than once a week, thus there is a degree of uncertainty within this estimate. We have presented central estimates throughout this document so the preciseness required for the calculation of the direct costs to business is transparent.

91. A consultation response from ASH and ASH Wales told us that an updated survey on e-cigarette use in 11-18 year olds has been completed, but the underlying data is not yet available (as it is awaiting

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<sup>44</sup> 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](http://www.ash.org.uk/files/documents/ASH_891.pdf)

<sup>45</sup> ONS. 'Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2013'. Available at: <http://www.ons.gov.uk/ons/rel/pop-estimate/population-estimates-for-uk--england-and-wales--scotland-and-northern-ireland/2013/index.html>

peer review for journal publication) to the Department and so has not been incorporated into our estimates. Further, we note that the estimates drawn from the 2013 survey are taken from summaries and may be subject to rounding inaccuracies<sup>46</sup>.

92. We further note contentions that the ASH/YouGov survey does not distinguish between nicotine and non-nicotine containing e-cigarettes. Nonetheless, we are unaware of any more appropriate data being available. We have assumed all responses relate to nicotine containing products and consequently may overestimate NIP use. Analysis of Nielsen data suggests 99.8% of products for sale, which label the amount of nicotine in the product, contain nicotine.

### **Market Estimation (Number of NIPs)**

93. We do not have data on how many e-cigarettes users aged 11-17 currently use. So whilst we know, for example, that 0.3% of those surveyed use them more than once a week, we do not know if this means 1 puff of an e-cigarette per week, or 100 puffs per day. We therefore looked to adult data to infer an estimate. The consultation responses did not offer any further information on this point.

94. Using data on NIP consumption among adults taken from the University College London Smoking Toolkit Study<sup>47</sup>, we calculated adult consumption of NIPs relative to tobacco cigarettes, split by smoking status (current smoker, former smoker).

95. We then applied this ratio to tobacco consumption by 11-17-year-olds, weighted by age, to produce an estimated average consumption of NIPs among under-18 regular NIP users, of approximately 21 NIPs per year.

96. Using the above estimate we calculate that regular users (under-18s) consume around 280,000 NIPs per year (13,368 users multiplied by 21 NIPs per user).

97. We then apply assumptions regarding the relative use of other usage categories ('occasional' and 'experimental' use).

98. The survey does not estimate consumption rates within each grouping, and so we assume that 'occasional' users consume at a rate of approximately one quarter that of 'regular' users (assuming 'more than once a month' is around one quarter as many as 'more than once per week'). Occasional users are thus estimated to consume 120,000 NIPs per year.

99. We assume that each 'experimental' user consumes the NIP equivalent of one full tobacco cigarette per year. Experimental users may not fully exhaust a device, but rather share with others who join together to purchase, or may try a smaller amount from a friend or relative who already uses a NIP.

100. We assume 1 NIP is the equivalent of 30 tobacco cigarettes<sup>48</sup>. This means that each experimental user consumes 1/30<sup>th</sup> of a NIP per year.

101. Given this assumption, we calculate consumption by this 'experimental' group of 138,133 users to be around 4,000 NIPs per year.

102. We note a consultation response from Blu eCigs (UK) that highlights the difficulties with comparing NIP and tobacco-cigarette consumption and equivalence; however this approach gives a credible estimate of usage and the Department was not made aware of any further information that would have enabled a more appropriate estimate, and note that favourable equivalence with tobacco cigarettes is sometimes used to market NIPs<sup>46</sup>. We further note that consultation response is supportive of our assumption that a proportion of under-18 NIP users will not exhaust a full NIP, but may share one between several experimental users.

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<sup>46</sup> ASH were unable to provide the full raw data for use in this Impact Assessment.

<sup>47</sup> West R, et al. (2014). Trends in electronic cigarette use in England, Smoking Toolkit Study. Available at: <http://www.smokinginengland.info/latest-statistics/>

<sup>48</sup> <http://www.e-lites.co.uk/>

103. The above usage estimates combine to a total of approximately 400,000 NIPs per year, mainly from ‘regular’ users. These calculations are shown in Table 1, below.

Table 1 – Estimated Number of Users in Population and Number of NIPs Consumed

Usage category	Proportion of Survey Respondents	Estimated Number of Users in Population (England and Wales)	Number of NIPs Consumed per year
I have tried them once or twice	3.1%	138,133	4,604
I use them sometimes (more than once a month)	0.5%	22,279	117,248
I use them often (more than once a week)	0.3%	13,368	281,396
Total		173,780	403,249

**Market Growth Projections (Number of Users, Number of NIPs)**

104. To calculate the impact of the policy, we assess costs and benefits arising over a 10 year period. To do this, we forecast the number of NIP users, and from this the number of NIPs affected by the policy.

105. The market for NIPs is relatively new and constantly changing. Surveys of the adult and under 18s population have found that e-cigarette use is mostly concentrated among smokers and ex-smokers of tobacco. Use by non-smokers is relatively small. These surveys lead us to conclude that the NIP use per year for a tobacco smoking child is much larger than the NIP use per year for a child that does not smoke tobacco. We therefore look at the growth in the NIP market by considering what we may expect to happen to the number of children who smoke tobacco and uptake of NIPs by non-smokers. Therefore, three main factors will determine the number of under-18 NIP users in the future:

- The number of new NIP users who are also tobacco smokers (since most NIP users are also tobacco users)
- The number of new NIP users who have never smoked tobacco
- Population growth

106. At consultation we assumed that the probability that someone uses (however frequently) a NIP increases by 10% each year from 2015 to 2024. Tobacco smokers consume more NIPs per year than non-tobacco smokers (since if they are a NIP user they are more likely to be a frequent user compared to a non-tobacco smoker), therefore if the proportion of smokers in the under 18 population reduces over time, the total number of NIPs sold to under 18s would grow at less than 10% per year.

107. There are some reasons to believe this 10% estimate may be too high. Latest data from the Smoking Toolkit Study shows that the proportion of adult smokers and recent ex-smokers who use e-cigarettes has not grown in the last 6 quarters. (21.5% in Q3 2013 to 21.8% in Q3 2014, falling to 18.6% in Q4 2014). E-cigarette use by never smokers is low, at 0.2%<sup>47</sup> of the non-smoking population. A recent article in the Financial Times<sup>49</sup> has also suggested ‘stagnant usage rates’ and ‘sales remaining broadly flat since April’ 2014.

108. We have also studied the latest accounts submitted by two e-cigarette manufacturers which show falling sales revenue between 2013 and 2014, although it is difficult to separate the effect of price, volume and market share, see Table 3.

109. There is, however, a report from E-cigintelligence which shows that growth may be much higher in the near future, at around 28%<sup>50</sup>.

