

<b>Title:</b> Tobacco Products Directive (TPD) <b>IA No:</b> 3131 <b>Lead department or agency:</b> Department of Health (DH) <b>Other departments or agencies:</b> Medicines & Healthcare Products Regulatory Agency (MHRA)	<b>Impact Assessment (IA)</b>			
	<b>Date:</b> 18 <sup>th</sup> April 2016			
	<b>Stage:</b> Final			
	<b>Source of intervention:</b> EU			
	<b>Type of measure:</b> Secondary legislation			
<b>Contact for enquiries:</b> DH Tobacco Programme				
<b>Summary: Intervention and Options</b>			<b>RPC Opinion: GREEN</b>	

**Cost of Preferred (or more likely) Option**

Total Net Present Value	Business Net Present Value	Net direct cost to business per year <small>(EANDCB in 2014 prices, 2015 present value)</small>	In scope of One-In, Three-Out	Measure qualifies as
£10,800 million	-£148 million	£16.4 million of which £0.63 million in-scope	Yes (Gold-plating only)	In

**What is the problem under consideration? Why is government intervention necessary?**  
Tobacco use remains one of the most significant challenges to public health across the United Kingdom. The Government remains concerned about the take up of smoking by young people, the difficulty that adult smokers have in quitting smoking, high levels of relapse of those smokers that do attempt to quit and the consequences for the health of others from exposure to second hand smoke (SHS). Action is required to harmonize certain aspects of tobacco control policies across the European Union and update earlier legislation to account for newly developed products. The UK is required to transpose the Tobacco Products Directive into domestic legislation by 20th May 2016.

**What are the policy objectives and the intended effects?**  
The Tobacco Products Directive was formulated with the intention to:

- Update harmonised European Union tobacco control rules which has not been done since 2001
- Introduce harmonised rules for novel tobacco products, herbals products for smoking and electronic cigarettes (e-cigarettes)
- Prevent distortion of the market as Member States consider their implementation of the global Framework Convention on Tobacco Control
- Improve the function of the internal market whilst maintaining a high level of health protection

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

Domestic legislation and enforcement provisions to implement the EU TPD must be put in place. We must also decide which optional national measures to adopt.  
Option 1: Implement the TPD at a minimum cost to business (do minimum)  
Option 2: Implement some selected optional elements of TPD (preferred option)

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** 05/2021

Does implementation go beyond minimum EU requirements?			Yes		
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> N/A		<b>Non-traded:</b> N/A

***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: Jane Ellison Date: 18<sup>th</sup> April 2016

# Summary: Analysis & Evidence Policy Option 1

**Description:** Transpose the Revised Tobacco Products Directive at a minimum cost to business

## FULL ECONOMIC ASSESSMENT

Price Base Year 2015	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £1.0 bn	High:21bn	Best Estimate: 11 bn

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			£0.47 bn
High			£4 bn
Best Estimate			£2.2bn

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

The largest cost is to the Exchequer of £2bn in lost tax revenue due to there being fewer smokers (discounted lifetime value). There are costs to the tobacco and e-cigarette industries due to measures including increased product notification requirements and relabelling requirements.

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

A reduction in the ability of tobacco companies to compete through offering products with certain characteristics (flavouring, pack size etc.). Potential loss of revenue streams from non-TPD2 compliant manufacturing equipment or additional costs of adjusting said equipment.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			£1.5bn
High			£25 bn
Best Estimate			£13 bn

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

The main benefit is the expected health gain due to there being fewer smokers, valued at £13bn (discounted lifetime value). There is a benefit to the tobacco industry of £0.66 million over the assessment period due to reduced TNCO labelling requirements.

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

Reduced smoking prevalence will provide benefits to productivity, reduced fire risk and reduced littering. The provisions on e-cigarettes will improve safety and standards in the industry. There may be a benefit to the tobacco industry due to the introduction of a EU central portal for submitting information.

<b>Key assumptions/sensitivities/risks</b>	<b>Discount rate (%)</b>	1.5/3.5
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Assumptions / sensitivities: The estimated impact on smoking consumption.  
Discount rate: 1½ % for health impacts denominated in life years and 3½% for monetised impacts.

## BUSINESS ASSESSMENT (Option 1)

<b>Direct impact on business (Equivalent Annual) £m:</b>	<b>In scope of OITO?</b>	<b>Measure qualifies as</b>
Costs: 15.8      Benefits: 0.1      Net: -15.7	No	N/A

## Summary: Analysis & Evidence Policy Option 2

**Description:** Transpose the Revised TPD taking account of additional flexibilities

### FULL ECONOMIC ASSESSMENT

Price Base Year 2015	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 1.0 bn	High: 21bn	Best Estimate: 10.8 bn

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			0.49 bn
High			4 bn
Best Estimate			2.2 bn

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

As Option 1 with two main differences. Firstly, the tobacco industry faces fees equivalent to the cost to Government for the cost of processing and storing data, peer reviewing additive studies and verifying TNCO measurements. Secondly, the tobacco industry faces additional costs due to the requirement for cigars and pipe tobacco to fully comply with the labelling requirements of TPD2 (excluding individually wrapped cigars & cigarillos and cigars weighing above 3g).

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

As Option 1

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			1.5 bn
High			25 bn
Best Estimate			13 bn

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

As Option 1 plus:

The Government receives revenue through charging the tobacco industry for the cost of processing and storing data, peer reviewing additive studies and verifying TNCO measurements.

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

As Option 1 plus:

There is a possible public health benefit in requiring cigars and pipe tobacco to fully comply with the labelling requirements of TPD2 (excluding individually wrapped cigars & cigarillos and cigars weighing above 3g).

Key assumptions/sensitivities/risks Discount rate (%) 1.5/3.5

Key assumptions / sensitivities / risks / discount rate are as identified under Option 1

### BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies
Costs:16.4	Benefits: 0.1	Net:-16.4 (-0.63 in)	Yes (marginal only)	IN

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# Evidence Base

## Background

1. The European Commission published a proposed revision to the 2001 Tobacco Products Directive (Directive 2001/37/EC) (henceforth referred to as TPD1) on 19 December 2012, the revised Tobacco Products Directive (2014/40/EU) (henceforth referred to as TPD2). Domestically, the UK Government's position on this proposal was secured via a write-round to the European Affairs Committee (EAC) and the devolved administrations in spring 2013. At a meeting of the EU Health Council on 21 June 2013, Member States 'voted' (through signalling support rather than via a formal vote) to agree a General Approach to the Directive, following lengthy and complex negotiations over six months. The UK Government supported the General Approach to the Directive although inevitable compromises to some of the UK's preferred positions were made to help to achieve agreement.
2. On 18 December 2013 EU Member States and the European Parliament approved additions and amendments to the initial proposal and the European Parliament and the Council formally approved the TPD2 in early 2014.
3. The TPD2 was published in the Official Journal of the European Union on 29 April 2014. This new directive will apply from 20 May 2016. EU Member States must have transposed the TPD2 into domestic law by this time.
4. The TPD2 contains several flexibilities that Member States can opt to take up and these flexibilities are considered in this final stage impact assessment.

## The problem under consideration

5. Tobacco use remains one of the most significant challenges to public health across the United Kingdom and Europe. Smoking is a leading cause of preventable morbidity and premature death, accounting for over 100,000 deaths in the UK each year<sup>1</sup>. One out of two long term smokers will die of a smoking-related disease<sup>2</sup>. While rates of smoking have declined over past decades, in recent years the rate of this decline has slowed. The Government remains concerned about the take up of smoking by young people, the difficulty that adult smokers have in quitting smoking, high levels of relapse of those smokers that do attempt to quit and the consequences for the health of others from exposure to second hand smoke (SHS). Tobacco use also contributes significantly to health inequalities.
6. While smoking prevalence has fallen steadily since its peak in the mid-20th century, smoking rates are today higher than average among particular groups meaning that smoking has emerged as one of the most significant contributors to health inequalities, accounting for approximately half of the difference in life expectancy between the lowest and highest income groups<sup>3</sup>. Smoking is most common among those who earn the least, and least common among those who earn the most. In 2014, smoking prevalence was more than twice as high among people in routine and manual occupations compared with managerial and professional occupations. Smoking rates are high in particular ethnic and social groups. Smoking rates among people with mental health problems are also significantly higher than among the general population<sup>4</sup>.

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<sup>1</sup> Action on Smoking and Health. Smoking Statistics – Illness and Death. November 2014.

<sup>2</sup> Doll, R, Peto, R, Boreham, J., Sutherland, I "Mortality in relation to smoking: 50 years' observations on male British doctors," British Medical Journal 2004, vol 328, pp. 1519–27.

<sup>3</sup> Marmot, M. et al. (2010). Fair Society, Healthy Lives: Strategic review of health inequalities in England post-2010. Marmot review secretariat, London.

<sup>4</sup> ONS Integrated Household Survey, 2014

7. Smoking rates are today broadly the same among men and women. Around two-thirds of smokers say that they started smoking regularly before the age of 18. In 2009, the Public Health Research Consortium (PHRC) published a review of young people and smoking in England. The review found that the onset of smoking is a function of individual factors (e.g. self-image), social and community factors (e.g. family circumstances) and societal factors (e.g. tobacco marketing)<sup>5</sup>.
8. Tobacco control policy across the UK aims to reduce youth uptake of smoking, and to encourage and support quitting amongst smokers who wish to quit; implementation of the TPD2 is expected to have a positive impact on both.
9. The TPD2 seeks to improve the functioning of the internal market and achieve a high standard of health by regulating tobacco products in a way that reflects its characteristics as an addictive product with proven negative health consequences linked to its consumption. As such the TPD2 aims to achieve a harmonised approach to the regulation of ingredients to reduce obstacles to smooth functioning of the internal market and ensure that ingredients and product presentation do not encourage or facilitate smoking uptake by young people and that consumers are able to take informed decisions about tobacco and related products.
10. The TPD2 focuses on initiation of tobacco consumption, in particular by young people, taking into account that 70% of smokers in Europe start before the age of 18 and 94% before the age of 25 years<sup>6</sup>. This picture is reflected in the UK where it is estimated that each year around 207,000 children start smoking<sup>7</sup> and most adult smokers take up smoking before the age of 20 with 40% taking up smoking regularly before the age of 16<sup>8</sup>.
11. Smoking initiation is associated with a wide range of factors including: parental and sibling smoking, the ease of obtaining cigarettes, smoking by friends and peer group members, socioeconomic status, exposure to tobacco marketing, and depictions of smoking in films, television and other media<sup>9</sup>. The TPD2 contains provisions to control the ingredients of tobacco products to reduce their palatability to minors, among other things, and strengthen existing harmonised labelling rules to better inform consumers about the health risks of tobacco products.
12. It is recognised that peer pressure and familial smoking patterns are most responsible for take up of tobacco consumption by young people. However, there is evidence to suggest that the appeal of flavoured tobacco does play a role in some individuals' decisions to start smoking. Eurobarometer data reports that 4% of UK current and ex-smokers identify mentholated cigarettes as one of the 3 main reasons they started smoking, with a further 1% identifying 'sweet, fruity or spicy' flavouring.<sup>10</sup>
13. As well as potentially encouraging smoking uptake, menthol cigarettes may currently mislead some consumers over their health effects. 11% of UK individuals surveyed in 2012 thought that menthol brands were less harmful than others. This could result in people underestimating the health cost associated with smoking and over-consuming relative to their true preferences.

## Rationale for intervention

14. Government (and EU) intervention is justified in several ways:

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<sup>5</sup> Public Health Research Consortium (2009). A Review of Young People and Smoking in England. PHRC, York

<sup>6</sup> Eurobarometer 2012

<sup>7</sup> Hopkinson, NS., Lester-George, A., Ormiston-Smith, N., Cox, A. & Arnott, D. Child uptake of smoking by area across the UK. Thorax 2013. doi:10.1136/thoraxjnl-2013-204379

<sup>8</sup> Office for National Statistics. General Lifestyle Survey Overview: A report on the 2011 General Lifestyle Survey. 2013.

<sup>9</sup> Passive smoking and children. Royal College of Physicians, London, 2010 (pdf).

<sup>10</sup> Eurobarometer, Attitudes of Europeans towards tobacco and electronic cigarettes: [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_429\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_429_en.pdf)

- To correct an information asymmetry by regulating to ensure that governments have access to more information about the products in scope of the TPD2 and to make more information publicly available to better inform consumer choice.
- To harmonise the EU market such that Member States cannot gain a competitive advantage by undermining public health benefits
- To regulate products which especially appeal to children, who are unable to make a fully informed choice about consuming a product which creates a future addiction.
- To reduce obstacles to trade in tobacco and related products within the EU by reducing differences between the regulatory regimes in different EU Member States.

## **Policy objective**

15. The TPD2 was formulated with the intention to improve the functioning of the internal market and improve health protection by:
- Updating harmonised EU tobacco control rules not done since 2001
  - Introducing harmonised rules for tobacco related products including herbal products for smoking, novel tobacco products (NTPs) and electronic cigarettes
  - Preventing distortion of the market as Member States consider their implementation of the global Framework Convention on Tobacco Control
  - Maintaining a high level of health protection

## ***Improve the functioning of the internal market***

16. The TPD2 will update already harmonised areas, thereby overcoming the obstacles for the UK in bringing national legislation in line with new market, scientific and international developments. It will also address product related measures not yet covered by the TPD1 insofar as heterogeneous development in Member States has led to, or is likely to lead to, fragmentation of the internal market. Finally, the proposal seeks to ensure that the provisions of the Directive are not circumvented by placing on the market of products not compliant with the TPD2. The proposal will also ensure a harmonised implementation of international obligations following from the Framework Convention on Tobacco Control (FCTC), which is binding for the EU and all Member States, and a consistent approach to non-binding FCTC commitments, if there is a risk of diverging national transposition.

## ***Health protection***

17. A high level of health protection has been considered in developing the TPD2. Over time the proposed measures are expected to impact on peoples' awareness of the risks associated with tobacco products, which in turn will lead to a change in behaviour. Fewer young people will start smoking and some adults will successfully quit smoking. This is expected to lead to an overall reduction of smoking consumption/prevalence.
18. The TPD2 seeks to regulate tobacco products in a way that reflects its characteristics as an addictive product with proven negative health consequences linked to its consumption (including mouth, throat and lung cancer, cardiovascular diseases including heart attacks, strokes, clogged arteries, increased risk of blindness, impotence, lower fertility and impacts on the unborn child).

19. Current legislation results in a framework that may confuse or mislead consumers over the health risks of certain products. The lack of mandated health warnings for herbal products for smoking, alongside the 'natural' style advertising for these products may lead people to underestimate their health risks. The TPD2 aims to create a comprehensive framework that encapsulates smoked and smokeless tobacco, other smoked products and electronic cigarettes & refill containers. The TPD2 removes the requirement to provide information on levels of tar, nicotine and carbon monoxide on packs, which some consumers are using as a relative-risk tool.
20. The revision focuses on initiation of tobacco consumption, in particular by young people, taking into account that the majority of adults start smoking before the age of 20 years. Tobacco control policy across the UK aims to reduce youth uptake of smoking and to encourage and support quitting amongst smokers who wish to quit; implementation of the TPD2 is expected to have a positive impact on both.