<sup>49</sup> <http://www.ft.com/cms/s/28a178b8-b1f4-11e4-8396-00144feab7de>

110. Given the wide range of estimates, and that we did not receive any quantitative analysis via the consultation which suggested that our growth figure of 10% was systematically biased upwards or downwards, we continue to use 10% p.a. as the estimated growth rate of the probability of any particular individual using a NIP.
111. Tobacco smoking rates among 16-17 olds and 11-15 year olds have been falling for the last decade. We project this trend forward to estimate what the tobacco smoking population of 11 to 17 year olds would be for each of the next 10 years. We find that the smoking prevalence rate halves to just under 5%.
112. Therefore, although tobacco smokers will be 10% more likely to use a NIP each year, the total population of smokers is projected to fall. The net effect is that the number of NIP users who also use tobacco will grow at an average annual rate (after general population growth) of 3.4%.
113. The number of children aged 11 to 17 who do not smoke tobacco will grow in line with the population, but also because fewer are starting to smoke due to reduced prevalence. Given the 10% increase in probability a child will use a NIP, the net effect is that non-tobacco users who use NIPs will grow by an average annual rate of 12.2% per year.
114. We have made assumptions about how many NIPs different frequency of users will consume and we assume that these remain fixed over time. Therefore a frequent (weekly) user will consume around 21 NIPs per year, an occasional (monthly) user around 5 NIPs per year and an experimenter (once or twice) around 1/30<sup>th</sup> per year (or the equivalent of 1 tobacco cigarette). But it should be recalled that tobacco smokers consume more NIPs per year than non-tobacco smokers (since if they are a NIP user they are more likely to be a frequent user compared to a non-tobacco smoker).
115. Overall, although the growth in the probability of using NIPs is assumed to grow by 10%, after taking into account that there will be fewer tobacco smokers (who are more likely to be frequent users) and population growth, we estimate that the number of NIPs consumed by 11 to 17 year olds will grow at an average annual rate of 4.0%.
116. The breakdown, by year and by frequency of user, is shown in Table 2.

Table 2 – Projected number of NIPs consumed by 11 to 17 year olds

Year	Population of 11-17 year olds	11-17 year old NIP users who are:		Total NIPs consumed by 11-17 year olds
		<i>Tobacco Smokers</i>	<i>Non-Tobacco Smokers</i>	
2015	4,455,897	132,895	40,885	394,229
2016	4,443,678	135,109	45,201	402,517
2017	4,467,807	138,486	50,351	414,478
2018	4,525,594	143,006	56,475	430,126
2019	4,621,985	148,893	63,833	450,214
2020	4,727,025	155,239	72,216	472,082
2021	4,830,344	161,719	81,594	494,796
2022	4,926,044	168,131	91,969	517,793
2023	5,021,416	174,720	103,579	541,873
2024	5,071,196	179,885	115,534	562,099
<b>Average Annual Growth</b>	<b>1.4%</b>	<b>3.4%</b>	<b>12.2%</b>	<b>4.0%</b>

### ***Profits Generated by NIPs***

117. Any restriction on age of sale may have impacts on those making profits from NIP sales. To estimate the profits generated by NIPs, and consequently the potential profits lost, we consider the price of NIPs and the profit margins achieved by those in the supply chain, including manufacturers, distributors, and retailers.

## ***NIP Types and Pricing***

118. The proposed regulations would apply to any device that can be used for inhaling nicotine, as well as to refill cartridges and nicotine liquids for those devices. One disposable NIP is priced between £1 - £8<sup>51</sup>, and is thought to be the equivalent of approximately 30 tobacco cigarettes<sup>52</sup>.
119. We encouraged anyone with further relevant information on pricing of NIPs to make it available through the consultation. We did not receive specific information on pricing.
120. We note analysis by ECigIntelligence<sup>53</sup> suggests a higher mean average price of £5.60.
121. We note that the same ECigIntelligence analysis suggests that disposable NIPs are the preferred product form in the UK<sup>54</sup>.
122. Purchasing a refillable NIP package (with a charger and nicotine cartridges) priced between £30 - £50, with refill cartridges £2 - £17 and being the equivalent of approximately 30 tobacco cigarettes in terms of number of puffs, makes NIPs approximately one-third as expensive as tobacco cigarettes<sup>55</sup>.
123. We have assumed that younger users will be more likely to purchase disposable NIPs as they are less-expensive and more readily accessible.
124. We have proceeded with our Consultation Stage IA estimate of £4 as we believe under-18s will tend to buy less expensive products than the mean average price of disposable NIPs.

## ***Retailer Profit Margins***

125. For retailers, it is likely that the aggregate impact of these regulations is not large compared to their total annual sales and profits, given that many retailers are already voluntarily applying an age of sale restriction to the NIPs they sell. This view was supported by consultation responses suggesting any impact on retailers was likely to be small.<sup>56</sup>
126. NIPs are a relatively new and novel product group, and consequently attract a high profit margin (of around 40% to retailers<sup>57, 58, 59</sup>).
127. In projecting impacts over a ten year horizon, we have assumed that increased competition will place downward pressure on retail prices and consequently on profit margins, such that retailers achieve a 40% margin in year 1, halving to 20% in year 2, and halving again to a 10% margin for year 3. The retail profit margin is held at 10% from year three onwards.
128. We accessed annual accounts from large retailers and note that these predominantly achieve a profit margin of around 5% and consequently our estimates may be overestimates. However, as a

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51 1) <http://www.electrictobacconist.co.uk/disposable-e-cigarettes-c4#t29>  
2) <http://nicolites-shop.co.uk/index.php?route=product/category&path=77>  
3) <http://www.10motives.com/disposables/>  
4) <http://www.vapestick.co.uk/v1-disposable-electronic-cigarettes-special-offer.html>

52 <http://www.e-lites.co.uk/>

53 ECigIntelligence, 'In depth: e-cigs in the UK – market and regulatory analysis'. 26 October 2015. Currently available at: <http://ecigintelligence.com/in-depth-e-cigs-in-the-uk-market-and-regulatory-analysis/>

54 'The UK is different from most of the rest of mainland Europe in terms of product. The form factor most common found in the UK is not the refillable tank e-cigarette that predominates in markets such as France, Germany and Italy, but rather the cigalike disposable or cartomiser rechargeable product, common also in the U.S.'

55 Assume disposable e-cigarette priced at £4 and delivers 300 puffs. Average RRP for a pack of 20 cigarettes (estimated 200 puffs) was £7.98 in 2013. (£7.98 x 1.5 = £11.97). Average RRP according to The Tobacco Manufacturers Association. Available at: <http://www.the-tma.org.uk/tma-publications-research/facts-figures/uk-cigarette-prices/>

56 ASH and ASH Wales; Imperial Tobacco; ECITA; Totally Wicked Ltd;

57 Scottish Grocer. 'High margin options and growing fast', March 2013. Available at: <http://www.scottishgrocer.co.uk/2013/03/high-margin-options-and-growing-fast/>

58 <http://vaperstore.co.uk/wholesale-trade-electronic-cigarettes-uk> shows 30-50%

59 <http://vapenetworks.com/retail-pack.html> shows up to 44%

number of larger retailers already subscribe to voluntary age-of-sale schemes we did not believe these data to be the most appropriate source. Smaller retailers are likely to operate a lower volume, higher margin operating model.

129. We encouraged anyone with further relevant information on profitability within the NIP retail industry and our approach in the IA to make it available through the consultation, but did not receive any further evidence on these profit margins, and so do not believe 10% to significantly underestimate the longer term retail profit margin.<sup>60</sup>
130. We note a number of consultation responses suggested that the impact on retailers was likely to be very small. This gives some reassurance that the low impact of under £1m per year on retailers that was calculated as part of the Impact Assessment appears not to be unreasonable.
131. The burden of enforcement falling on retailers is considered separately in section ‘Cost of Enforcement borne by retailers (the costs of ID checks)’ below.

**Manufacturer Profit Margins**

132. We encouraged anyone with further relevant information on profitability and ownership within the NIP manufacturing industry to make it available through the consultation. We did not receive any responses which helped to inform our manufacturer profit estimates.
133. We have therefore looked at the most recent set of accounts filed to Companies House for 2 NIP manufacturers, Zandera Ltd (makers of E-lites) and Ten Motives Ltd. Between them they had combined revenue of £25m in their most recent accounting year and manufacture 2 of the biggest brands in the UK market. The results are shown in Table 3, below.

Table 3 – Manufacturer Profit Margins

	Zandera Ltd		Ten Motives Ltd	
	2013	2014	2013	2014
Turnover £(000)	17,878	15,797	11,840	8,812
Profit for the financial year £(000)	3,403	2,312	2,696	1,875
Profit Margin (over revenue)	19%	15%	23%	21%

134. For our estimate of manufacturer lost profits we therefore use 18% (average of the two 2014 profit margin figures) as the starting point, but note that margins have fallen from 2013, and we would expect this decline to continue into the future. Barriers to entry into the generic manufacture of NIPs are likely to be low and so it is unlikely that these high levels of profit will be sustained indefinitely. We therefore assume margins drop to 15% in 2015, 13% in 2016 and 11% in 2017.
135. Many e-cigarette brands have been acquired by the tobacco industry and so we expect that as NIP manufacturer margins fall over time, in the long run they will fall to the level of the tobacco industry<sup>61</sup>. Therefore we assume profit margins of 11% (average of PMI and JTI) for the NIP manufacturers from 2018 onwards.

<sup>60</sup> The overall impact is not hugely sensitive to this assumption. For example if profit margins dropped to 10% in year 8 instead of year 3, there would be an additional cost of around £0.3m per year to retailers.

<sup>61</sup> Philip Morris International (which ultimately own Nicolites) had 15.7% profit margin in 2013 (and is reasonably consistent for other years) see PMI 2013 report available at: <http://investors.pmi.com/phoenix.zhtml?c=146476&p=irol-reportsannual> (note profit margins estimated include tobacco taxes in the denominator).

Japan Tobacco International (who ultimately own Elites) had a 4.8% profit margin in 2010 (estimated by EBITDA less Depreciation and Amortisation divided by revenue). 2010 is used since that is the latest year when accounts include tobacco tax in their revenues, and it should be noted that other years have similar EBITDA, although Depreciation and Amortization is more variable and suggests that the 4.8% estimate could increase to around 6.7% (estimated by EBITDA 2010 less Depreciation and Amortisation 2011 divided by revenue 2010). See JTI annual Report 2013 available at: <http://www.jti.com/media/investor-information/>



## **Distributor Profit Margins**

136. In the Consultation Stage IA, we stated that we had limited information on the market for distributors, but believed it to be a low profit margin industry given a high degree of competition and low barriers to entry. We therefore expected any lost profits to be relatively small, and made no attempt to quantify these costs.
137. We encouraged anyone with further relevant information to give us more information about distributors as part of the consultation. We did not receive any responses to this question, but have refined our approach and now quantify the impact on distributors below.
138. We note that some manufacturers have their own distribution networks, or use generally available delivery companies. It is possible that we have therefore captured an element of these profits within the manufacturer profit estimate calculated earlier. Our understanding of the distribution network is in part informed by ECigIntelligence<sup>62</sup>.
139. It is likely that the smaller retailers who are selling NIPs to under-18s will use a mix of distribution and delivery services, including parcel delivery companies, wholesalers, and direct distribution. By analysing company accounts, we estimate a profit margin for distributors of 3%<sup>63</sup>.

## **Description of the Modelling of Lost Profits**

140. In order to calculate the direct impact on UK business of the policy the profits margins for retailers, distributors and manufacturers are used to calculate the total profits foregone by removing under 18s from the NIP market.
141. We start by assuming an average retail price in 2015 of £4 per NIP. By applying the profit margins described in the sections above (with the profiles over time as discussed) we find that the average profit per NIP for each sector is as given in Table 4.

Table 4 – Profit per NIP by sector from 2015 to 2024.

Year	Retail Profit Loss per NIP (£)	Distributor Profit Loss per NIP (£)	Manufacturer profit loss per NIP (£)
2015	1.60	0.07	0.36
2016	0.60	0.07	0.36
2017	0.26	0.07	0.30
2018	0.25	0.07	0.25
...	...	...	...
2024	0.25	0.07	0.25

*Figures given in a 2015 price base, undiscounted.*

142. Combining these estimates with the number of NIPs calculated in Table 1 results in total lost profits as given in Table 5.

<sup>62</sup> ECigIntelligence, 'In depth: e-cigs in the UK – market and regulatory analysis'. 26 October 2015. Currently available at: <http://ecigintelligence.com/in-depth-e-cigs-in-the-uk-market-and-regulatory-analysis/>

<sup>63</sup> This is an average of the profit margins achieved by the companies considered: Royal Mail, 3.8% (excluding share offer and pension deficit effects); Booker (A 'Cash and Carry' Wholesaler) 2.2%; DHL (a parcels and distribution business) 4%.

Table 5 – Lost profits due to fewer sales of NIPs, by sector 2015 to 2024

Year	Retail Profit Loss (£)	Distributor Profit Loss (£)	Manufacturer profit loss (£)	Manufacturer profit loss (UK) (£)
2015	630,767	28,385	141,579	11,326
2016	241,510	28,981	144,556	11,564
2017	107,758	29,095	124,677	9,974
2018	109,470	29,557	108,814	8,705
2019	114,583	30,937	113,896	9,112
2020	120,148	32,440	119,428	9,554
2021	125,929	34,001	125,174	10,014
2022	131,782	35,581	130,992	10,479
2023	137,911	37,236	137,084	10,967
2024	143,059	38,626	142,201	11,376

Figures given in a 2015 price base, undiscounted.

143. Lost profits are therefore felt most by retailers, which enjoy the highest profit margin of the sectors. Distributors are making a low margin (as they operate a high volume, low margin business, in a sector with very low barriers to entry and high levels of competition) and so lose less profits than retailers. The impact on manufacturers is similar to retailers, although only 8% of this production is located within the UK (see section later showing how this was calculated) and so the total UK loss is relatively small, at around £10,000 per year.