***Decrease in illicit trade***

21. The measures in the TPD2 dealing with cross-border distance sales and traceability and security features are expected to contribute to a drop in consumption, in particular in the illicit segment of the market. Part of this demand would be expected to return to the legal supply chain, which is more expensive and therefore may encourage some consumers to not start smoking, to smoke less or to quit. This effect will be most noticeable amongst groups who are more sensitive to changes in prices, such as young people and those on low incomes<sup>11</sup> where the burden of ill health due to tobacco smoking currently falls most heavily. Moreover, consumers are better informed of the health risks of tobacco products and other products for smoking (e.g. herbal products) because they carry the information required by the TPD2.

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<sup>11</sup> The Demand for Cigarettes & Other Tobacco Products, WHO  
[http://www.who.int/tobacco/economics/meetings/dublin\\_demand\\_for\\_tob\\_feb2012.pdf](http://www.who.int/tobacco/economics/meetings/dublin_demand_for_tob_feb2012.pdf)

## **Counterfactual (Option 0)**

22. As an EU directive, the TPD2 must be transposed into domestic legislation by the 20<sup>th</sup> May 2016. However, in order to assess the impacts of this policy, a counterfactual needs to be established. In the case of EU legislation, the agreed counterfactual for Impact Assessment purposes is a state in which the EU had not passed legislation.

## Implementing TPD2 at minimum regulatory burden (Option 1)

23. Option 1 constitutes the implementation of the TPD2 consistent with a minimal overall impact on business. Implementation of the TPD2 is required by 20 May 2016, except where specific extensions have been allowed. This involves<sup>12</sup>:

- Ingredients and emissions
  - Maximum emission levels for tar, nicotine, carbon monoxide (TNCO) and other yields (Article 3)
  - Measurement methods (Article 4)
  - Reporting of ingredients and emissions (Article 5)
  - Priority list of additives and enhanced reporting obligations (Article 6)
  - Regulation of ingredients (Article 7)
- Labelling and Packaging
  - General provisions (Article 8)
  - General warning and information messages on tobacco products for smoking (Article 9)
  - Combined health warnings for tobacco products for smoking (Article 10)
  - Labelling of tobacco products for smoking other than factory made cigarettes, hand-rolled tobacco and waterpipe tobacco (Article 11)
  - Labelling of smokeless tobacco products (Article 12)
  - Product presentation (Article 13)
  - Appearance and content of unit packs (Article 14)
- Track and Trace (Illicit trade)
  - Traceability (Article 15)
  - Security feature (Article 16)
- Tobacco for oral use, cross border-distance sales of tobacco products and novel tobacco products
  - Tobacco for oral use (Article 17)
  - Cross-border distance sales of tobacco products (Article 18)
  - Notification of novel tobacco products (Article 19)
- Electronic cigarettes and herbal products for smoking
  - Electronic cigarettes (Article 20)
  - Herbal products for smoking (Article 21)
  - Reporting of ingredients of herbal products for smoking (Article 22)
- Transitional provision (Article 30)

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<sup>12</sup> The description of the TPD2 contained in this IA is not a full and complete account of the Directive or the UK Government's approach its transposition. This description is intended to highlight requirements that are most likely to result in costs and benefits to businesses, individuals and the Government. The Directive should be used for determining specific legal requirements.

24. Under this option, where given any flexibility on implementation, the UK will choose the option least burdensome to business. For the purposes of this IA the following options are considered least burdensome to industry:
- To adopt transitional periods to allow for the sell through of old stock at retail level not in compliance with the TPD2 including tobacco products, herbal products and e-cigarettes until May 2017 (the latest allowed by the TPD2).
  - To exempt all tobacco products other than cigarettes, hand rolling tobacco (HRT) and waterpipe tobacco from carrying the information message and combined health warning and require them to carry a text-only warning instead.
  - We consider the choice of one written health warning over another (a choice of two options for both tobacco products and e-cigarettes) is cost neutral and either would be a lowest cost option.
  - To implement a notification system versus an authorisation system of novel tobacco products.
  - To adopt a registration scheme for companies wishing to sell to consumers outside of the UK and require them to adopt an age verification scheme rather than ban sales of tobacco products, e-cigarettes and refills that are sold to consumers across UK borders.
  - Not to require peer review of the comprehensive scientific studies into certain additives that manufacturers will be required to carry out.
  - Not to charge the industry directly for the proportionate cost of the following services:
    - The verification of TNCO levels in cigarettes
    - The receiving, storing, handling, analysis and publishing information on ingredients and emissions of tobacco products
    - If the UK chooses to implement an authorisation system for NTPs then a fee can be charged for that authorisation (Option 1 would implement a notification scheme, so this charge is not relevant)
    - The peer review of scientific studies on additives undertaken by the tobacco industry.
  - Charging the e-cigarette industry for the cost of receiving, storing, handling and analysing information submitted is considered to be an equally least burdensome option for industry. This is because this will be handled by the Medicines & Healthcare Products Regulatory Authority (MHRA), an industry funded body. Therefore industry will incur the cost regardless of whether there is a direct charging system.

**Table 1:** TPD2 and additional provisions with an impact on Business/Central Government/Enforcement Community

<b>TPD2 Article</b>	<b>Additional provisions with an impact on Business/Central Government/Enforcement/Community</b>
<i>4 - Measurement methods</i>	Member States will be required to notify the Commission of any measurement methods they use for emissions from cigarettes other than TNCO emissions and for emissions from tobacco products other than cigarettes. The UK does not currently require testing of cigarettes beyond TNCO emissions.
<i>5 - Reporting of ingredients and emissions</i>	Manufacturers and importers of tobacco products will be required to provide additional information on ingredients and emissions as well as submit available market research studies and data on sales volumes on a yearly basis.  Member States (MS) will be required to publish a wider range of data on ingredients and emissions.
<i>6 - Priority list of additives and enhanced reporting obligations</i>	Enhanced reporting obligations for manufacturers will apply to certain additives contained in cigarettes and hand-rolled tobacco that are included in a priority list of 15 additives (to be announced in an Implementing Act); if manufacturers have products containing an additive in this list they must carry out studies examining toxicity, addictiveness, flavour etc.
<i>7 - Regulation of ingredients</i>	The placing on the market of cigarettes and HRT with a characterising flavour and tobacco products with certain additives will be prohibited.
<i>8 - General provisions</i>	There are changes to the general provisions relating to the position, size, and formatting of the written health warnings.
<i>9 - General warning and information messages on tobacco products for smoking</i>	Changes to the general warning and information messages on tobacco products for smoking relating to their position, wording and surface coverage.  Further requirements regarding the precise positioning of the general warning and information message on HRT are defined in Commission Implementing Decision (EU) 2015/1735.
<i>10 - Combined health warnings for tobacco products for smoking</i>	Graphical warnings will be mandatory and must appear on the front and back of the pack and increase in size to 65% of each surface.  Further requirements regarding the layout, design and shape of graphical health warnings are defined by the Commission Implementing Acts Decision (EU) 2015/1842 of 9 <sup>th</sup> October 2015.
<i>11 - Labelling of tobacco products for smoking other than cigarettes, hand-rolled tobacco and waterpipe tobacco</i>	Provides the possibility for MS to exempt tobacco products for smoking other than cigarettes, HRT and waterpipe tobacco, from some of the labelling requirements in articles 9 and 10 and to impose an alternative regime.
<i>12 - Labelling of smokeless tobacco products</i>	Specific requirements regarding the position, size and format of health warnings for smokeless products.
<i>13 - Product presentation</i>	Whilst the text implementing this Article was included in the Standardised Packaging Legislation (SPoT) this Impact Assessment includes the costs and benefits accruing from the TPD2 provisions. The SPoT Impact Assessment covers the additional costs of standardised packaging over and above the TPD2 provisions which include

	restrictions on misleading elements/features of labels, for example that the product has health or lifestyle benefits and must not refer to taste, smell or flavourings.
<i>14 - Appearance and content of unit packets</i>	Whilst the text implementing this Article was included in SPoT legislation, this Impact Assessment includes the costs and benefits accruing from the TPD2 provisions. The SPoT Impact Assessment covers the additional costs of standardised packaging over and above the TPD2 provisions which include prescribing shape, closure mechanisms and materials that can be used for packaging materials. TPD2 also imposes minimum content levels e.g. 20 cigarettes or 30g of hand-rolled tobacco.
<i>15 - Traceability</i>	Enhanced traceability system. Commission Implementing Act to further set out specification for the system to be adopted and detail of indelible unique identifier what that identifier must reveal. This is not covered in this IA and will be assessed by HMRC when the full detail is known.
<i>16 - Security feature</i>	All unit packets of tobacco products which are placed on the market must carry a tamper proof security feature, composed of visible and invisible elements. Commission to define in Implementing Act technical standards for security feature including any need for rotation. This is not covered in this IA and will be assessed by HMRC when the full detail is known.
<i>18 - Cross-border distance sales of tobacco products</i>	Provisions that allow MS to ban cross border distance sales or to introduce and operate a registration scheme and age verification requirement for cross border distance sale of tobacco products, e-cigarettes and refills.
<i>19 - Notification of novel tobacco products</i>	Manufacturers and importers of novel tobacco products must submit a notification in electronic form accompanied by a detailed description of the novel tobacco product, along with studies on its addictiveness etc.  Option for MS to introduce an authorisation scheme.
<i>20 - Electronic cigarettes</i>	Requirements relating to the composition, labelling, advertising and reporting of e-cigarettes and refills.  Further requirements regarding the common format for notification of ingredients and emissions data and technical specifications for refill mechanisms are to be established by the Commission in Implementing Acts.  MS required to make certain information available to the public, other MS and the Commission.
<i>21 - Herbal products for smoking</i>	Requirements for herbal products for smoking including health warnings and their position.
<i>22 - Reporting of ingredients of herbal products for smoking</i>	Manufacturers and importers of herbal products for smoking must submit to their competent authorities a list of all ingredients used and quantities thereof.  MS to make available this information to the public.

25. Maximum levels of tar, nicotine and carbon monoxide were agreed under the TPD1. The TPD2 imposes the same maximum levels, keeping this requirement unchanged. The revised Tobacco Products Directive provides the EU with the power to adopt delegated acts to adapt the currently agreed maximum levels, taking into account scientific developments.
26. The TPD1 requires TNCO emissions to be verified in laboratories which are approved and monitored by the competent authorities of Member States. The TPD2 imposes an additional requirement over TPD1 that these laboratories shall not be owned or controlled directly or indirectly by the tobacco industry. This requirement is already met by the UK, requiring no changes as a result of this article.
27. Tobacco manufacturers and importers are currently required to report product ingredients and emissions to Member State competent authorities on an annual basis. The TPD2 removes this burden, instead requiring a one-off reporting of existing products and new or modified products prior to placing on the market.
28. The TPD2 imposes an additional reporting requirement for information on emission levels other than TNCO – for cigarettes and emissions from other tobacco products where these are available to the producer.
29. In addition to ingredient and emission data, manufacturers will be required to submit, where they are available, internal and external studies on market research and summary results from market surveys.
30. Manufacturers and importers will be required to provide data on sales volumes per brand and variant on an annual basis.
31. The Commission has consulted Member States, businesses and other interested parties on a draft implementing act establishing the format of notification of ingredients and emissions data. The draft act mandates the use of a central EU portal, for the submission of notification data for tobacco products and e-cigarettes. The implementing act expected to be adopted and published in the Official Journal of the European Union by the end of 2015.
32. The data provided under this act shall be made publically available on a website. Member States shall take the need to protect trade secrets into account.
33. Further reporting requirements will be imposed on a specific set of commonly used or potentially hazardous additives. This list is yet to be determined, but will be agreed and adopted by 20 May 2016 and shall contain at least 15 additives.
34. For these additives, manufacturers and importers of cigarettes and HRT tobacco will be required to carry out comprehensive studies assessing toxicological, flavouring, nicotine uptake and carcinogenic, mutagenic and reprotoxic effects. The results of these studies must be reported to the relevant competent authority within 18 months of the additive being added to the priority list.
35. Small and Medium Enterprises (SMEs) are exempted from the obligations of this article if a report on an additive is prepared by another manufacturer or importer and a list of such additives will be published by the Commission to inform businesses where this applies..
36. The TPD2 requires Member States to prohibit the placing on the market of cigarettes and HRT with a characterising flavour, or any tobacco product that contains the following additives:
  - Vitamins or other additives that imply a health benefit
  - Caffeine, taurine or other stimulant compounds associated with energy and vitality
  - Those with colouring properties for emission

- Those that facilitate inhalation or nicotine uptake
  - Those that have carcinogenic, mutagenic and reprotoxic properties in unburnt form.
37. Member states must also prohibit the placing on the market of any cigarette and HRT product components (filters, papers, capsules etc.) that contain flavourings.
38. The provisions of this article shall only apply from 20 May 2020 for tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category. Based on current market data, this temporary exemption only applies to mentholated cigarettes. Member States are required to notify the Commission when they deem a product to have a characterising flavour. The Commission is consulting Member States, businesses and other interested parties on further Implementing Acts which established the procedure on how characterising flavours should be determined and the setting up of an EU advisory panel. The implementing acts are not expected to be adopted until end of 2015.
39. The TPD2 reinforces and expands upon the labelling requirements of 2001/37/EC. These changes include the following requirements:
- Unit packets must contain the information message ‘Tobacco smoke contains over 70 substances known to cause cancer’ and a general warning “smoking kills – quit now” and a graphical warning
  - Mandating of a combined health warning (consisting of a text and picture warning and smoking cessation message) and an increase in the size of combined health warnings to 65% of the front and back surfaces
  - Minimum size requirement for general warnings, information messages and combined health warnings
  - Health warnings must remain intact upon opening packets, except in the case of flip-top lids (subject to graphical integrity and clarity)
  - Combined health warnings must be rotated on an annual basis. Warnings are grouped into 3 sets, and each set shall be used in a given year
40. Further requirements regarding the precise positioning of the general warning and information message on HRT and on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking are defined in Commission Implementing Decisions supplementing the TPD2.
41. The TPD2 allows Member States to choose to provide for less onerous labelling requirements for tobacco products for smoking other than cigarettes, HRT and waterpipe tobacco. These lesser requirements are similar to those of the TPD1. If the UK Government took this option up, the lesser labelling regime would apply to all cigars, cigarillos, pipe tobacco and tobacco blunts. The TPD2 would mandate that the general and text warnings on those products would still be required to appear on the two most visible surfaces of the unit packaging. For products in packets with hinged lids the second most visible surface is defined as the one that becomes visible on opening. These warnings will also be required for individually wrapped (single) cigars which are currently exempt from labelling in the UK. Under Option 1 these less onerous requirements will be applied to all tobacco products for smoking other than cigarettes, HRT and waterpipe tobacco.
42. Requirements for smokeless tobacco products remain largely unchanged. Whilst the surface coverage of warning messages remains at 30% (for a single official language country), there will be a new requirement for warnings to appear on the two largest surfaces of unit products rather than one as previously required.
43. The TPD2 restricts certain marketing claims and features as part of tobacco product presentation. These include messages that:

- Promote a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions. Labels may not contain any information about the nicotine, tar or carbon monoxide of the product
  - Suggest that a particular product is less harmful than others or aims to reduce the effect of some harmful component of smoke, or has vitalising, energetic, healing, rejuvenating, natural / organic properties or other health or lifestyle benefits.
  - Refer to taste, smell, flavouring or other additives or absence thereof
  - Resemble a food or cosmetic product
  - Suggest improved biodegradability or other environmental benefits
  - Suggest economic advantages by providing discounts.
44. Unit packets of cigarettes will be required to have a cuboid shape; unit packets of HRT either cuboid, cylindrical or pouch. Cigarette packs may contain no fewer than 20 cigarettes, and HRT packets must contain at least 30g of tobacco.
45. Unit packets of cigarettes may not be re-sealable except for flip-top and shoulder box hinged lids.
46. Member States will be required to ensure that all tobacco products must be marked by a unique identifier. This feature shall be used in conjunction with tracking equipment to monitor the movement of products. This requirement will apply to cigarettes and HRT from 20 May 2019, and all other tobacco products from 20 May 2024. In addition to the unique identifier, all products will require tamperproof security features.
47. Track and trace systems and the provision of security features are not assessed as part of this Impact Assessment, as these are yet to be set out by the Commission in relevant Implementing and Delegated Acts. HMRC will be responsible for the implementation of Articles 15 and 16 and will conduct an independent Impact Assessment once further detail of the required scheme and technical specifications for security features is available.
48. Tobacco for oral use remains banned without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.
49. The TPD2 gives Member States two options in relation to cross-border distance sales to consumers – either to prohibit such sales or to require sellers to register with the competent authorities in Member States where actual or potential customers are located. This registration requires the reporting of minimal amounts of information about the company. Sellers must receive receipt of confirmation of registering prior to placing items for sale. If a registration scheme is implemented, retail outlets must implement an age verification system to ensure that purchasers of tobacco products are above the minimum legal age for consumption in the Member State of destination. The Directive defines ‘age verification system’ as ‘a computing system that unambiguously confirms the consumer’s age electronically in accordance with national provisions’.
50. Member states shall require manufacturers and importers of novel tobacco products to submit a notification to the competent authority 6 months prior to the product being placed on the market. This notification should contain information as required under Article 5, and any further available information on toxicological and addictive effects, consumer studies and market research, and the additional information indicated at Article 19.
51. The introductory text to paragraph 2 of Article 20 on electronic cigarettes reads:

*“Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. The notification shall be submitted in electronic form six months before the intended placing on the market... A new notification shall be submitted for each substantial modification of the product.”*

52. The Directive’s text that specifies the information that needs to be included in each notification can be found under Article 20 (2). Along with the information required for tobacco and herbal products, the EC will adopt an Implementing Act to specify the form in which information should be notified to competent authorities. The format for the submission of information under Article 20(2) will be outlined by the Commission in an implementing – as outlined in paragraph 27.
53. Member States are required to restrict the volume and strength of nicotine containing liquids. Dedicated refill containers may not exceed 10ml; disposable e-cigarettes, single use cartridges or tanks may not exceed 2ml. Nicotine containing liquid may not contain nicotine in excess of 20mg/ml, additives listed under Article 7(6), ingredients must be of high quality and (other than nicotine) must not pose a risk to human health. E-cigarettes must deliver nicotine doses at consistent levels under normal use, and e-cigarettes and refill containers must be child and tamper proof. The EC will adopt an Implementing Act setting out the technical standards for the refill mechanism of these products.
54. Manufacturers are required to provide an information leaflet with unit packets of e-cigarettes and refill containers. These leaflets must contain information on toxicity and addictiveness and a number of other pieces of information. Unit packets must display information on ingredients and one of two health warnings to be decided by the Member State (see Option 2) among other prohibitions and requirements.
55. The TPD2 requires Member States to prohibit all commercial communications (advertisement, product placement etc.) of e-cigarettes and refill containers in information society services, in the press and other printed publications, (except in trade publications and publications which are printed and published in third countries, where those publications are not principally intended for the European Union market) on the radio, on TV as well as certain types of sponsorship. The Directive does not cover rules on so called “domestic” advertising (such as billboards).
56. The UK Government shall publish the information received in e-cigarette notifications on a website, having taken the need to protect trade secrets into account.
57. Manufacturers and importers of e-cigarettes are required to submit annual data on sales volumes, consumer preferences, modes of sale and summaries of any market surveys undertaken.
58. Manufacturers, importers and distributors will also be required to maintain a system for collecting information on the potential adverse effects on human health of e-cigarettes and refill containers. Businesses will be required to take corrective action where electronic cigarettes or refill containers, are not safe or are not of good quality, to withdraw or to recall them, as appropriate. They will also be required to inform the central competent authority giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action. The central competent authority also has powers to take appropriate provisional measures to deal with any e-cigarettes or refill containers that pose a serious risk to human health. The Commission will be notified and must determine whether the measures taken are justified and whether harmonised measures are required (where prohibitions apply in at least three Member States).
59. Member States may also request additional information from the economic operators, for example on the safety and quality of the product or any adverse effects of e-cigarettes or refill containers.

60. Herbal products for smoking were not covered by the TPD1. The TPD2 would require the inclusion of health warnings on unit packaging, compliant with Article 9 and covering at least 30% of the surface area of the unit pack in countries with one official language.
61. Herbal products for smoking must also be compliant with parts of Article 13 on how products can be presented and may not make claims to be free of additives or flavouring.
62. Member States shall require all manufacturers and importers of herbal products for smoking to submit lists of product ingredients to the central competent authority.
63. Member States shall make the information submitted by manufacturers of herbal products for smoking and e-cigarettes publically available on a website.
64. The TPD2 offers Member States the option to allow products that are compliant with the TPD1 and are manufactured prior to 20 May 2016 to be sold until 20 May 2017.

## Implementing TPD2 with additional flexibilities (Option 2)

65. With regards to the flexibilities available in transposing the TPD2, having considered the responses to the consultation, the Government intends to:
- Adopt transition periods to allow the sell through of old stock (tobacco products, e-cigarettes and herbal products for smoking)(unchanged from Option 1)
  - Adopt less onerous labelling requirements for individually wrapped cigars and cigarillos rather than all tobacco products other than cigarettes HRT and waterpipe tobacco.
  - Adopt less onerous labelling requirements for cigars weighing greater than 3g.
  - Use “Smoking kills – quit now” as the text warning message (considered cost neutral)
  - Use “This product contains nicotine which is a highly addictive substance.” as the text warning message on e-cigarettes and refill containers (considered cost neutral)
  - Adopt measures that would allow the Government to obtain peer reviews on tobacco industry’s studies and recoup the cost of doing so from the industry
  - Adopt a notification scheme rather than an authorisation scheme for novel tobacco products (unchanged from Option 1)
  - Introduce a registration system for cross border distance sales of tobacco products and e-cigarettes with an age verification requirement rather than ban such sales (unchanged from Option 1)
  - Charge the tobacco & e-cigarette industries proportionate fees to recover costs associated with TPD2 activities
66. Option 2 therefore assesses the costs and benefits under this implementation.

## Assessment of Impact of Option 1

### Prevalence impact

68. The benefits of this policy primarily come from the expected reduction in smoking prevalence. The European Commission Impact Assessment (referred to as the EU IA from here on) on the TPD2 estimated that there would be a reduction in tobacco consumption of 1.7-2.6% across the EU. This assumption is deemed to be in line with the experiences of other tobacco control agencies that have implemented comparable measures.<sup>13</sup> Figure 1 shows how the different elements of TPD2 are expected to contribute to this overall decrease.

Figure 1: Tentative contributions of individual policy areas<sup>14</sup> to the projected decrease of cigarette/HRT consumption

Policy area		Foreseen contribution to the decrease in %
Scope	(STP)	0.2-0.3
	NCP	
	(Herbal)	
Packaging & Labelling		1-1.5
Ingredients		0.5-0.8
<b>TOTAL</b>		<b>1.7-2.6%</b>
Cross-border distance sales + Illicit trade		Additional decrease of consumption, however not in the legal supply chain. (Decreases in illicit consumption could mitigate the decrease in the legal chain).

69. The UK however has more tobacco control measures than many other countries, notably requiring picture warnings for unit packets of cigarettes (since 2009) and other tobacco products (since 2010). It is likely, therefore, to have already experienced some of the reduction in smoking prevalence associated with visual warnings (although the UK's implementation of graphical warnings was only on one side of tobacco product packaging compared to the TPD2's two-sided requirement and the label is a smaller size).
70. The TPD2 as assessed here also differs slightly from that assessed in the EU TPD2 IA. The EU IA assumed warnings would cover 75% of packets and that slim cigarettes would be banned, whilst the TPD2 adopted will have warning coverage reduced to 65% and no ban on slim cigarettes.
71. As such, we expect the reduction in consumption due to packaging & labelling to be at the lower end of the expected range, i.e. 1%. This leads to an overall expected decrease of 1.7%-2.1%, from which the central figure of 1.9% is taken. This figure is consistent with that used in the Impact Assessment for Standardised Packaging of Tobacco Products<sup>15</sup> and suggests that, from May 2016, tobacco prevalence would decrease by 0.36 percentage points<sup>16 17</sup> due to TPD2 (assuming that consumption is linearly related to prevalence).

<sup>13</sup> Commission Staff Working Document – Impact Assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and tobacco related products, 2012 – Section 5.7

<sup>14</sup> STP refers to Smokeless Tobacco Products, NCP to Nicotine Containing Products

<sup>15</sup> Standardised Packaging of Tobacco Impact Assessment, <https://www.gov.uk/government/publications/impact-assessment-opinion-standardised-packaging-of-tobacco-products-final>

<sup>16</sup> 1.9% of expected prevalence of 19.0% in 2016

72. The EU IA assumes that the decrease in consumption is achieved evenly over 5 years. However when this was written, it was expected that all parts of TPD2 would come into force simultaneously in 2016. The TPD2 as adopted includes a transition period for menthol cigarettes, meaning the ban will only apply from 2020 and we therefore adjust the path of prevalence reduction accordingly, delaying some of the impact. It is assumed that banning menthols contributes 0.5% to the overall reduction, the lower end of the estimated impact of ingredients<sup>18</sup>. We therefore calculate that 26% (0.5/1.9) of the reduction in prevalence only occurs from 2020.
73. This is a change which has been made since the consultation after the issue was brought to our attention. Whilst it has only a very small impact on the overall number of fewer smokers<sup>19</sup>, it does make a difference to the subsequent cost and benefit estimates as the delay in prevalence reduction means these are discounted more heavily.

### **Benefits (Option 1)**

#### Health benefits due to reduced smoking prevalence

74. We value the health benefits gained from reduced prevalence in a similar way to the IAs on the legislation to stop the sale of tobacco from vending machines, legislation to end the display of tobacco display in shops and the introduction of standardised packaging. The detailed methodology is shown in Annex A and estimates the number of life years gained for an average person who quits smoking.
75. We start by considering the smoking prevalence rate we expect when TPD2 is due to be enforced. The latest data from the Opinions & Lifestyle Survey shows prevalence of 19.2% in Great Britain, 2013<sup>20</sup>. The tobacco display ban is expected to reduce prevalence by 0.04 percentage points each year<sup>21</sup> and applying this to the latest prevalence data suggests that prevalence in 2016 will be 19.0%.
76. Applying the 1.9% reduction expected due to TPD2 gives a decrease of 0.36 percentage points. Applying this to the UK population (16+) gives approximately 200,000 fewer smokers beyond the baseline<sup>22</sup>, spread out across the expected period of impact. On average each additional non-smoker will gain 1.2 life years (discounted) and, valuing each life year gained at £60,000<sup>23</sup>, this gives lifetime health benefits of £13 billion.

#### Reduced reporting & labelling costs

77. The TPD1 requires manufacturers and importers of tobacco products to submit ingredient and quantity data annually, and manufacturers and importers of cigarettes to submit TNCO data annually. The TPD2 replaces this with a requirement to submit ingredient information once on entry to the market or upon a product being changed. Sales and market survey data will be required annually however this will likely be less of a burden meaning there may be a reduction in administrative costs associated with

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<sup>17</sup> Figures in this IA are rounded to 2 significant figures. Some numbers may therefore appear not to add up due to this rounding

<sup>18</sup> The lower bound is used to reflect that, whilst menthol is expected to be the most impactful change to ingredients, other changes such as restrictions on additives and flavour capsules will also have some impact

<sup>19</sup> This increases as a result of prevalence falling more in later years when the UK population is higher  
<sup>20</sup> OLS was used over the Integrated Household Survey as it includes 16 & 17 year olds. The survey doesn't cover the entire UK so GB prevalence is used to proxy for this.

<sup>21</sup> Display ban Impact Assessment, <https://www.gov.uk/government/publications/impact-assessment-on-the-prohibition-of-display-of-tobacco-products-at-the-point-of-sale-in-england>

<sup>22</sup> Whilst the legal age of tobacco consumption is 18, it is known that many people aged 16 & 17 smoke, and therefore it is considered more appropriate to use the 16+ population.

<sup>23</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.

annual reporting. Further administrative savings can also be expected by the introduction of a central EU portal particularly for businesses operating in multiple markets and for Member State Competent Authorities.

78. The TPD1 requires that cigarette packages contain printed TNCO information but this will be prohibited by the TPD2. There will be an enduring cost saving to manufacturers from the removal of this burden.
79. RAND Europe<sup>24</sup> consulted three large European cigarette manufacturers on the administrative burden caused by TNCO labelling. Annual costs were reported at £670-1400 per year per Stock Keeping Units (SKU)<sup>25 26</sup>. In our estimate we use the midpoint of this range which is £1100. Nielsen ScanTrack for 2015 data indicates that there are 722 cigarette SKUs for sale in the UK market, therefore TPD2 will result in a cost saving of £760,000 per year. Over 10 years this gives a discounted saving of £6.6 million.

#### Benefits from e-cigarette provisions

80. There are further expected benefits from the provisions on e-cigarettes. The requirements for childproof containers, along with the restrictions on size and nicotine strength will reduce the risk of poisonings due to consuming e-liquids. This will provide some benefit in the form of fewer accidents and potential deaths.
81. The warning labels and restrictions on advertising are expected to reduce the appeal of e-cigarettes to non-smokers. This will help prevent individuals acquiring an addiction to nicotine.
82. The requirements for product notifications may also put off producers with lower standards and therefore may improve the general safety standards of the industry. This may mean public bodies have more confidence in promoting e-cigarettes as an alternative to smoking, therefore leading more smokers to switch to e-cigarettes. The notification requirements will also mean consumers can access more information on e-cigarette products.
83. These benefits are left unquantified due to the significant difficulties in estimating them and the fact that they do not form part of the costs to business.