### **Cost of Enforcement borne by Retailers (the costs of Identification Document (ID) checks)**

144. This option may cause an increase in the average time for retailers to serve customers, since more customers are likely to have to prove their age. We raised this in the Consultation IA alongside the Department’s anticipation that setting an age of sale for NIPs would not bring any significant new burdens on retail transactions. We note we have not received any evidence against this view. However, to provide context, here we illustrate what the magnitude of such a cost could be.

145. In our illustration we assume that all those under-18s who would have obtained a NIP under Option 1 (do nothing option) try to buy one under Option 2 (minimum age of sale option). We also assume that they have to prove their age, and are denied purchase. We assume no other effects on retailers.

146. We assume it takes an average of 15 seconds per transaction to provide proof of age.

147. Taking the number of NIP sales to under-18s in year one of around 394,000 and applying it to the 15 second estimate above gives around 1,650 hours of retailer time per year spent proving customers age.

148. There is uncertainty when assessing the value to retailers of any small amounts of extra time spent on tasks such as proof of age. Many 15 seconds across the UK in one day summing to an hour or two in total for the entire UK is not the same as one retailer gaining an hour or two of work from an employee. Therefore, on the one hand there is an argument that most of these extra seconds are not likely to result in any extra costs, since the retailer could not have made productive use of these extra seconds of time. However, on the other hand there is the chance that this extra time may have a disproportionate effect, since it may feed into wider step change decisions, such as employing another member of staff. For this illustration we apply a cost to retailers of £10 per hour<sup>64</sup>.

149. Taking the values above and discounting gives an illustrative cost of £16,426 in year one, and a discounted total cost of £165,885 over the 10 year appraisal period.

<sup>64</sup> This is similar to the value used in the Standardised Packaging of Tobacco Products IA which in turn was based on the Annual Survey of Hours and Earnings - “sales assistants and retail cashiers” with a 30% uplift to allow for overheads with prices adjusted using the GDP deflators

150. We note that this estimate may be an overestimate for the following reasons:
- a. Once the law is changed the number of children trying to buy NIPs may decrease.
  - b. Many retailers already do not sell to children and these children may already be getting NIPs from adult friends and family.
  - c. It takes no account of the decreased sales which free up retailers' time (when one only considers the direct effects i.e. Before one considers the increase in serving time from the increase in products bought instead). If the time taken to serve NIPs is the same as to prove age, then this cost would reduce to zero.
  - d. It may take less than 15 seconds on average if a child cannot prove they are an adult, since they do not need to look for documentation that does not exist.
  - e. Children may dual purchase e-cigarettes with other age restricted products which are already being challenged.
151. We note that this estimate may be an underestimate for the following reasons:
- f. More adults may be asked for proof of age when buying NIPs.
  - g. Children may be asked for proof of age, and be denied sale at more than one retailer.
  - h. It may take more than 15 seconds on average if a child cannot prove they are an adult, since they may argue over misleading documents or 'fakes' to falsely 'prove' they are adults.
  - i. If children falsely 'prove' they are adults, they may not be asked for proof of age for their next purchase.
  - j. Compliance of retailers may not reach 100%.
152. We use the above illustrative cost of £165,885 (in total over the 10 year appraisal period) in the One in Two Out, Equivalent Annual Net Cost to Business, and Net Present Value calculations, acknowledging the uncertainty in this estimation.

### ***Cost of Staff Training and Awareness***

153. It is anticipated that there will be a one-off cost for retailers in terms of training staff and raising awareness of the new age of sale restriction and the product range to which it applies. We expect there will be a low ongoing cost in terms of ongoing staff training and replacement. Retailers are already familiar with the concept of age of sale across a range of products (i.e. alcohol, knives, fireworks, tobacco) and the addition of a new product to existing training should not be unduly burdensome.
154. In the Consultation Stage IA we assumed that these costs were not significant and relatively immaterial when compared to the impacts modelled and so made no attempt to quantify them.
155. We encouraged anyone with further relevant information on profitability and ownership within the NIP distribution industry to make it available through the consultation. Consultation responses, including from the Co-operative group and Trading Standards, suggested these costs would not be negligible.
156. The Trading Standards Institute (TSI) provided estimated costs of enforcement for a large county council (Staffordshire). (The costs falling on TSI are considered separately below.) These estimates included one of £3,000 for advisory visits to retailers. We have based our estimate of the corresponding costs to retailers on the TSI data, assuming that where TSI accrue costs as a result of making visits, retailers will also accrue some costs associated with receiving visits<sup>65</sup>.
157. We scaled these costs to the population of England and Wales using ONS population data<sup>66</sup>. This suggested a cost in year 1 of £99,675, which is included in the OITO, EANCB and NPV calculations.

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<sup>65</sup> We assume that the cost accruing to retailers will be half that of TSI, given that TSI cost will include costs and time of travel and preparation.

<sup>66</sup> ONS, 'MYE2: Population Estimates by single year of age and sex for local authorities in the UK, mid-2013'. Currently available at: <http://www.ons.gov.uk/ons/rel/pop-estimate/population-estimates-for-uk--england-and-wales--scotland-and-northern-ireland/2013/index.html>

## **Proportion of Manufacture Profits Accruing Domestically**

158. Calculations of EANCB for OITO purposes require that we apportion the share of the impact that will fall on the UK. To this purpose, a 'GDP approach' is adopted to assess the direct impact on UK-based activities. We estimate that **8%** of NIP manufacture and value-adding occurs domestically. The calculation of this estimate is given below. It should be noted that the proportion of retail and distribution profits accruing domestically are both assumed to be 100% and hence do not have a similar section in this IA.
159. As noted previously, the majority of NIP sales are by brands partly or wholly owned by tobacco cigarette manufacturers. Major tobacco cigarette manufacturers are large, multinational operations and it is possible that value will be added to the final good in a number of different countries.
160. Detailed data on NIP production is not available – related business activity is not uniquely identified in national accounts, nor can e-cigarettes and e-liquid be distinguished from other products in trade data (both fall under miscellaneous trade codes that encompass a variety of products). Unlike in the case of tobacco, manufacturers of e-cigarettes and e-liquid are not required to specifically register with DH or HMRC for specific tax purposes. We therefore do not have any systematic information on the number of manufacturers located within the UK.
161. ECigIntelligence report that the vast majority of e-cigarettes and e-liquids are currently produced in the Shenzhen region of China<sup>67</sup>. They have also produced an assessment of the UK market for e-cigarettes<sup>68</sup>, which lists the top 30 e-cigarette brands as compiled by Alexa. It is recognised that this list does not reflect the top 30 by market size, but by online brand presence. ECigIntelligence assessed the top 20 of these brands to check for claims that they manufacture their e-liquid in the UK. Of the 20 brands, 12 claim to produce e-liquid in the UK, while 8 do not. To assess the proportion of activity that occurs within the UK, we then link these brands to Nielsen ScanTrack data on smoking control products. Of the 12 brands that claimed UK-based productions, 6 can be successfully linked to Nielsen data, while data for 5 of the 8 brands that did not claim UK production could be found. That the data linkage is not a simple process reflects the fragmented nature of the market and the difficulty in monitoring sales occurring through non-conventional channels.
162. 41% of total e-cigarette sales<sup>69</sup> as identified by Nielsen related to the 11 brands that could be linked. The 6 brands claiming to produce in the UK accounted for 16% of the sales identified for the top 20, or 7% of total sales. The remaining 84% are from non-UK producers, accounting for 33% of total sales.
163. Due to the design of the ECigIntelligence list, some of the largest manufacturers of e-cigarettes for the UK market were excluded. The two largest of these, E-lites and Nicolites, account for 43% of sales as identified by Nielsen. Based on the available evidence, it appears that neither of these manufacture product within the UK<sup>70,71</sup>.
164. We can therefore estimate that 7% of UK e-cigarette sales do contain e-liquid manufactured in the UK and 78% do not, with the remaining 16% being unclear. Assuming that the distribution of location for these unknowns is the same as for those we do know results in an estimate of 92% of manufacturing occurring outside of the UK. We therefore estimate that **8%** of costs to the e-cigarette manufacturers fall on UK-based business activity.
165. It should be noted that these assessments relate to the production of e-liquid – it is generally noted that the vast majority, if not all, hardware is manufactured in China. As such, applying these