#### **Costs (Option 1)**

84. The costs of the policy fall in a number of areas. Due to the reduction in prevalence there will be lost profits to retailers, wholesalers and manufacturers of tobacco, as well as a loss of tax receipts to the Government. Further to this tobacco manufacturers will face increased costs due to additional reporting and labelling requirements. The e-cigarette industry will face costs due to notification and labelling requirements. The Government will also face costs to process and store the additional data reported to them.

#### Loss of profits due to reduced smoking prevalence

85. The reduced consumption described above will impact on the profits of retailers, wholesalers and manufacturers. Forecasts of cigarette & HRT clearances are used and assumed to fall in proportion to prevalence as a result of TPD2<sup>27</sup>. An estimated 220 million cigarette 20 packs and 84 million HRT “20 pack equivalents” are not sold due to TPD2 over the assessment period.

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<sup>24</sup> ‘Assessing the impacts of revising the Tobacco Products Directive: Study to support DG SANCO Impact Assessment’, RAND, 2011, Henceforth referred to as the ‘RAND Europe’ report / consultation

<sup>25</sup> SKU means a distinct item for sale. For example a 10 pack of Marlboro Reds is an SKU, a 20 pack is another SKU and a 20 pack of Marlboro Golds is another etc...

<sup>26</sup> All RAND costs were reported in Euros. These have been converted into GBP using the average 2011 (or 2004 where appropriate) exchange rate, and inflated to 2015 prices.

<sup>27</sup> OBR March 2014 Economic and Fiscal Outlook: Fiscal Supplementary Tables & Forecast for Hand Rolled Tobacco Clearances 23 April 2014

86. For retailers, an estimate of 32p profit per pack is estimated using information on profit margins on cigarettes provided by a UK retailer. Applying this to the estimate of cigarette & HRT packs not sold due to TPD2 gives an estimated discounted profit loss of £78 million over the assessment period.
87. For wholesalers, an estimate of 17p profit per pack is estimated using evidence from the annual reports of a UK wholesaler.<sup>28</sup> Applying this to the estimate of cigarette & HRT packs not sold due to TPD2 gives an estimated discounted profit loss of £42 million over the assessment period.
88. For manufacturers, an estimate of 30p profit per pack is estimated using evidence from the annual reports of two tobacco manufacturers<sup>29 30</sup>. Applying this to the estimate of cigarette & HRT packs not sold due to TPD2 gives an estimated discounted profit loss of £74 million over the assessment period.
89. Only direct impacts on business should be counted for One-In-Three-Out (OITO) purposes. Losses of profits to tobacco companies and others in the supply chain due to reduced consumption of tobacco are contingent on the changed behaviour of smokers and so were excluded from OITO calculations in previous tobacco IAs. The Regulatory Policy Committee have now advised that policies which ban or severely restrict a particular activity, that explicitly prohibit a form of promotional activity, and have a primary objective to reduce sales (even if by promoting behaviour change) should be considered as having a direct impact on businesses. Whilst the primary reason for the TPD2 is to harmonise rules across the EU, this legislation is explicitly attempting to maintain a high level of health protection. In this IA we therefore treat profit losses resulting from the expected reduction in tobacco consumption as a direct impact for OITO purposes. We note that the Better Regulation Executive's Framework review is considering the question of the definition of "Direct" for OITO purposes.
90. This reduced consumption of tobacco is expected to be offset by increased consumption of an equal value elsewhere in the economy. Therefore an equal offsetting benefit is included in the NPV for this policy. However this impact is considered to be indirect, and is therefore not included in the EANDCB.
91. Note that because the impact of the menthol ban on prevalence only occurs from 2020 onwards, we model the impact of this on profits until 2030, to ensure the impact is assessed over the standard 10 year assessment period.
92. Other aspects of TPD2 besides the expected reduction in consumption may have an impact on profits, including the banning of certain products such as menthol cigarettes and smaller packets of cigarettes and HRT. This is considered in the later section on tobacco product restrictions.
93. The impact on profits due to changes in illicit trade and cross-border shopping in tobacco is considered in the relevant section below.

#### Loss to tax receipts due to reduced smoking prevalence

94. Due to the high level of tax levied on tobacco, any reduction in consumption will have an impact on government revenues, even if this consumption is offset elsewhere in the economy (as is expected). This could be viewed as a transfer payment and would therefore have no effect on the policy's NPV. However, when considering policies that transfer spending from higher taxed goods to lower taxed goods, DH identify an adverse impact since if the Government decides to maintain public spending

<sup>28</sup> P54 Booker annual report and accounts 2014 available at <http://www.bookergroup.com/~media/Files/B/Booker-Group/pdf/investor-centre/reposts-presentations/rp2014/booker-group-ar14-06062014.pdf?>

<sup>29</sup> Page 31 BAT Annual Report 2013 (available at [http://www.bat.com/group/sites/uk\\_\\_9d9kcy.nsf/vwPagesWebLive/DO9DCL3B/\\$FILE/medMD9HEGPT.pdf?openelement](http://www.bat.com/group/sites/uk__9d9kcy.nsf/vwPagesWebLive/DO9DCL3B/$FILE/medMD9HEGPT.pdf?openelement))

<sup>30</sup> 2nd cover page PMI 2013 report available at <http://investors.pmi.com/phoenix.zhtml?c=146476&p=irol-reportsannual>

additional tax would have to be raised and the public would lose benefit. Therefore, when considering policies that transfer spending from higher taxed goods to lower taxed goods, DH attributes an adverse impact to such a policy, affecting its NPV.

95. For changes in tobacco consumption, we report a potential lifetime impact on duty consistent with the magnitude of the impact on health. The estimates of lost duty and VAT use the same methodology as for health benefits, described in Annex A. For every additional adult smoker who quits, there is an average discounted lifetime loss of duty of around £11,000. These estimates allow for mortality, consumption of non-UK duty paid tobacco, consumption of HRT, and the probability that those not smoking as a result of the TPD2 may have quit at some point in the future.
96. Applying this loss of duty per quitter to the expected reduction in prevalence gives a cost of £2 billion over the 10 year assessment period from those quitting due to the policy. Further losses of tax revenue due to changes in the illicit market are considered in the relevant section below.
97. As packs of less than 20 cigarettes generally have a higher price per stick than 20 packs, the duty per stick will also be higher. Therefore the ban on these packs is likely to lead to a further loss in tax revenue. However, given the small difference in price per stick and the fact that the majority of duty is not based on product price, the impact of this is will be relatively small.
98. The loss of duty mentioned above is for net present value purposes. This will differ significantly from any Exchequer impact incorporated into the Public Finances, which is certified by the Office for Budget Responsibility (OBR). In part the differences will be down to issues that are not appropriate for inclusion in this Impact Assessment e.g. not discounting, different relevant timeframes etc. In addition consideration will have to be given to various behavioural responses which are relevant to both the Public Finances and the Impact Assessment. There are significant elements of judgement involved in the applicable behavioural responses around which the OBR have taken their own view. In addition over time as more evidence becomes available this may impact on relevant estimates. We therefore expect that the figure into the Public Finances will differ significantly in light of appropriateness of inclusion (e.g. discounting), OBR judgements and new evidence.

#### Increased reporting/notification costs to business

99. The TPD2 requires manufacturers of tobacco products, novel tobacco products, herbal products for smoking and e-cigarettes (covered in the e-cigarettes section) to report varying degrees of information on their products.

#### *Tobacco Products*

100. Excluding the requirements outlined under the priority additive list section below, tobacco product manufacturers are only required to additionally report “where available”, information on cigarette emissions other than TNCO and emissions from other tobacco products and their levels. We expect there to be minimal administrative costs associated with this task given the ongoing requirement to report a much wider range of information. A cost of £1,000 per formulation was assumed in the consultation IA<sup>31</sup>. Further information to inform this estimate was requested at consultation but the responses have neither provided further evidence or any indication that this estimate is unreasonable.
101. Approximately 160 cigarette formulations are currently reported to the DH, with a further 40 having been notified. Assuming all of these products are on the market on 20th May 2016 implies a total reporting cost of £200,000. In addition to factory manufactured cigarettes, there are an estimated 1000 cigar, 30 fine cut (HRT) tobacco and 160 pipe tobacco products available. Assuming the same £1,000 cost

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<sup>31</sup> Based on rough calculations on 1-2 weeks of time for an employee earning £25,000 - £50,000

would imply an additional £1.2m cost, or £1.4m in total, all incurred in year 1 of the policy.

102. The RAND Europe study also considered the impact of the new reporting requirements on manufacturers, noting that 2 of the major cigarette manufacturers already voluntarily report in the required format and it is unclear whether the remaining 2 also do. For these companies the initial self-reported cost ranged from €50,000 to €950,000 per company and there were no ongoing costs reported. For cigar manufacturers that provided estimates the costs ranged from €14,000 to €125,000 leading to an overall cost to the industry of €96,000 to €471,000, with no ongoing costs. These estimates confirm the approximate order of magnitude of the costs but are not used in the NPV or EANDCB.
103. There will be further costs faced by manufacturers upon bringing new products to market after 2016. These are expected to be equally small, but estimation of the total costs to industry is difficult given the uncertainty around future product creation. Inclusion of the 40 cigarette products currently notified to the DH as potentially entering the market in the future will likely capture some of this cost, as it is probable that many will not have entered the market by 2016 or may never do so.

#### *Priority additive list*

104. A priority list of additives, containing no fewer than 15 additives, will be adopted by the EU prior to 20 May 2016. We are awaiting a Delegated Act that will set out precisely what, and how many, additives will be included. In order to provide some estimate of cost we operate under the assumption that 15 additives will be placed on this list.
105. Manufacturers will need to produce a comprehensive study on any additives placed on the priority list covering emissions, toxicological and flavouring characteristics and report their findings to the government and the Commission. These studies can be done jointly between manufacturers and a report on the results of these studies needs to be submitted no later than 18 months after an additive has been placed on the additive list. Depending on the current state of the evidence base for the chosen additives, it may be possible for manufacturers and industry to satisfy this requirement with a literature review. However, it is also possible that further data collection and analysis would be required.
106. The consultation IA assumed a cost of £50,000 per additive on the list would be incurred by the tobacco industry, based on the costs associated with creating peer reviews for chemical regulatory submissions to Government scientific advisory committees (which is an estimated £25,000<sup>32</sup>). This could reasonably be considered a lower bound for the requirements, for additives where there is already a strong evidence base and only a literature review will be required. Responses to the consultation suggested that this underestimated the true cost, with one submission from the tobacco industry providing an estimate of £1.1 million (\$1.5 million) per additive, although there is no indication of how this figure was derived or the original source. This estimate is therefore used as an upper bound, representing the costs incurred where manufacturers will be required to do more than simply a literature review.
107. In the absence of more robust evidence we therefore use the mid-point of these two sources, £560,000, as an estimate of the cost of producing a report for each additive on the list. Given the uncertainty surrounding the additives to be placed on the list, and the details around what each study will entail this is considered a reasonable estimate. The total cost is therefore £8.4 million.

#### *Herbal products for smoking*

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<sup>32</sup> Described in more detail under "Peer review " in Option 2

108. Importers and manufacturers of herbal products for smoking will be required to submit information on their ingredients and quantities thereof. There is currently no systematic evidence on the number of herbal products for smoking available in the UK, or any trade body representing a significant proportion of relevant businesses. However, a 2012 HMRC consultation<sup>33</sup> on herbal products liability to tobacco products duty received responses from a small number of producers and retailers. A total of 30 herbal products for smoking related to these organisations were identified as being available for purchase in the UK.
109. Whilst the manufacturers of these products are not currently required to report ingredient data, it is expected that this information will already be known. As such, a £1,000 administrative cost per product category is applied (consistent with the estimate made for tobacco products), resulting in a total expected cost of £30,000. Again further information to inform this estimate was requested at consultation but the responses have neither provided any evidence or any indication that this estimate is unreasonable.

#### *Novel tobacco products product notification*

110. The TPD2 provides for Member States to implement either a notification scheme or a prior authorisation scheme for novel tobacco products (NTPs). A notification of a novel TP requires information on new products to be submitted 6 months in advance of placing the product on the market and will be supported by the existing strong consumer protection enforcement regime which will allow the withdrawal of products that evidence demonstrates not to be safe.
111. Under Option 1, the notification will include available studies on toxicity, addictiveness, attractiveness and market research and additional tests or information if required, as is the minimum requirement set out in TPD2. Given that only available information will need to be submitted, as is the case for conventional tobacco products, the cost of notification is expected to be minimal and the estimate of £1,000 used for tobacco notifications is again used.
112. It is difficult to estimate how many novel tobacco products will be notified following the implementation of TPD2. Up to now, only one novel tobacco product is available in the UK, Ploom<sup>34</sup>, manufactured by JTI. However there is increased interest in producing novel tobacco products so it is expected that more will soon follow. A consultation response from one tobacco manufacture indicated that they have various products in development. Given the high cost of developing them, it is likely that only the large tobacco manufacturers, who have the finance and expertise required, will be able to fully develop and bring to market novel tobacco products. We therefore assume that each of the largest four manufacturers<sup>35</sup> will notify 1 product each year, giving an annual total of 4. Given the minimal cost per notification the overall NPV & EANDCB are not sensitive to this assumption.
113. There will therefore be an estimated annual cost to tobacco manufacturers of £4,000 for notifying novel tobacco products, giving a discounted cost of £34,000 over the appraisal period.

#### *Cost of processing & storing data to UK government*

114. Costs will be incurred by the Government for processing and storing the data supplied by tobacco manufacturers and importers as described above. The TPD2 provides the option of charging the industry proportionate fees to cover this cost. Under Option 1

<sup>33</sup> Treatment of herbal products for smoking, HMRC, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/179256/herbal\\_smoking\\_products.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/179256/herbal_smoking_products.pdf)

<sup>34</sup> A device that heats, rather than burns, tobacco

<sup>35</sup> Japan Tobacco International, British American Tobacco, Phillip Morris International and Imperial Tobacco

TPD2 is implemented at the minimum cost to business and therefore this option would not be taken up.

115. Similarly there will be a requirement for processing and storing data provided by e-cigarette manufacturers described below. MHRA will be responsible for providing the notification and vigilance service for e-cigarettes. As MHRA is funded by businesses, the costs will fall on businesses whether the option for charging the e-cigarette industry proportionate fees is taken up or not. Therefore charging industry is considered to be an equally least burdensome option for business and is included under Option 1.
116. A central estimate has been made of £590,000 in year 1, followed by a recurring annual cost of approximately £140,000, for providing the system for e-cigarettes. The higher initial cost is a result of the large volume of notifications expected in the first year, and IT implementation costs.
117. Therefore the discounted cost to the e-cigarette industry, through charging for MHRA's costs of processing and storing data provided in e-cigarette notifications is equal to £1.7 million over the assessment period.
118. The tobacco products system will be operated by DH. Due to the lower number of tobacco products there are expected to be fewer notifications to handle, therefore the costs for processing notifications will be lower. We estimate a cost of £320,000 in year 1, followed by a recurring annual cost of approximately £42,000.
119. Therefore the discounted cost to the Government of processing and storing data provided in tobacco notifications is equal to £640,000 over the assessment period.

#### Labelling/packaging adjustment costs

120. The TPD2 will require manufacturers to redesign packaging for a number of reasons, including larger health warnings and removal of certain claims, elements and features.
121. RAND Europe<sup>36</sup> assessed the potential one-off costs faced by manufacturers in order to redesign packaging. It was noted that general labelling redesigns tend to occur every 2 years for cigarette Stock Keeping Units (SKUs), and every 5-7 years for cigar SKUs. As compliance with the TPD2 is required by 20 May 2016, it is likely that many of the non-compliant packs will redesign packaging in the intervening window as part of natural ongoing business. Therefore, there is an argument that the incremental costs of the TPD2 are zero. However, numerous technical aspects of the packaging requirements are still to be determined by the European Commission, with some Implementing Acts not expected until 2015 Q4<sup>37</sup>. The changes required by the TPD2 may also necessitate a more expensive redesign process than is usual. As such, we estimate the potential total costs faced of adjusting all non-compliant SKUs.

#### *Cigarettes & hand-rolling tobacco*

122. The RAND Europe study estimated the costs of redesigning packaging to allow for pictorial warnings to be £17,000 to £19,000 per SKU to tobacco manufacturers. However, as pictorial are already required in the UK, any redesign due to TPD2 is likely to be less extensive. Evidence from the food industry suggests that a minor redesign costs £1,700 to £3,400 per SKU, whilst a major redesign costs £5,900 to £7,600<sup>38</sup>.

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<sup>36</sup> [http://www.rand.org/pubs/technical\\_reports/TR823.html](http://www.rand.org/pubs/technical_reports/TR823.html)

<sup>37</sup> [http://ec.europa.eu/health/tobacco/docs/implementation\\_plan\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/implementation_plan_en.pdf) - Accessed December 2014

<sup>38</sup> EAS, The Introduction of Mandatory Nutrition Labelling in the European Union. Impact Assessment Undertaken for DG SANCO, Brussels: European Advisory Services (EAS), 2004.

123. Using Nielsen data for 2015 we have estimated that 420 cigarette SKUs (114 mentholated<sup>39</sup>, 61 making labelling claims<sup>40</sup>, 81 with bevelled edges or Glide-Tec packaging<sup>41</sup> and 164 otherwise compliant with TPD2) will require relabelling. Of these, it is assumed those that are otherwise compliant with TPD2 will require only a minor redesign, whilst mentholated, bevelled edge packs and those making labelling claims will require a major redesign, as some degree of rebranding will be involved. For HRT tobacco 85 SKUs (40 brands only available in lower than 30g packs, 12 making labelling claims and 33 otherwise compliant with TPD2) were identified as requiring relabelling. Again it is assumed those that are otherwise compliant will require a minor redesign whilst the brands that are only available in lower than 30g packs and those making labelling claims will need a major redesign.
124. Alternative data on the number of SKUs was received in the consultation, suggesting that there are substantially fewer cigarette and HRT SKUs (but more cigar and pipe tobacco) available. However no source was stated for this data therefore we continue to use the estimates derived from Nielsen data.
125. The European Commission IA reported industry estimates of 1.3-1.5% ongoing cost increases associated with the introduction of pictorial warnings across the EU, however this recurring cost increase has not been applied in this IA because of the current requirement for pictorial warnings in the UK.
126. Applying the midpoints of the above estimates from the food industry, the estimated cost to industry due to relabelling requirement is £2.1 million for cigarettes and £430,000 for HRT tobacco. It is assumed that these costs occur in year 1.
127. Responses received during the consultation didn't provide any alternative estimates for the costs of relabelling of cigarettes and HRT or suggest that the methodology used was unreasonable. The methodology is therefore the same as was used in the consultation IA, updated to 2015 prices and SKU numbers.
128. It has been suggested in responses received, that the requirement for picture warnings to rotate on an annual basis will impose additional costs, as the gravure cylinders used in printing, will require replacement after 1 year, rather than the usual 3 and will not be reusable if the warnings are then updated. There could therefore be an additional cost, however this is reliant on the picture warnings being changed, something which is not expected to happen. We therefore do not include any further cost.
129. It has been assumed that cigarette packets utilising Glide-Tec technology will require a major redesign, as this type of packaging will be prohibited by TPD. Information was requested in the consultation about further potential costs resulting from this, for example due to the need to retire machinery used in the production of Glide Tec packs, but no evidence that there would be any substantial additional cost was received.
130. Another issue highlighted by the industry is that, for HRT sold in wraparound pouch packaging, there will be an increase in material costs due to the requirement for the general warning to be printed on the inside surface which becomes visible on opening. A transition period of two years will be provided during which this warning can be printed on the outside surface. This means that producers will have sufficient time to transition to other packaging types, of which there are many. Given that relabelling will already be required we therefore estimate there to be no additional cost arising from this issue.

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<sup>39</sup> No mention of flavours or additives will be allowed on packets

<sup>40</sup> Inclusion of any feature that implies reduced harm or positive effects on packets will be prohibited

<sup>41</sup> Since the consultation the Commission has produced guidance which indicates that in its view, health warnings will not be allowed to be printed across the bevel on packs with bevelled edges. SKUs with bevelled edges are therefore also assumed to require a major redesign. Glide Tec packs will also be prohibited

### *Other tobacco products*

131. A slightly different approach is taken to calculate the costs of relabelling for cigars, given the more complex nature of the market, which includes many SKUs, often sold in low volumes.
132. Under Option 1 other tobacco products for smoking would be subject to less onerous labelling requirements than cigarettes & HRT which would include a general warning and text warning but no picture or cessation information. However there will still be a requirement for relabelling.
133. 90% of the UK cigar market consists of machine-made cigars, sold by three large tobacco companies<sup>42</sup> (Imperial, JTI and Scandinavian Tobacco Group). The production process and sales volumes in this sector are more similar to that of cigarettes, therefore a relabelling cost per SKU is applied. Using Nielsen data we have estimated that these companies sold 69 different SKUs. Applying the cost for a minor labelling redesign to this figure gives a total one-off cost of £170,000 for these three large manufacturers. 18 of these SKUs are individually wrapped cigars which will require warnings for the first time. The RAND Europe study provides a range of £150 to £300 for the recurring annual cost of including textual warnings of cigars. Applying the mid-point of this, £230, therefore gives an additional annual cost of £4,000.
134. Beyond this, 9.2% of the market is machine-made cigars imported and sold by smaller distributors. According to information provided in consultation<sup>43</sup>, currently the foreign manufacturers take responsibility for ensuring packs meet labelling requirements, therefore the majority of the costs fall outside of the UK. However costs will still be incurred due to relabelling requirements. Some manufacturers are expecting to no longer supply certain SKUs as their low volume sales cannot justify the cost of printing packs. This will lead to a loss of profits for UK based distributors and retailers. However the loss of profits on these SKUs is expected to be offset by increased profits on others in the same industry, therefore no cost is included in EANDCB or NPV. Evidence received in the consultation from a tobacco importer and distributor<sup>44</sup> suggests that there will be a cost due to expected write off of non-compliant stock not sold during the sell-through period, due to the slower moving nature of this sector of the market. Using evidence provided by the same distributor this will result in a one-off cost of £160,000.
135. The remainder of the UK cigar market (0.8%) consists of premium hand-made cigars. Consultation responses have indicated that the foreign manufacturers of these tend to delegate responsibility for labelling of these to the importers and distributors, therefore the entire cost is expected to fall on UK businesses, which will be required to print and apply the appropriate labels. Costs will therefore be incurred for printing new plates and expanding current health warning application facilities, amongst others. Using evidence provided by the same tobacco distributor as previously, there is expected to be an initial cost of £370,000, with a recurring annual cost of £210,000.
136. The market for pipe tobacco is similar to that of hand-made cigars, with small-scale distributors and retailers dealing with many low-volume SKUs. To estimate the impact we therefore scale the cost calculated for hand-made cigars. Data provided in the consultation identifies 893 cigar SKUs and 509 pipe tobacco SKUs. The cost of relabelling for pipe tobacco is therefore estimated to be 57% (509/893) of that for handmade cigars, giving an initial cost of £210,000 and an annual recurring cost of £120,000. The entirety of this cost falls on UK business.

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<sup>42</sup> According to market data provided by one Hunters & Frankau, a cigar importer and distributor in the consultation

<sup>43</sup> From various cigar manufacturers, importers and distributors

<sup>44</sup> Provided by Hunters & Frankau

137. The TPD2 will require that online images used by retailers are presented in compliant packaging. The costs associated with this requirement are expected to be covered by the above estimates.

#### *Herbal products for smoking*

138. Herbal products for smoking will be required to include text health warning messages for the first time. We have identified 30 relevant SKUs currently available in the UK market. The specific cost of relabelling would be expected to fall in the range of a minor relabelling change per product as identified by RAND. Applying the mid-point (described above) results in a total cost to industry of £76,000.
139. Further to this there will be a recurring annual cost to manufacturers. This was identified as £1,800 - £9,000 per SKU by cigarette manufacturers and £150 - £300 per SKU by cigar manufacturers in the RAND study. The stark difference between these estimates results in considerable uncertainty around the potential cost to manufacturers of herbal products for smoking. We take the average of the two ranges' mid-points, £2,800 per SKU per year, as the cost of requiring textual health warnings on herbal products. Applied to the 30 SKUs previously identified results in annual costs of £84,000.
140. None of the consultation responses received gave any suggestion that these cost estimates for herbal products for smoking were unreasonable, and therefore they are unchanged from the consultation IA.

#### *Tobacco product restriction costs*

141. TPD2 will prohibit the sale of cigarettes in packs of less than 20, HRT tobacco in packs of lower than 30g and flavoured tobacco products, including menthol from 2020. The loss of these product lines is not however expected to have a major impact on business as, given the highly addictive nature of tobacco, consumers of these products are expected to switch to others that will continue to be available under TPD2. Those that don't switch will make up part of the reduction in prevalence and consumption, the impact of which has already been assessed above. Evidence on relative profit margins was requested in the consultation but no responses have suggested that these restricted products are more profitable than those that will remain on the market. No further impacts of these restrictions are therefore included in this IA.
142. There are currently a number of HRT brands that only supply products in non-TPD2 compliant sized packs. There is the potential that these brands may lose customers to those brands with an established presence in the otherwise TPD2 compliant market. However this would not represent an overall loss of profit to the industry, but a transfer across businesses in the same industry.
143. It is also possible that the reduction in numbers of SKUs and product lines will reduce costs to manufacturers and retailers in the long term.

#### *Cross-border distance sales*

144. TPD2 provides the option to either prohibit cross-border distance sales of tobacco, or to UK require sellers to register before doing so. Under option 1 the least burdensome option to business is taken up which in this case is registration. There is therefore a cost to retailers to register to sell to other EU member states as well as to provide an age-verification system for any cross-border transactions.
145. There are expected to be very few UK tobacco retailers registering. This is because the UK has higher tobacco duties than other Member States and therefore there is little demand tobacco from UK retailers. Given this and that only a minimal amount of information is required to register there is assumed to be close to no cost associated with the registration requirement.

146. Retailers that do make cross-border distance sales will be required to verify the age of customers. According to data provided by Euro-monitor, in 2014, 2.3% of cigarette sales, 12.7% of cigar sales and 5.8% of pipe tobacco sales were made by UK retailers via the internet. Cross-border sales will form some subset of these sales. However given the high duties imposed on tobacco in the UK in comparison to other EU countries it seems unlikely that there will be much demand for cross-border sales from the UK. An assumption that 1% of internet sales are cross-border is therefore applied. By making an assumption about the amount of tobacco bought per transaction<sup>45</sup> we are able to estimate that 2,000,000 cross-border transactions are completed each year. Information provided in the consultation shows that using Experian software (a possible age-verification software package) an age-verification check costs 2.3 pence, giving an overall annual cost of £4,600 to UK retailers or a discounted cost of £39,000 over the 10 year assessment period.
147. It is likely that many businesses making cross-border distance sales will already have age-verification systems in place and therefore will incur no additional cost due to TPD2. It is also likely that some transactions will be repeat transactions from already verified customers and therefore would not need to be verified.

#### Increase in non-duty paid tobacco consumption

148. The non-duty paid tobacco market consists of cross-border shopping and the illicit trade. It is possible that the restrictions imposed by TPD2 will provide drivers to both increase and decrease illicit trade. In particular it is thought that the introduction of minimum pack sizes and the prohibition of flavoured cigarettes (including menthols) could lead some smokers to use illegal channels to purchase their favoured products. The provisions in TPD2, in particular the Track & Trace system, are expected to reduce the illicit trade in tobacco. However Track & Trace is not assessed in this IA so only the potential increase is included.
149. A tobacco industry funded report by Transcrime estimated that restricting the availability of menthol cigarettes would result in UK illicit trade increasing by 1.5%<sup>46</sup>. Being funded by the industry, this report may overstate the potential impact. It also relies on data from KPMG's Project Star which has a number of methodological issues.<sup>47</sup> We therefore use this as an upper bound impact. For a lower bound we assume an impact of 0%<sup>48</sup> and use the mid-point of 0.75% as the expected impact in our estimate. As the ban on menthols only applies from 2020, the impact also only happens from this year.
150. The report provided no estimate for the overall impact of TPD2 on illicit trade so it is assumed that there will be a further 0.75% increase as a result of the other provisions, in particular the restrictions on pack size. This is considered reasonable as, whilst 10 packs of cigarettes make up a larger proportion of the total market than menthol, it is less likely that consumers of these products will move to the illicit market, as they will still be able to purchase them legally only in different pack sizes. Therefore on balance the impact may be similar. This impact will apply from 2016.
151. Applying this total 1.5% increase in illicit trade results in 0.14% (0.07% before 2020) of remaining cigarette smokers, and 0.53% (0.26% before 2020) of remaining HRT smokers moving into the illicit market. The assessment of the menthol impact is extended through to 2030 to ensure a 10 year assessment period.
152. An increase in the illicit market can have a number of impacts. Firstly tax revenues will decrease as no duty is paid on illicit tobacco. There will also be an impact on the

<sup>45</sup> Based on looking at online tobacco retailers to determine the most common pack sizes we assume an average transaction consists of 200 cigarettes, 10 cigars or 50 grams of pipe tobacco

<sup>46</sup> TransCrime report available at [http://www.transcrime.it/wp-content/uploads/2013/11/Crime-Proofing-of-the-NEW-TPD\\_6.pdf](http://www.transcrime.it/wp-content/uploads/2013/11/Crime-Proofing-of-the-NEW-TPD_6.pdf)

<sup>47</sup> <http://www.bath.ac.uk/news/2014/01/22/illicit-tobacco/>

<sup>48</sup> Based on there being a chance that there will be no impact on the size of the illicit market, despite the risks identified

profits of retailers, wholesalers and manufacturers who will lose sales to the illicit market. Finally it is possible that the health benefits bought about by TPD2 could be diminished, as smokers who would have quit due to the product restrictions are able to continue smoking as before.