<sup>67</sup> ECigIntelligence, 'In depth: the outlook for China's e-cig manufacturing industry'. 5 February 2015. Currently available at: <http://ecigintelligence.com/in-depth-outlook-for-chinas-e-cig-manufacturing-industry/>

<sup>68</sup> ECigIntelligence, 'Data in depth: UK e-cig brands, products, pricing analysis'. 26 October 2014. Currently available at: <http://ecigintelligence.com/data-in-depth-uk-e-cig-brands-products-pricing-analysis/>

<sup>69</sup> Sales data relate to all identified e-cigarette related products, including disposables and e-liquid refill vials.

<sup>70</sup> <http://www.birminghampost.co.uk/business/bromsgrove-electronic-cigarettes-firm-e-lites-3907715>

<sup>71</sup> <http://grocerytrader.co.uk/?p=17905>

proportions may overestimate the proportion of value-added activity that occurs in the UK. On the other hand, many of these e-cigarette firms maintain their head office and marketing teams in the UK, which would lead to these figures underestimating the UK burden. Any attempt to adjust our estimates to account for these factors would require detailed knowledge of the internal workings of e-cigarette manufacturers. It seems plausible that the value-add associated with the creation of e-cigarette hardware is at least as great as that added by UK-based service, not least because UK e-cigarette consumers commonly use disposable products<sup>72</sup> for which the hardware will likely account for a considerable proportion of the cost. Therefore we assume that these effects cancel, and we retain 8% as our e-cigarette UK share of production.

### **Summary of One-in-Two-Out (OITO) and Equivalent Annual Net Costs to Business (EANCB)**

166. Table 6 (below) shows the costs that are considered in the calculation of EANCB for OITO purposes. Note that these costs are presented in 2015 prices and not discounted. For the EANCB calculator we use a 2009 Price Base and 2010 PV base.

Table 6 – Direct effects and OITO net costs of the policy

Year	Manufacturer Profit Lost (£)	Distributor Profit Lost (£)	Retailer Profit Lost (£)	Retailer Familiarity Costs (£)	Retailer Costs of Lost Time (ID Checks) (£)	Total (£)
2015	11,326	28,385	630,767	99,675	16,426	786,579
2016	11,564	28,981	241,510	-	16,772	298,827
2017	9,974	29,095	107,758	-	17,270	164,097
2018	8,705	29,557	109,470	-	17,922	165,654
2019	9,112	30,937	114,583	-	18,759	173,391
2020	9,554	32,440	120,148	-	19,670	181,813
2021	10,014	34,001	125,929	-	20,616	190,561
2022	10,479	35,581	131,782	-	21,575	199,418
2023	10,967	37,236	137,911	-	22,578	208,692
2024	11,376	38,626	143,059	-	23,421	216,481
Total	103,072	324,839	1,862,918	99,675	195,009	<b>2,585,513</b>

### **Other (Non-business) Costs**

#### **Cost of Enforcement by Local Authorities through Trading Standards**

167. In the Consultation stage IA, we assumed that, as the proposed legislation for NIPs is similar to existing age of sale provisions surrounding alcohol and tobacco that are currently enforced by trading standards officers, any additional cost of monitoring NIP sale and purchase would be marginal; we therefore made no attempt to quantify this cost.

168. We encouraged anyone with views on this approach to enforcement costs to state them through the consultation. We received a number of responses addressing this issue, suggesting that these costs were not negligible. The Trading Standards Institute (TSI) helpfully provided estimated costs of enforcement for a large county council (Staffordshire)<sup>73</sup>.

169. We scaled these costs to the population of England and Wales using ONS population data<sup>74</sup>. This suggested a cost in year 1 of £598,051. This cost is counted in the calculation of NPV but not towards EANCB, as it does not fall directly on business.

<sup>72</sup> ECigIntelligence, 'In depth: e-cigs in the UK – market and regulatory analysis'. 26 October 2015. Currently available at: <http://ecigintelligence.com/in-depth-e-cigs-in-the-uk-market-and-regulatory-analysis/>

<sup>73</sup> TSI's consultation response estimated costs of £3,000 for 'advisory visits and £6,000 for test purchases.

<sup>74</sup> ONS, 'MYE2: Population Estimates by single year of age and sex for local authorities in the UK, mid-2013'. Currently available at: <http://www.ons.gov.uk/ons/rel/pop-estimate/population-estimates-for-uk--england-and-wales--scotland-and-northern-ireland/2013/index.html>

170. Local authority trading standards officers would be responsible for enforcing legislation relating to the age of sale for NIPs covered by these proposed regulations. The proposal would bring NIPs into the age restricted product category, which includes a range of products such as tobacco, alcohol, butane gas lighter refills and fireworks.
171. We estimate that ongoing costs of enforcement falling on Trading Standards are £79,740 per year. This is calculated by taking the TSI estimate of test purchase costs only (not advisory visits, which we regard as a one-off cost occurring in year one and supporting retailers during transition), scaled to the England and Wales population as above. We further assume that a proportion of test purchases will already be covered in the existing test regime for other age restricted products<sup>75</sup>.
172. Given that a number of large retailers have confirmed that they already prohibit sale of NIPs to under-18s, we estimate that most of the impact of this policy will be as a result of independent retailers and stall owners refraining from selling to under 18's. We note that primarily targeting independent retailers as opposed to national chains will likely increase enforcement and compliance costs, as enforcement will be at the unit level as opposed to national/ Head Office level. As our cost data was supplied through TSI's consultation response, we believe this issue is reflected in these cost estimates.
173. Government would encourage local authorities to continue to take a "compliance building" approach with retailers, so that retailers are aware that NIPs are no longer available for purchase by under-18s. We would encourage enforcement action to be taken especially in cases where legislation has been persistently breached.