153. The above changes are estimated to result in approximately 17 million packs of cigarettes and 25 million HRT pack equivalents moving into the illicit market due to TPD2. Applying the estimated profits per pack described in previously<sup>49</sup> gives a discounted loss of profits of £10 million to manufacturers<sup>50</sup>, £11 million to retailers and £6 million to wholesalers. Using the estimates described in Annex A of the average duty and VAT loss per cigarette and HRT pack gives an estimated loss of £160 million to the exchequer.<sup>51</sup> These impacts are not considered direct for EANDCB purposes as they are contingent on behaviour change and not a primary objective of the policy.
154. The possibility that an increase in illicit trade detracts from the expected reduction in smoking prevalence is considered in the sensitivity analysis below.
155. There may also be an increase in cross-border shopping due to the restrictions of TPD2. This will cause lost profits for UK retailers and wholesalers as well as losses of tax revenue. As TPD2 will apply to all EU member states there is no expected impact on cross-border shopping within Europe as a result of the product restrictions. There may be a small increase due to cross-border shopping from countries outside the EU. However if, as is expected, some EU Member States choose to ban cross-border distance sales, then there may be a decrease in within EU cross-border shopping. We therefore expect that on balance there will be no significant change in the level of cross-border shopping.

#### Electronic cigarettes

156. As well as regulating tobacco products, the TPD2 includes various regulations and requirements for electronic cigarettes.
157. Annex B describes some of the assumptions and calculations behind the estimates below in more detail.

#### Labelling and packaging

158. TPD2 imposes labelling and packaging requirements on electronic cigarettes. Packaging must display a warning message as well as information about ingredients. An information leaflet containing information about toxicity and addictiveness must also be included in the package.
159. Responses received in the consultation suggest that the requirement to display warning messages will impose minimal costs as most products already include such warnings. We therefore use the cost for a minor labelling redesign described previously<sup>52</sup> of £2,500 and apply this to an estimate for the number of e-cigarette SKUs described in Annex B of 5,200, giving a one-off cost of £13 million.
160. The requirement for an information leaflet will add to the cost of e-liquids particularly, which are usually sold as a bottle only and will therefore require either external packaging or a fold-out leaflet. Various estimates ranging from 1p to 10p were received for the additional cost of including information leaflets per bottle from e-cigarette manufacturers and the average of these, 4p, is used in estimating the impact.

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<sup>49</sup> Profit loss due to reduced prevalence section

<sup>50</sup> A slight adjustment is made to account for the fact that manufacturers don't lose profit on the 6% of the illicit market that is contraband

<sup>51</sup> The loss of duty is for illustrative net present value purposes. This is likely to differ significantly from any Exchequer impact that will eventually be incorporated into the Public Finances (see paragraph 98)

<sup>52</sup> In the cigarette & HRT relabelling section

161. Using information received in the consultation from an e-cigarette manufacturer on the number of e-liquid bottles they sell and their estimated market share, we estimate that 38 million bottles are currently sold each year. This is expected to increase as the market grows. Using forecasts from Euromonitor for the value of the e-liquid market we estimate the number of bottles sold each year over the 10 year assessment period.<sup>53</sup>
162. Applying the 4p cost for including a leaflet with each bottle to the number of bottles sold in each year gives a discounted cost of £39 million over the 10 year assessment period.

#### *Cross-border distance sales*

163. The requirements on cross border distance sales for registration and age-verification will also apply to e-cigarette cross-border distance sales. A minimal amount of information is required to register therefore a cost of £1,000 per registration, consistent with the notification costs described above, is used. We have estimated there are 950 e-cigarette companies and we assume that 50% of these companies would wish to register for cross-border distance sales. There is therefore a one-off cost of £475,000.
164. Euro-monitor data shows that UK retailers' internet sales were valued at £230 million in 2014. It is assumed that 15% of this was from cross-border sales and that an average transaction is worth £20<sup>54</sup>. This gives an estimate of 1.8 million transactions requiring age verification in 2014. The market is however expected to grow so Euro-monitor forecasts of the value of the industry are used to forecast the expected number of cross-border transactions each year over the assessment period. Multiplying this by the 2.3 pence cost gives a discounted cost of £930,000 over the 10 year assessment period.
165. It is likely that many businesses making cross-border distance sales will already have age-verification systems in place and therefore will incur no additional cost due to TPD2. It is also likely that some transactions will be repeat transactions from already verified customers and therefore would no need to be verified.

#### *Advertising*

166. TPD2 will restrict advertising of e-cigarettes, allowing for only some local print advertisements such as billboards and leaflets. Advertising broadly can have two impacts, on one hand, advertising by the industry can be expected to grow the market and increase demand for e-cigarettes and related products. Restricting this advertising effect will therefore be expected to reduce consumption in the e-cigarette industry, and therefore profits, relative to the counterfactual. This would impose a cost on the industry business equal to this loss of profits.
167. On the other hand, some advertising may only serve to increase the market share of individual firms. Whilst spend on advertising of this kind is beneficial to an individual firm, there is no benefit to the industry as a whole. This spending effectively amounts to competitive waste, and restricting this will be a benefit to the e-cigarette industry, as spend on advertising will be reduced, without impacting overall consumption and profits for the industry.
168. The impact on demand in the industry is expected to be insubstantial. A systematic review of the evidence on the impact of advertising bans on tobacco consumption suggests there can be a negative, but often insignificant impact. Furthermore, partial bans, as will be imposed by TPD2, were found to have little or no impact on

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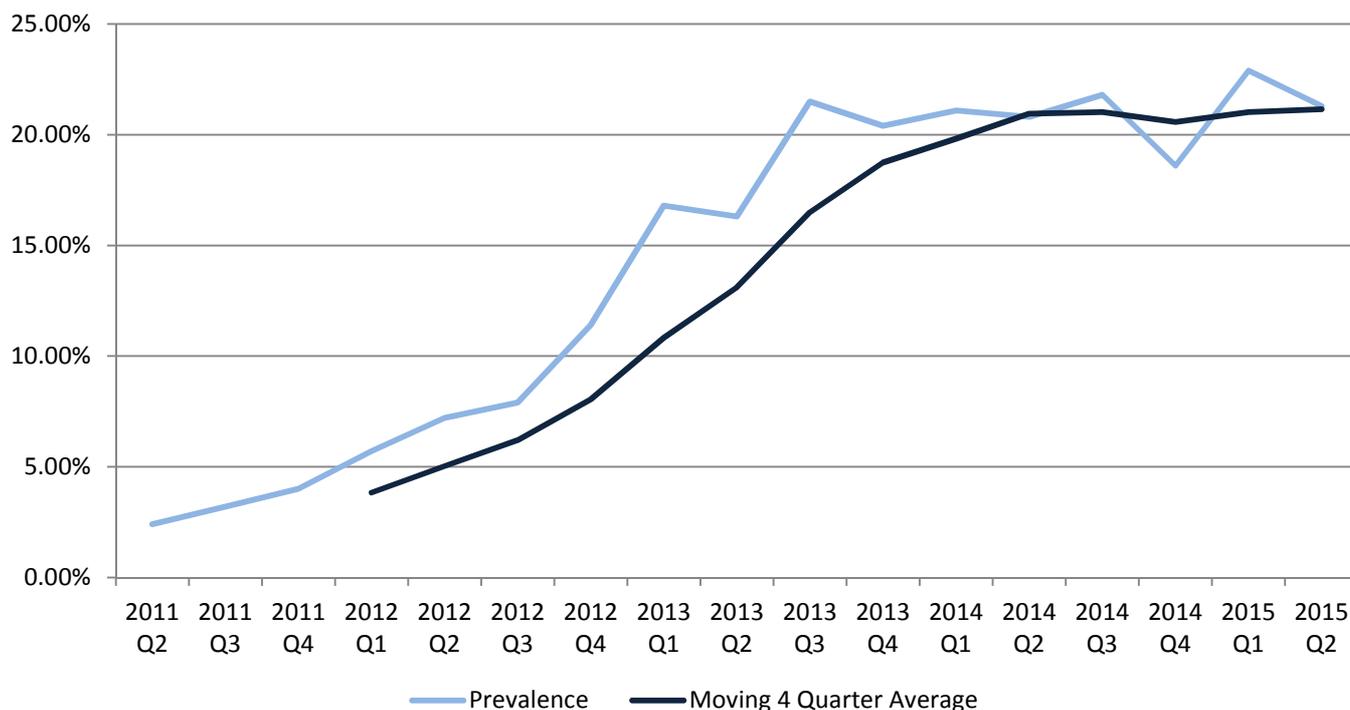
<sup>53</sup> This is expected to grow each year until 2019, with 110 million bottles being sold each year from then on

<sup>54</sup> Information provided by one e-cig manufacturer & retailer shows that 11% of their registered customers live in other EU countries. Data from e-cig intelligence shows an average 10ml e-liquid costs £4.04 (other products such as tanks are more costly) and it is expected that EU customers would buy multiple per transaction given delivery costs

aggregate consumption.<sup>55</sup> There are of course substantial differences between the tobacco and e-cigarette industries which may limit the applicability of evidence to this case.

169. Whilst the e-cigarette industry has grown rapidly in terms of market value in recent years, this growth is slowing and is expected to level off by 2019 according to Euro-monitor forecasts (which do not include any impact from TPD2). Data on usage also suggests that growth is levelling off. (see Graph 1)<sup>56</sup>

**Graph 1 – Use of e-cigarettes amongst smokers and recent ex-smokers**



170. Until 2014 statutory guidance prevented images of e-cigarette use on television. Existing medicines legislation prohibits the making of any claims, in advertising or on packaging, that e-cigarettes can help people quit smoking. As the graph shows, the levelling off of e-cigarette use began before this point. It is only recently that the industry has used significant marketing campaigns, with the period of fastest growth in the market being a result of social media and word of mouth.
171. Awareness of e-cigarettes is high<sup>57</sup> at 95% amongst smokers and 93% amongst non-smokers. Amongst 11-18 year olds awareness was 93%, varying from 85% for 11 year olds to 97% for 18 year olds.<sup>58</sup> A report on e-cigarette advertising in Europe<sup>59</sup> found that 62% of people in the UK had seen advertisements for e-cigarettes in the past month, with point of sale, newspapers & magazines, and television the most common source.

<sup>55</sup> Quentin et al. Advertising bans as a means of tobacco control policy: a systematic literature review of time-series analyses. (2007)

<sup>56</sup> Smoking Toolkit Study: <http://www.smokinginengland.info/>

<sup>57</sup> 95% amongst smokers & 93% amongst non-smokers, [http://www.ash.org.uk/files/documents/ASH\\_891.pdf](http://www.ash.org.uk/files/documents/ASH_891.pdf)

<sup>58</sup> ASH Smokefree 2015

<sup>59</sup> Eurobarometer, Attitudes of Europeans towards tobacco and electronic cigarettes: [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_429\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_429_en.pdf)

172. It is only the recent arrival of the tobacco industry into the e-cigarette market that has seen increased investment in advertising. E-cig Intelligence note various industry reports of total 2013 UK advertising spend at £10m - £11.5m, and £15 - £25m in 2014. Since this time, Skycig/Blu (Imperial Tobacco) alone has announced a £20m investment in a new marketing campaign<sup>60</sup>. It is therefore likely that, under the counter-factual, advertising spend would be larger than this, and possibly increasing, from 2016 onwards. Advertising spend is therefore forecast using Euro-monitor forecasts for the value of the e-cigarette industry, and assuming that advertising spend increases in proportion to this, from its estimated levels in 2013 & 2014.
173. The expected benefit businesses accrue from advertising should be greater than the amount they spend on it, otherwise it would not be optimal to spend on advertising. The benefit of advertising to the individual firm is therefore this additional return. Estimating this is however difficult,<sup>61</sup> and for the purposes of an Impact Assessment it is the effect on the industry as a whole, rather than individual firms, that must be taken into consideration.
174. When considering the above evidence we conclude that the ability of advertising to grow the market further may be limited, and the largest effect of advertising spend will be to attempt to grow an individual firm's market share at the expense of other e-cigarette firms<sup>62</sup>. Therefore, when comparing TPD2's cost to the e-cigarette industry of reduced market growth, to the benefit of reduced competitive waste, we conclude that the benefit to the e-cigarette industry will be at least equal to the costs.
175. To test how reasonable this conclusion is, we consider a possible scenario where the advertising restrictions reduce the value of the e-cigarette market by 20% compared to the Euro-monitor forecasts. We can be fairly certain that the actual impact will be much less than this. Using a profit margin of 20% this gives a reduction in profits of around £58 million each year following the implementation of TPD2. This is similar to the forecast savings in spending on advertising, leading to an overall small annual profit loss of around £4.5 million. Given that there is only a small profit loss net of reduced advertising spending under these fairly extreme assumptions we believe it is reasonable to include zero cost to the industry as a central estimate in the IA in the absence of better evidence.
176. There will also be an impact of reduced profits to advertising agencies. Some advertising will still be permitted in cinema, fax, outdoor posters, posters on sides of buses, leaflets (and other take away kinds of media such as beer mats) and direct mail. We make the assumption that advertising spend will therefore reduce by 90%, as these remaining avenues are likely to be lower cost. Using a profit margin for advertising agencies of 11%<sup>63</sup>, the loss of profit is equal to £47 million over the 10 year assessment period. This cost is considered indirect for EANDCB purposes following discussions with the RPC.
177. There may be potential benefits of increased health and reduced addiction if the restrictions on advertising reduce the number of non-smokers taking up e-cigarette use. There may also be potential negative health implications if the restrictions on advertising reduce the number of consumers switching from tobacco products to e-cigarettes. Survey evidence suggests that the vast majority of e-cigarette users are current or ex-smokers, with use by never smokers negligible.<sup>64</sup> The potential for the

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<sup>60</sup> PHE, E-cigarette Uptake & Marketing, [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>61</sup> On the near impossibility of measuring the returns to advertising, (2013), [http://justinrao.com/lewis\\_rao\\_nearimpossibility.pdf](http://justinrao.com/lewis_rao_nearimpossibility.pdf)

<sup>62</sup> Advertising will have an impact on people taking up e-cigarettes, but this is expected to be less than the brand switching impact

<sup>63</sup> <http://www.campaignlive.co.uk/article/top-50-ad-agencies-lowest-profit-margins-seven-years/1358676>

<sup>64</sup> <http://www.smokinginengland.info/>

restrictions on e-cigarettes to impact on the expected reduction in smoking prevalence, by discouraging smokers from switching to e-cigarettes, is explored in the sensitivity analysis.

#### *Reporting sales information*

178. Manufacturers and importers of e-cigarettes will be required by TPD2 to submit annual data on sales volumes, consumer preferences, modes of sale and executive summaries of any market surveys undertaken.
179. Companies are not required to gather new data on the preferences of consumer groups, or to commission market surveys. They are required to submit this information to government when it is available to them. We assume that companies will already have the mandatory information on sales volumes as businesses will already track their sales for tax and stock keeping purposes<sup>65</sup>. Therefore there will be no additional costs of acquiring the information.
180. Therefore the only additional cost will be staff time spent collating and submitting information. These costs may prove more burdensome for smaller companies, whose systems for collating sales information are unlikely to be sophisticated.
181. If we multiply the median UK hourly wage<sup>66</sup> £11.61 by the number of companies<sup>67</sup> and hours taken<sup>68</sup>, this gives the total cost of this requirement for the UK. This gives a total cost of £130,000 in year 1 followed by an annual cost of £120,000 from year 2 onwards.

#### *Toxicology & emissions testing*

182. Businesses may need to carry out toxicology and emissions testing as part of the notification process. We assume that responsible businesses use ingredients where the toxicity has been characterised. Businesses should not currently put a product on the market without satisfying themselves that it is safe in normal use. The majority of ingredients in e-cigarettes are commonly used in other consumable goods, so the toxicology of the ingredients will be known. Therefore we assume that the majority of products will not require additional toxicology or emissions testing. In support of this, we found that the websites of some manufacturers include details of the testing they have carried out<sup>69</sup>.
183. However the consultation responses show that some businesses will need to conduct additional tests, so we have modelled a best estimate of the costs if 10% of the products required an additional emission and toxicology test.
184. This is a best estimate of the costs of these tests; however they are subject to numerous uncertainties. As Annex B explains, we have limited knowledge of the number of products which require notifications. One manufacturer could do the test for multiple distributors, therefore it is possible that using the number of notifications as a proxy for the number of tests is an over estimate. Also not all products to be notified on will require toxicology and emissions tests, therefore the “number of product” column may be an over estimate. We would expect an initial wave of testing in year one, then new products from year two onwards. An assumption of 25% growth has been made (see Annex B)

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<sup>65</sup> It should be noted that a consultation respondent disagreed with this, stating they would need to invest £150,000 to meet this requirement. However it is considered unlikely that a company would not currently have the ability to monitor its own sales, and would need to invest in a new IT system to do this.

<sup>66</sup> Hourly pay - Gross (£) - For all employee jobs: United Kingdom, 2014 ONS

<sup>67</sup> See Annex B for a more detailed breakdown of these estimates

<sup>68</sup> Estimates provided by Steven Hey, an Industry Commercial Performance Analyst

<sup>69</sup> <http://www.totallywicked-eliiquid.com/news/2015/july/totally-wicked-e-liquid-test-results.html>

185. A cost per test of £3,500 for toxicology testing<sup>70</sup> and £350 for emissions testing<sup>71</sup> is used. Therefore a best estimate for toxicology testing of £1.8 million in year 1 and £450,000 recurring annually from year 2 onwards is used. A best estimate for emissions testing of £180,000 in year 1 and £45,000 recurring annually from year 2 onwards is used.

#### *Notifications*

186. Manufacturers and importers will be required to submit a notification to the competent authority of any products they intend to place on the market. The system for these notifications is still under development so exact costs are not known.
187. Aside from the emissions and toxicology data, we expect manufactures, importers and distributors of e-cigarettes to already have all the knowledge required to submit an electronic notification. There may be a cost to companies who have to request information from their suppliers and gather existing data. Companies will also have to spend resource filling in the form. We expect these tasks to take between 10-15 hours per notification. We expect that approximately 25% will require resubmission, so we have increased the time per submission by 25% on each estimate. There may be costs of translating information to submit notification, however given that all companies notifying the UK will be selling to or operating in the UK, we expect these costs to be negligible.
188. We therefore make an estimate of £940,000 for year 1, with a recurring annual cost of £240,000 from year 2 onwards.

#### *Adverse effects reporting*

189. Manufacturers, importers and distributors will be required to maintain a system for collecting information on the potential adverse events on human health of e-cigarettes and refill containers. Businesses will be required to take corrective action where e-cigarettes or refill containers are not safe or are not of good quality, to withdraw or to recall them as appropriate. They will also be required to inform the national competent authority giving details, in particular, of the risk to human health and safety and of any corrective action taken, and the results of such corrective action. The national competent authority also has powers to take appropriate provisional measures to deal with any e-cigarettes or refill containers that pose a serious risk to human health. The Commission will be notified and must determine whether the measures taken are justified.
190. Member States may request additional information from the economic operators, for example on the safety and quality of the product or any adverse effects of e-cigarettes or refill containers. Medicines and Healthcare products Regulatory Agency will do this on a case by case basis.
191. Businesses will only be required to take action when an adverse event occurs. Evidence from the consultation demonstrates that the number of adverse events is likely to be minimal.

*“Over [a] seven year period, Totally Wicked has sold around 1.5 million products and has received only one complaint regarding a suspected adverse effect in relation to one of its products. When the complaint was subject to independent expert analysis it was found to be unfounded” Totally Wicked consultation response 2015.*

*“Over the last 2 years we have seen only 2 individuals who have suffered any form of adverse reaction, which in both cases was a sensitivity to Propylene Glycol. We advised both to seek advice from their GP. Both were*

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<sup>70</sup> From the consultation responses

<sup>71</sup> Information from Essentra Scientific Services

*advised by their GP who fully documented their findings.” Go Vapour UK Ltd consultation response 2015.*

192. In the absence of this legislation we expect that manufacturers, importers and distributors would still take corrective action when presented with information regarding an adverse effect from one of their products. Therefore the only additional cost would be to write a report to the competent authority. For these reasons we expect any additional costs to business from this requirement to be negligible.

#### *Familiarisation*

193. We expect all companies in the e-cigarette industry to spend time familiarise themselves with these new regulations. MHRA will provide clear guidance to minimise these costs. We estimate that 15 hours of employee time will be required per company. Multiplying by the number of companies and the median hourly wage, gives an estimated one-off cost of £170,000.

#### *Child resistant & tamper evident packaging*

194. E-cigarettes must deliver nicotine doses at consistent levels under normal use, and e-cigarettes and refill containers must be child resistant and tamper evident.

*“The National Poisons Information Service received 241 telephone enquiries about e-cigarettes or refill solutions during 2014/15, an increase of 18% compared with 2013/14. A quarter of these involved children under five years and, overall, 85% of exposures were accidental. Of fifteen reported cases of eye contact, nine occurred when the liquid was mistaken for eye drops and conjunctivitis was the predominant feature. Of all patients exposed, most (133) had no features of toxicity, but there were seven patients with moderate toxicity and one with severe toxicity. Clinical features associated with ingestion included irritation of the oral cavity, anxiety, nausea, vomiting, dizziness and changes in heart rate. These data emphasise the need for safe storage and packaging of these products”<sup>72</sup>.*

195. ECITA told us they thought all nicotine containing products should already be either inherently child resistant, or held within child resistant packaging, and that the TPD will not add any additional costs in this regard. ECITA told us they thought most liquid containing products are similarly already tamper evident and while extending this may carry some extra cost, unless the requirements are applied in an overly strict way (for example to items such as batteries, where there is little to tamper with), the impact will not be significant. We do not intend to apply the requirements in an overly strict way.
196. One consultation response stated that it costs £6000 to make a container child resistant. We have no information on how many of the products on the market are not currently child resistant; however ECITA’s response gives us confidence that it will be a small proportion. For a best estimate we use 10% of products. This gives a year 1 cost of £3.1 million and an annual cost of £780,000 from year 2 onwards.

#### *Market effects*

197. Due to the poor quality data available and the number of opposing pressures on the market coming from the regulation it is not possible to model the new market equilibrium, or the welfare loss or gain, with any accuracy. Any attempt at doing this would be spurious. In lieu of this a description is given of possible market effects.
198. The restrictions on advertising may lead to a reduction in demand. The ban means e-cigarette companies will no longer spend money on advertising, thus lowering the costs of production; therefore there may be an increase in supply.

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<sup>72</sup> <http://www.npis.org/NPISAnnualReport2014-15.pdf>

199. The regulation will give public bodies more confidence in recommending e-cigarettes, and may give consumers and potential consumers more confidence in using them. Therefore there may be an increase in demand.
200. Member States are required to restrict the volume and strength of nicotine containing liquids. Consumers may switch to buying more lower concentration products due to no longer being able to purchase higher concentrations. This may lead to an increase in demand. Conversely, there may be a reduction in demand as if users can't get the desired nicotine level from e-cigarettes they may switch to cigarettes.
201. Barriers to entry from the regulations mean small and medium enterprises may not be able to compete in the market; therefore they may be forced to withdraw, leading to a decrease in supply.
202. The market currently has a huge variety of products. Products may homogenise due to the notification cost, leading to a decrease in supply. This will give consumers less choice, and may lead to a decrease in demand.
203. If consumers are no longer able to purchase the products they require legally, they may seek the products on the black market. This would lead to a decrease in demand in the legal market, and an increase in demand on the black market.
204. It may take up to six months to obtain a notification for a new product, therefore the rate of innovation and growth in the market may decrease, therefore decreasing supply and potentially decreasing demand when compared to the counterfactual.
205. The packaging and labelling requirements may drive costs up, which may lead to a decrease in supply.
206. Stakeholders have flagged that there may be an effect on intellectual property. We have been told that the e-cigarette market uses trade secrets as oppose to intellectual property rights. Although Government will take the need to protect trade secrets in to account when publishing, industry have raised a concern that they will be forced to share their trade secrets with those in their supply chain when making a notification. They may choose to withdraw from the UK market instead of risking this, causing a decrease in supply.

### *Risks*

207. There is a risk that due to the potential price increase and reduction of choice of e-cigarettes, people will choose to switch back to smoking, thus harming their health. This possibility is considered in the sensitivity analysis.
208. There is a risk that a black market will develop with potentially harmful e-cigarette products, due to consumers no longer having the same degree of choice in the legal market.
209. There is a risk that people may misinterpret the regulation, and think all e-cigarettes are medicines or regulated to the same standards and scrutiny as medicines, giving them false confidence in e-cigarettes.
210. There is a risk that the regulations will create barriers to entry for small and medium enterprises, thus reducing competition in the market.
211. There is a risk that restrictions on what products can be sold may cause businesses to incur significant costs in terms of losing stock and changing manufacturing processes. Decisions are ongoing regarding what restrictions need to be implemented, so this cost could not be monetised at the time of this impact assessment.

### *Branding*

212. TPD2 prohibits tobacco and e-cigarette products from including claims that suggest that a particular product is less harmful than others or aims to reduce the effect of

some harmful component of smoke, or has vitalising, energetic, healing, rejuvenating, natural / organic properties or other health or lifestyle benefits.

213. This will also apply to the brand names themselves. Some current e-cigarette brands will therefore be required to change their brand names, for example E-lites & Nicolites, two of the biggest firms. The purpose of this provision is to prevent consumers from being misled into believing that e-cigarettes branded as “lite” or similar, are healthier or safer than alternative brands of e-cigarettes.
214. Whilst these individual firms may lose profits as a result of this, the impact on the industry as a whole is likely to be neutral as customers are likely to switch brands rather than stop using e-cigarettes altogether.
215. However we expect that the firms affected will have to engage in rebranding and invest increased amounts in communications to inform consumers and establish their new brand in the market. To estimate this cost we use evidence on past advertising spend in the e-cigarette industry. As described in the previous section on advertising restrictions, E-cig Intelligence note various industry reports of total 2013 UK advertising spend at £10m - £11.5m, and £15 - £25m in 2014. We estimate advertising spend in earlier & later years by using Euromonitor data and forecasts on market value and assuming advertising spend is proportional to this. This gives an estimate of cumulative spend on advertising of £68 million up to 2016.
216. Using Nielsen ScanTrack data we have estimated that 33% of the market<sup>73</sup> is currently made up of brands that will be required to change their brand name due to TPD2. We therefore estimate that £23 million will need to be spent on advertising & marketing by these firms. It is assumed that this entire cost is incurred in year 1 of the policy.
217. This estimate may be an underestimate as it uses advertising spend as its basis, however it is likely that further costs will be incurred internally by firms for re-branding and re-designing.
218. However there are other reasons why it may be an overestimate. It is assumed that the firms affected will need to spend an amount equal to that that they had already spent on their previous brand name, to establish their new brand name. It is possible that the cost will be less, as a simple campaign making the change clear to consumers could be enough to transfer consumer brand preferences across. Furthermore the restrictions on advertising described above will limit them to cheaper forms of media such as billboards and leaflets.
219. Whilst we only consider here the costs to the e-cigarette industry, there will also be a benefit to the advertising industry due to the increased advertising spend required.
220. The cost is considered as direct for EANDCB purposes.

### ***UK proportion of impacts***

221. The figures presented above relate to the total impact resulting from TPD2. However much of this impact will not fall on the UK population or UK businesses, therefore it is necessary to adjust the figures to calculate the UK impact.
222. For the purposes of EANDCB calculation a “GDP based” approach is adopted, assessing the impact on UK based production, regardless of where the profits of this production may be repatriated to. It is known that the 2 largest UK production facilities, the Imperial Tobacco factory in Nottingham and the Japan Tobacco International factory in Lisnafillan, producing 44% and 41% of the UK market

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<sup>73</sup> Using market share based on value sales

respectively<sup>74</sup>, are scheduled to close before (Imperial)<sup>75</sup> or shortly after (JTI)<sup>76</sup> implementation of TPD2. Therefore in the 10 year evaluation period, 4.1% of UK tobacco consumption is expected to be UK produced.

223. However simply using this 4.1% proportion would be assuming that the decision to close these factories is unrelated to TPD2. The success of tobacco control policies, including the upcoming TPD2, is likely to have been a factor in the decision of where to locate production. To resolve this issue it is assumed that the closure decisions were influenced by TPD2, but only in proportion to its expected impact on smoking prevalence in the UK, relative to recent changes in smoking prevalence. Assuming that the closure decision is affected by changes in prevalence over the last decade, it is noted that prevalence has decreased by 7 percentage points over this period, whilst TPD2 is expected to further reduce prevalence by 0.36 percentage points. There is therefore considered to be a 1 in 20 chance that TPD2 was pivotal to the closure decision.
224. This gives a 1 in 20 chance that UK production would have accounted for 85% of the UK market in the absence of TPD2, and a 19 in 20 chance that it would have accounted for 4.1%. Weighting these possibilities together gives an estimated UK proportion of 8.1%. This figure is applied to the costs incurred by cigarette manufacturers to calculate the direct UK impact for OITO purposes.
225. There are some uncertainties in this approach. The 10 year decision time frame chosen may be incorrect, there is however little evidence available to inform this. The above methodology may overestimate the impact that TPD2 has had on the decision to close factories as factors such as costs and productivity may be more important than tobacco consumption when choosing a production location. On the other hand however some head office functions remain based in the UK and these will provide some value-added to the production process, although this is difficult to quantify. Therefore although there is no agreed upon method for such assessing the proportion of UK based activity, any such assessment would be small relative to the absolute profits from UK consumption.
226. A similar methodology is employed for the cigar industry. As the relabelling costs for the 10% of the market served by smaller distributors and importers were estimated explicitly based on the UK impact, we assume that 100% of the costs are UK based. We therefore provide a separate estimate for the “Big 3” manufacturers, which represent 90% of the UK market. According to Nielsen data, JTI, Imperial & Scandinavian Tobacco Group (STG) account for 36% and 18% and 36% of the UK cigar market respectively. It follows that they account for 40%, 20% and 40% of the “Big 3” sector of the market respectively.
227. STG doesn’t have any manufacturing locations in the UK, and Imperial only manufacture cigarettes in the UK<sup>77</sup>. It is assumed that 100% of JTI’s market share is produced at their UK factory. Following from the above logic, in the 10 year period after the introduction of the TPD2 the proportion of UK consumed cigars that comes from UK-based production from this factory is around 4%. We then estimate the statistically expected level of production, with a 1 in 20 chance of this factory

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<sup>74</sup> ASH factsheet 18 tobacco Industry, quoting Annual Cigarette Synopsis. Citi Research, 25 March 2014 as original source. Available at [http://www.ash.org.uk/files/documents/ASH\\_123.pdf](http://www.ash.org.uk/files/documents/ASH_123.pdf). Note that although 85% of the UK market may be supplied by them some of that production may be non-UK based. The Imperial factory produces around 17 billion sticks per year i.e. equivalent to around 46% of the 37 billion in the UK market (see Imperial press release 15/4/2014 available at <http://www.imperial-tobacco.co.uk/index.asp?page=78&newsid=2000>). The proportion exported is not known.