***Cost falling on Ministry of Justice (from the Justice Impact Test)***

174. We estimate that there would only be a small impact of around £5,000 per year falling on HM Courts & Tribunals Service (HMCTS), due to an increase in court cases following non-adherence to the proposed policies.
175. With appropriate discounting, this amounts to a total cost of £43,038 over a 10-year horizon.
176. The cost to HMCTS per case is estimated to be £500 per defendant (using MoJ analysts estimates based on the existing offence of under-age sales of tobacco to under-18s ) with an estimated 10 defendants (combined proceedings against retailers and for proxy purchase offences)<sup>76</sup> per year totalling £5,000 per annum.

***Second-round Business Impacts***

177. The direct costs of a loss of profits to retailers, distributors, and manufacturers from removing under-18s from the NIP market are likely to be partially offset by increased profits from redirected spending on goods and services elsewhere in the economy (although we class these as indirect and out of scope of OITO).
178. In the long run we would expect the profit margins and returns on capital to equalise throughout the economy, and the long run effects of switching spending between goods and services would lead to no loss of output for the economy as a whole.
179. NIPs presently attract a high profit margin (of around 40% to retailers, and 18% to manufacturers) owing in part to them being a relatively new and novel product. Initially, any spending redirected to other goods and services would be likely deliver lower profit margins.

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<sup>75</sup> We assume 20% of test purchases are outside of existing visits, including to specialist NIP retailers.

<sup>76</sup> Previously calculated usage estimates of under 18 NIP-users are used to calculate the relative size the under-18 NIP and tobacco markets (tobacco statistics are taken from the Smoking, drinking and drug use among young people, 2013, HSCIC). Information on proceedings in Scotland are scaled to the population of England and Wales using ONS population data.

180. The money not being spent on NIPs will now be spent on other goods and services. We assume that these goods attract a profit margin of 10%, equal to the rate NIPs generate from 2017 onwards. In NPV terms, there is therefore a net cost to retailers in the first two years of the policy.

181. Similarly, these extra goods need to be delivered to retailers, or pass through a distribution network. We therefore assume the direct cost on distributors of not delivering NIPs will be offset by the profits of delivering and distributing other goods and services. In NPV terms there is therefore no effect on distributors.

182. As the NIP industry matures, the profit margin made by manufacturers will reduce to a level commensurate with an economy wide average return on capital employed. It is likely however, that the loss of profits made by manufacturers in the early years of this policy will not be redistributed as in the short run this capital is likely to be tied up in the NIP industry. In NPV terms there is therefore a net cost to manufacturers in the first 3 years of the policy<sup>77</sup>.

### Summary of Net Costs for NPV Purposes

183. The effects discussed above are summarised in Table 7 below.

Table 7 – Direct and Indirect effects and net costs of the policy

Year	Direct Costs (from EANCB calculation) £	Enforcement Costs £	Justice System Costs £	Indirect benefits of redirected spend £	Net Costs £	Discounted Net Costs £
2015	786,579	598,051	5,000	186,076	1,203,554	1,162,854
2016	298,827	79,740	5,000	149,736	233,831	218,284
2017	164,097	79,740	5,000	136,853	111,984	101,003
2018	165,654	79,740	5,000	147,732	102,662	89,464
2019	173,391	79,740	5,000	154,632	103,499	87,143
2020	181,813	79,740	5,000	162,143	104,410	84,938
2021	190,561	79,740	5,000	169,944	105,357	82,809
2022	199,418	79,740	5,000	177,843	106,315	80,737
2023	208,692	79,740	5,000	186,114	107,318	78,743
2024	216,481	79,740	5,000	193,060	108,161	76,677
<b>Total</b>	<b>2,585,513</b>	<b>1,315,713</b>	<b>50,000</b>	<b>1,664,134</b>	<b>2,287,092</b>	<b>2,062,653</b>

184. Prohibiting NIP sales to under-18s may decrease the probability of those individuals becoming NIP users as adults. This is analogous to tobacco, where we observe that addiction begins in childhood and adolescence (two-thirds of all smokers started before they were 18). This may reduce the future number of adult consumers, which will in turn decrease future profits in the adult market. However, as adults will be able to legally purchase NIPs, we categorise this potential impact as an indirect cost; *the policy influences behaviour in this case, but it is not a determinant*. We further assume that any reductions in profit accruing to NIP manufacturers, distributors, and retailers in the future that are due to this effect will be wholly offset by increased profits elsewhere.

185. No further information was available from the consultation responses to refine these estimates.

186. We therefore calculate the discounted net costs of the policy for NPV purposes over the 10 year appraisal period as £2.1 million.

<sup>77</sup> However it is possible that spending would redirect to UK made products which would more than offset the 8% UK made NIPs.

## Benefits

### *Informed Choice*

187. It is assumed that under-18s are less able to make informed, rational decisions. Further, it is recognised that these decisions (particularly with regard to consumption that may lead to developing addiction) may affect the rest of their life. This is evidenced by research undertaken in Cheshire and Merseyside that found that young people aged 13-17 in that area ‘showed a real uncertainty and lack of awareness of the potential risks and harms associated with e-cigarettes, current and proposed future regulation in the UK, and the actual chemical content and functional components of these devices’<sup>78</sup>
188. Nicotine is an addictive substance. When the effect of addiction on decision-making is considered, it may be argued that addicted consumers are less able to fully exercise choice. The benefit of Option 2 is in aiding under-18s to make more-informed choices, and in potentially preventing addiction to nicotine.
189. The impact on consumer surplus may differ from that of a normal good, due to nicotine being an addictive good. Although an individual’s initial consumption may be driven by the rational desire to consume the product (and will result in consumer surplus), following addiction to that product, the decision to consume is no longer driven wholly by the desire to consume but rather the compulsion to satisfy the symptoms of nicotine addiction. As a result, individuals addicted to nicotine must spend money on alleviating symptoms of addiction that they might otherwise spend on other goods and services that would give them pleasure.
190. We conclude therefore that the expenditure on other products in place of NIPs by people addicted to nicotine should be counted as a benefit of the proposed age of sale restriction, as this spending will yield greater pleasure. We lack information on the number of under-18s that may become addicted to nicotine, and on the likely duration and effect of their addiction. This lack of information remains after consultation. Therefore, we have not attempted to quantify this effect, but it should be noted that although unquantified this is likely to be a large benefit compared to the costs.

### *Health Effects*

191. In the earlier ‘Uncertainty about whether e-cigarettes are safe for children to use’ section we state that we are not aware of any long-term studies that suggest the use of e-cigarettes is safe, particularly for young people. We also consider the PHE- commissioned report that says “*Although levels of these substances are much lower than those in conventional cigarettes, regular exposure over many years is likely to present some degree of health hazard, though the magnitude of this effect is difficult to estimate*”. Option 2 is likely to cause some who would not have smoked tobacco but would have been a NIP user under Option 1, to not use either under Option 2. Therefore Option 2 has reduced this health risk. We do not attempt to quantify this benefit due to lack of evidence.
192. It is important to note that the previous paragraph discusses the health risk from using a NIP for someone who currently does not smoke tobacco. It does not consider the risk of using a NIP compared to smoking tobacco. It is generally accepted (although not necessarily universally) that “*Compared with smoking using an electronic cigarette is safer*”<sup>79</sup>.

### *‘Gateway’ Effects*

193. We consider that it is possible that NIPs could act as a gateway into tobacco smoking. If NIPs were to have such a gateway effect, decreasing NIP use would be a benefit. On the other hand, for some under-18s they may also act as a gateway out, and if the policy was to prevent this it would be a cost. The respective effects (and net effects) are considered below.

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<sup>78</sup> Hardcastle, K. and Bennett, A. (2014). “Most people I know have got one”: Young people’s perceptions and experiences of electronic cigarettes. Centre for Public Health at Liverpool John Moores University, Liverpool.

<sup>79</sup> ASH briefing, Electronic cigarettes, November 2014 currently available at [www.ash.org.uk/files/documents/ASH\\_715.pdf](http://www.ash.org.uk/files/documents/ASH_715.pdf)



### ***Preventing a Gateway into Tobacco Smoking***

194. It is possible that NIPs could act as a gateway into tobacco smoking. Tobacco smoking causes various health harms and can lead to premature death. Therefore, if NIPs were to have such a gateway effect, if Option 2 were to decrease NIP use it would result in decreased tobacco smoking (relative to Option 1) and thus a health benefit.
195. We do not assume that there is a gateway effect. But we recognise that whatever the probability, however small, is not currently possible to accurately quantify. We therefore do not quantify this potential benefit of the policy.

### ***Preventing a Gateway out of Tobacco Smoking***

196. It is possible that Option 2 would make it more difficult for under-18s who presently smoke tobacco to utilise NIPs as a way of quitting tobacco smoking. Tobacco smoking causes various health harms and can lead to premature death. Therefore, if NIPs were to have such a gateway effect, if Option 2 were to decrease NIP use it would result in increased tobacco smoking (relative to Option 1) and thus a health cost.
197. Evidence is scarce on the effectiveness of using NIPs to quit tobacco smoking in children. Further, there is very limited evidence that NIPs are used in this way amongst under-18s. We therefore note that there is a possible cost associated with preventing NIP use as a gateway out of smoking, but do not quantify this in NPV calculations.
198. We note that this potential effect would be partially mitigated by measures to make NIPs licensed as medicines available to children in certain limited circumstances, including smoking cessation.

### ***Net Gateway Effect***

199. Consultation responses confirmed that evidence on 'gateway' effects is still inconclusive (both into and out of tobacco smoking). We have revised our approach to consider the *net effect* of gateways into and out of smoking, and believe this to more accurately reflect the likely impact and state of the literature. This analysis has been consequently amended to reflect this.
200. We note that evidence on any 'gateway effect' is as yet inconclusive, and so have not included a quantification of potential benefits of avoiding under-18s becoming tobacco cigarette smokers in NPV estimates. We do however present a breakeven analysis below for illustrative purposes. This analysis considers how many under-18s it would be necessary to prevent from taking up tobacco-cigarette smoking (resultant from a supposed 'gateway effect') in order for the quantified benefits of the policy, realised in health gains, to outweigh the costs.
201. For every under-18 NIP consumer for whom NIP use acts as a net gateway into smoking, and as a result develops an addiction to smoking tobacco, we have estimated that, on average, they would lose 1.0 discounted life year<sup>80</sup> through increased mortality risk (a weighted average of the life year gain depending on duration of addiction). Thus, preventing a net gateway into smoking tobacco results in an average 1.0 life-year gain per individual. We value each life-year gained at £60,000<sup>81</sup>.
202. Thus, if this policy prevents a minimum of 38 people (or 4 per year) from taking up tobacco smoking more than it prevents from quitting tobacco smoking over the 10 year period considered, the quantified benefits will outweigh the quantified costs (it should be noted that all quantified benefits do not include all benefits).

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<sup>80</sup> See Standardised packaging of tobacco products Impact Assessment February 2015, Annex A. currently available at <https://www.gov.uk/government/consultations/standardised-packaging-of-tobacco-products-draft-regulations>

<sup>81</sup> DH assigns a value of £60,000 to a Quality Adjusted Life Year. Where Quality Adjusted Life Year estimates are not readily available, and it is appropriate this value is used for Life Years. This is consistent with similar valuation of policies that mitigate mortality or morbidity risk by other Government departments, based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes.

## Specific Impact Tests

### Small and Micro Business Assessment (SaMBA)

203. Of the retail outlets potentially affected, the “Grocery Retail Structure 2013”<sup>82</sup> records a total of 50,313 convenience stores/independent newsagents and petrol forecourts, plus 9,379 supermarkets in the UK, all of which could potentially sell NIPs. Convenience stores, independent newsagents, specialist NIP retailers, and petrol forecourts that do not belong to a national chain (i.e. unaffiliated independents) could be recognised as small and micro businesses, as would market stall-holders and some independent NIP shops.
204. A number of large supermarkets have confirmed that they already have voluntary practices in place not to sell NIPs to under-18s. It is likely therefore that the under-18s who are currently purchasing NIPs are more likely to be doing so from small and micro business retailers. We therefore expect the loss of profits associated with fewer sales to retailers to impact primarily on small and micro businesses.
205. Given that many of these businesses have not chosen a voluntary approach of restricting sales (as per the large supermarkets) legislation is needed to restrict sales to under-18s and to ensure consistency and clarity for retailers. A voluntary agreement with retailers would not only result in inconsistency but is likely to be exploited by under-18s wishing to buy NIPs and associated products such as e-liquids containing nicotine. It would therefore not deliver the policy aims.
206. We encouraged anyone with views or evidence as to what proportion of the identified lost profits are likely to affect small and micro businesses to state them through the consultation, but we did not receive any quantitative analysis.
207. We do not believe exempting small and micro business from this regulation would enable any of the identified benefits to be realised, given that the benefits are contingent on reduced NIP uptake. This would not happen if under-18s were able to simply switch their purchase from one type of retailer to another. We therefore will not be exempting or modifying the regulations for small and micro retailers.
208. We received a consultation response from The Association of Convenience Stores (ACS), who represent some of the small and micro retailer businesses affected, who support this position:
- “We believe the introduction of a regulatory measure will be far more beneficial than if Department of Health introduced a voluntary agreement with retailers to not sell to individuals under 18 year olds. A number of our members already impose a voluntary age restriction of 18 on e-cigarettes in their stores, and in a recent report by Trading Standards Institute suggests that 60% of retailers already impose a voluntary age limit of 18<sup>83</sup>. However, the introduction of a voluntary measure could only lead to inconsistency in the market place and therefore give retailers who do not sign up to the agreement, a competitive advantage. An inconsistency within the market place could also lead to confusion among both consumers and retailers.”*
209. We note that these direct costs in the form of lost profits will be matched to some extent by increased indirect benefits from increased profits in other industries, of which small and micro businesses are likely to benefit.
210. The Government would encourage local authorities to continue to take a ‘compliance building’ approach with retailers, so that retailers are fully aware that NIPs are no longer available for purchase by under-18s. (We would encourage, however, enforcement action to be taken especially in cases where legislation has been persistently breached.) Given that specialist NIP retailers, and small and micro retailers may be more unfamiliar with age of sale restrictions, a compliance building

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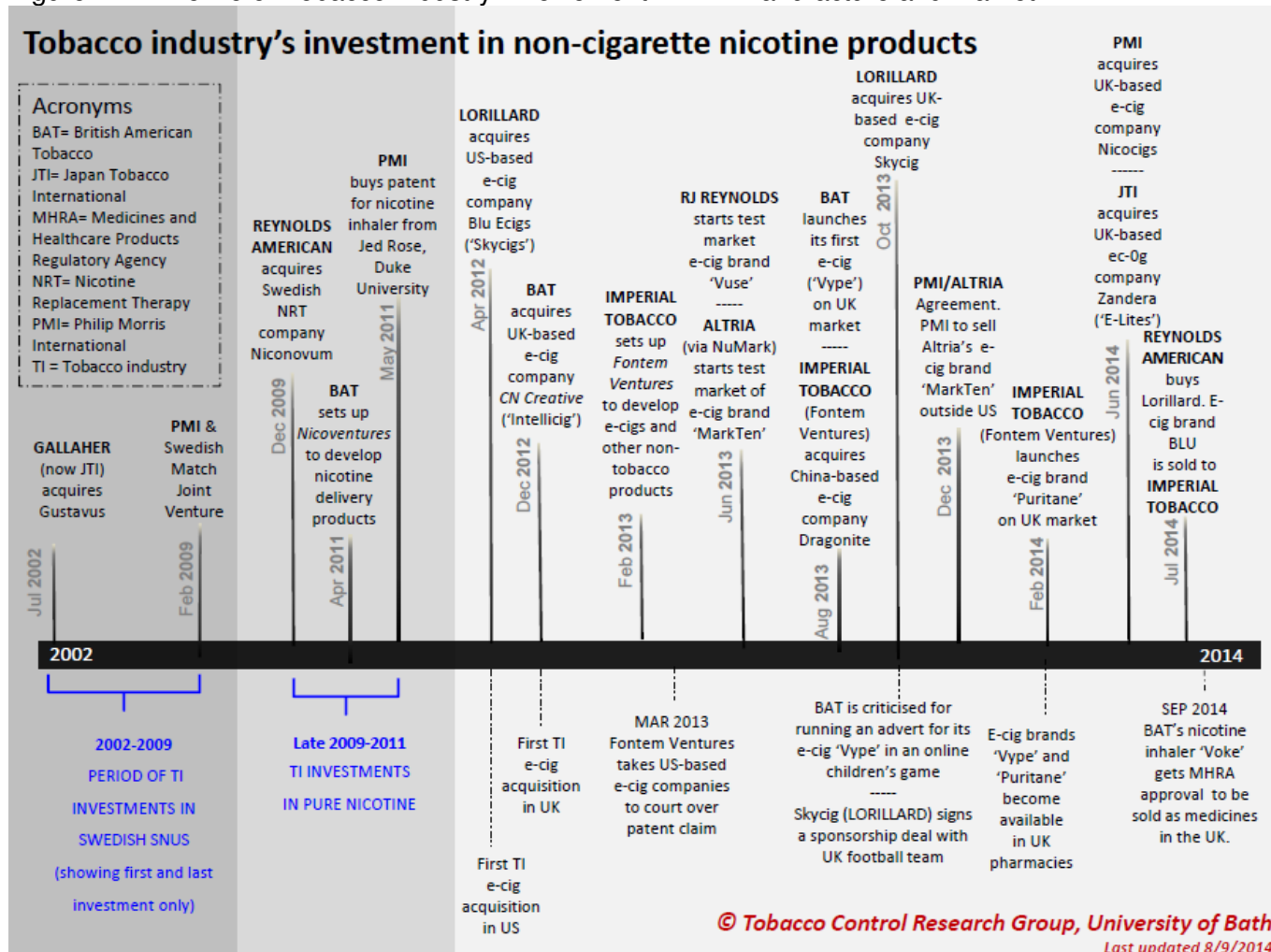
<sup>82</sup> The Grocer (2013). Grocery Retail Structure. Available at: <http://www.thegrocer.co.uk/reports-and-advice/rankings/grocery-retail-structure-2013/343572.article>

<sup>83</sup> Trading Standards Institute: Youth Access to E-Cigarettes and Associated Products

approach should decrease the risk of offending small and micro retailers becoming disproportionately affected if they offend whilst becoming familiar with the new regulations.

211. In view of the ongoing consolidation within NIP manufacturers (the majority of independent NIP manufacturers (as measured by sales) have been acquired by the established tobacco manufacturers), we believe that any effects on small or micro-manufacturer profits are small. Research by the University of Bath supports this view, shown in Figure 1.

Figure 1 – Timeline of Tobacco Industry Involvement in NIP Manufacture and Market



212. We do however recognise there may be some small and micro manufacturing businesses based in the UK who are still independently owned, although we think these represent a small proportion of the market given the ownership of the leading brands and ongoing consolidation in the market. We therefore attribute 10% of the lost manufacturer (UK) profit to small and micro businesses.

213. Similarly, distributors, by their nature, are more likely to be large firms with distribution centres, warehouses and/or a fleet of vehicles, given the high volume low margin nature of the market. We do not believe therefore that small and micro distributors are affected, but again note that they would be expected to benefit from any re-directed spending on other goods and services in the economy.

214. In summary we estimate that of the £200k EANCB identified, £170k falls on retailers, of which we expect all to be small and micro businesses. The remaining £30k we expect to fall on distribution and manufacture firms, of which £1k we attribute to small and micro manufacturers.

### **Competition Test**

215. We do not anticipate any reduction or increase in the competitiveness of the NIP manufacture, retail, or distribution industries as a result of introducing a minimum age of sale of 18.

### **Equalities Test**

216. We have conducted a separate analysis of the likely impact of this policy on all the relevant equality characteristics under the public sector equality duty. This Equalities Analysis will be conducted alongside this Impact Assessment.

### **Sustainability Test**

217. We do not anticipate any reduction or increase in the sustainability of the NIP industries by introducing a minimum age of sale, given that sales to under-18s represent a very low proportion of total sales (0.64%).

### **Environmental Test**

218. We do not anticipate any impact on the environment.