<sup>75</sup> Closure date May 2016. Nottingham Post 18/6/2014 available at <http://www.nottinghampost.com/Redundancypackage-agreed-Imperial-Tobacco-staff/story-21255473-detail/story.htm>

<sup>76</sup> Correspondence from JTI to Northern Ireland Office 7/10/14 “all manufacture at Lisnafillan ceasing by the second quarter of 2017”. Consistent with JTI press release 7/10/14 which discusses closure of this factory as well as one in Belgium stating “factory closures completed between 2016 and 2018.”

<sup>77</sup> <http://www.imperial-tobacco.co.uk/index.asp?page=137>

producing 40% of sales and a 19 in 20 chance of it producing 4%. This results in an expected UK share of cigar manufacturing of 5.8%.

228. The total estimate for the UK share of the “big 3” sector of cigar manufacturing is therefore 5.8%. Note that this estimate is not applied to the estimate of relabelling costs for smaller distributors & importers of cigars, which is already based only on the burden on UK businesses.
229. This figure is also applied to the pipe tobacco market, a niche market that is most similar to cigars. DH has no information on the production of pipe tobacco in the UK beyond inferences possible from the very small number of tobacco manufacturers notified to us.
230. The above methodology may overestimate the impact that TPD2 has had on the decision to close factories, especially as production is potentially switching to other EU countries covered by TPD2 (Poland or Romania)<sup>78 79</sup>. It would seem more likely that these decisions are made on the basis of production costs and efficiency. On the other hand however some head office functions remain based in the UK and these will provide some value-added to the production process, although this is difficult to quantify.
231. The above describes how much impact is UK attributed for EANDCB purposes. For NPV purposes the share of the impact that falls on the UK is based on shareholder residence, which is estimated to be 10% for the entire tobacco industry.<sup>80</sup>
232. For herbal products for smoking, where little is known about shareholders or manufacturing locations, we assumed that 100% of impacts are UK based.
233. Further evidence on the proportion of activity that is UK based was sought during the consultation but no further evidence was received. We therefore apply the same methodology used in the consultation IA.
234. E-cig Intelligence report that the vast majority of e-cigarettes and e-liquids are currently produced in the Shenzhen region of China. They have also produced an assessment of the UK market for e-cigarettes<sup>81</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. E-cig Intelligence 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 linked these brands to Nielsen ScanTrack data on smoking control products. Of the 12 brands that claimed UK-based productions, 6 could 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.
235. 41% of total e-cigarette sales<sup>82</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

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<sup>78</sup> <http://www.jti.com/media/news-releases/jti-consult-proposal-restructure-manufacturing-facilities-europe/>

<sup>79</sup> <http://www.telegraph.co.uk/finance/newsbysector/retailandconsumer/leisure/10768270/Imperial-Tobacco-calls-time-on-last-UK-factory.html>

<sup>80</sup> The 10% is not based on any one specific source, but was stated clearly during the consultations on Standardised Packaging of Tobacco. However, it does draw on 3 pieces of information. Firstly 10% is a figure used for previous IAs for the proportion of multinational profits that should be considered in the NPV. Secondly there is some information on the shareholdings of multinational tobacco companies, however, this is information about the institutional shareholdings rather than the individual shareholdings. Thirdly, if one was to assume a perfectly globalised market where all companies were multinational, then the proportion of profits received by UK shareholders would be approximately the ratio of GDP for the UK to that of the world which is around 3-4% (IMF – World Economic Outlook Database) using current prices and 2014 figures.

<sup>81</sup> <http://ecigintelligence.com/data-in-depth-uk-e-cig-brands-products-pricing-analysis/>

<sup>82</sup> Sales data relate to all identified e-cigarette related products, including disposables and e-liquid refill vials.

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.

236. Due to the design of the 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>83</sup> <sup>84</sup>.
237. 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 that we do know results in an estimate of 92% of manufacturing occurring outside of the UK.
238. 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 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.
239. Responses received in the consultation suggest that manufacture is increasingly moving from the UK to China, particularly that of e-liquids. However no specific evidence was received to inform our estimates. We therefore make the assumption that the proportion of sales by UK based brands increases from 16% of sales identified for the top 20, to 20%. Carrying through the calculation as above this means 8% of total sales can be identified as coming from UK producers. Assuming the same proportion of the remaining unknowns are UK based gives an estimate of 9.5% for the proportion of e-cigarette economic activity that is UK based. This represents a 25% increase on the figure used in the consultation IA.
240. For NPV purposes, a proportion of 10% is assumed. This is consistent with the proportion used for EANDCB purposes as well as being the same as that assumed for the tobacco industry, reflecting the growing presence of the major tobacco manufacturers in the e-cigarette industry.
241. For the impacts on the advertising industry from the restrictions on e-cigarette advertising we assume that 100% of the cost is UK based. The UK has a strong and growing advertising industry<sup>85</sup> and it is therefore likely that most e-cigarette companies will use UK based agencies for their UK advertising.

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<sup>83</sup> <http://www.birminghampost.co.uk/business/bromsgrove-electronic-cigarettes-firm-e-lites-3907715>

<sup>84</sup> <http://grocerytrader.co.uk/?p=17905>

<sup>85</sup> <http://www.thecreativeindustries.co.uk/industries/advertising/advertising-facts-and-figures/advertising-headline-statistics>

**Summary table – Option 1**

Category	Sub-category	Total cost (millions)	In EANDCB	In NPV	Para.
<b>Health gain</b>		<b>£13,000</b>	<b>0%</b>	<b>100%</b>	<b>74-76</b>
<b>Reduced labelling</b>		<b>£6.6</b>	<b>8.1%</b>	<b>10%</b>	<b>77-79</b>
<b>E-cigarettes</b>		<b>Unquantified</b>	<b>-</b>	<b>-</b>	<b>80-83</b>
<b>TOTAL BENEFIT</b>		<b>£13,000</b>	<b>£0.53</b>	<b>£13,000</b>	
<b>Tax loss</b>		<b>£2,000</b>	<b>0%</b>	<b>100%</b>	<b>94-98</b>
<b>Profit loss</b>	Retail	£78	100%	0%	85-93
	Wholesale	£42	100%	0%	85-93
	Manufacture	£74	8.1%	0%	85-93
	<b>Total</b>	<b>£190</b>	<b>£130</b>	<b>£0</b>	<b>85-93</b>
<b>Notifications</b>	Cigarettes/HRT	£0.23	8.1%	10%	100-103
	Cigar/pipe	£1.2	5.8%	10%	100-103
	Priority additives	£8.4	8.1%	10%	104-107
	Herbal	£0.03	100%	100%	108-109
	NTPs	£0.034	8.1%	10%	110-113
	<b>Total</b>	<b>£9.8</b>	<b>£0.8</b>	<b>£1</b>	<b>99-113</b>
<b>Data storage</b>	Tobacco	£0.64	0%	100%	114-119
	E-cigarette	£1.7	9.5%	10%	114-119
	<b>Total</b>	<b>£2.3</b>	<b>£0.16</b>	<b>£0.8</b>	<b>114-119</b>
<b>Labelling</b>	Cigarettes/HRT	£2.6	8.1%	10%	122-130
	“Big 3” Cigars	£0.21	5.8%	10%	131-137
	Other cigar/pipe	£3.6	100%	100%	131-137
	Herbal	£0.8	100%	100%	138-140
	<b>Total</b>	<b>£7.2</b>	<b>£4.6</b>	<b>£4.7</b>	<b>120-140</b>
<b>Cross-border distance sales</b>	Registration	£0	100%	100%	144-147
	Age verification	£0.039	100%	100%	144-147
	<b>Total</b>	<b>£0.039</b>	<b>£0.039</b>	<b>£0.039</b>	<b>144-147</b>
<b>Illicit &amp; CBS</b>	Retail profit	£10	0%	100%	148-155
	Wholesale profit	£6.1	0%	100%	148-155
	Manufacturer profit	£11	0%	10%	148-155
	Lost tax	£160	0%	100%	148-155
	<b>Total</b>	<b>£190</b>	<b>£0</b>	<b>£180</b>	<b>148-155</b>
<b>E-cigarette</b>	Advertising	£47	0%	100%	166-174
	Sales reporting	£0.93	9.5%	10%	175-178
	Toxicology/emissions	£5.3	9.5%	10%	179-182
	Notification	£2.7	9.5%	10%	183-185
	Familiarisation	£0.17	9.5%	10%	190
	Labelling	£52	9.5%	10%	158-162
	Cross-border distance sales	£1.4	9.5%	10%	163-165
	Child/tamper proofing	£9	9.5%	10%	191-193
	Branding	£23	9.5%	10%	209-217
	<b>Total</b>	<b>£140</b>	<b>£9</b>	<b>£57</b>	<b>156-217</b>
<b>TOTAL COST</b>		<b>£2,500</b>	<b>£140</b>	<b>£2,200</b>	

## Assessment of Impact of Option 2

243. Option 2 considers the impacts of any provisions in which the UK has gone beyond the minimum requirements and gold-plated TPD2. The costs and benefits are therefore assessed relative to Option 1, although the summary sheets at the front of the IA show the full costs relative to Option 0.

### **Benefits (Option 2)**

#### UK government revenue from charging industry

244. The TPD2 allows for industry to be charged directly for the cost of the regulatory regime in some areas. Taking up this option would create a benefit to the government over Option 1, with an equivalent cost to industry. However, as the tobacco industry consists of large multi-national companies, this would represent a shift in the cost away from the UK government, to firms that are only partly UK based (as discussed above). It is therefore likely to yield a net benefit for UK tax payers.
245. Consultation responses largely supported this choice as the tobacco industry is very profitable and should bear some of the costs created by the harmful products it sells. One of the large tobacco manufacturers also agreed with the principle of charging, provided the fees charged reflect actual costs and are calculated transparently.
246. The costs to industry of taking up this option are considered in the “costs” section below.

#### Verification of TNCO levels in cigarettes

247. The contract for verification of TNCO data currently costs the DH £130,000 per year, with a further cost for contract management and monitoring contact with companies, estimated at £30,000 annually. Assuming that these costs remain constant in real terms means that charging for verification of TNCO would provide annual revenue of £160,000 to government over Option 1.

#### Processing and storing data from notifications

248. As described under Option 1, the cost to the Government of storing and processing the data provided by tobacco manufacturers for product notification is £320,000 initially with a recurring annual cost of £42,000. There is therefore annual revenue to the government of this value over Option 1.

#### Health benefit from reduced prevalence

249. It is expected that applying the full labelling regime to tobacco products other than cigarettes & HRT (with exemptions for individually wrapped cigars, and cigars weighing above 3g) will make some contribution to reduced smoking prevalence. Whilst this is left unquantified in the NPV, we consider here for illustrative purposes the number of fewer smokers that would be required for these benefits to offset the additional costs associated with this labelling.
250. The additional labelling costs under Option 2 compared to Option 1 are around £5.5 million (see below). Every additional non-smoker provides a net benefit of £58,000.<sup>86</sup> However this assumes that an additional non-smoker of cigars or pipe tobacco will provide the same benefit as an additional non-smoker of cigarettes or HRT. Due to different usage patterns this may not be true. Adjusting the net benefit per additional non-smoker in proportion to the relative amounts of tobacco smoked by cigar or pipe smokers, compared to cigarette or HRT smokers, gives a reduced estimate of £44,000.<sup>87</sup>

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<sup>86</sup> 1.2 additional life years valued at £60,000 per year minus a tax loss of £11,000 (see Option 1 section)

<sup>87</sup> Data on the average number of cigarettes smoked per day taken from ONS Opinions & Lifestyle Survey 2013 and multiplied by 0.7 grams of tobacco per cigarette. Then total grams of cigar and pipe tobacco cleared (from HMRC Tobacco Tax Bulletin) divided by the number of cigar or pipe smokers gives an estimate of tobacco consumed by

251. Using this estimate, around 130 additional non-smokers would be needed to off-set the additional labelling costs.
252. Using data on the prevalence of cigar and pipe smoking<sup>88</sup> suggests that there are around 270,000 smokers of tobacco other than cigarettes and HRT in the UK. Therefore this population would need to decrease by approximately 0.047% for the health benefits to off-set the additional labelling costs.
253. Given that the EU IA estimates labelling and packaging changes to reduce prevalence by 1-1.5%, we expect applying the full regime to cigars & pipe tobacco (with the exceptions of individually wrapped cigars, and cigars weighing above 3g) to reduce prevalence by at least 0.047%, if not higher.

### **Costs (Option 2)**

#### Transitional provisions for tobacco products, e-cigarettes and herbal products for smoking

254. The TPD2 permits Member States to allow the sell through of old stock at retail level until May 2017, so long as the tobacco or herbal product was produced before May 2016, and that the product is compliant with the old regulatory regime or for e-cigarette that was produced before November 2016.
255. Implementing these transitional provisions is preferred as it allows retailers to sell stock they have already paid for which would otherwise become obsolete. This may be of particular benefit to small and micro businesses with lower, less consistent sales volumes. The additional cost is that it may be possible for old packs of fewer than 20 cigarettes or old labelling to persist which is likely to undermine the health benefits. We expect this effect to be small relative to the NPV of the policy given what we expect to be a relatively short sell through period compared to the enduring timescale for benefits.
256. The costs and benefits are unchanged from Option 1.

#### Choice of health warnings

257. The TPD2 provides a number of options on the wording prescribed in the health warnings:
258. For tobacco products
  - a) 'Smoking kills': or
  - b) 'Smoking kills – quit now'
259. And for e-cigarettes
  - a) 'This product contains nicotine which is a highly addictive substance'; or
  - b) 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'
260. The Government intends to adopt option b for tobacco products and option a for e-cigarettes because these options support other policies to encourage smokers to quit and position e-cigarettes as an alternative to smoking.
261. The costs of either option are deemed to be the same but adopting the second option in both cases would, in the Department of Health's opinion, strengthen the public health message and give the best chance for the health benefits to be realised.
262. Consultation responses largely supported this choice as it is a change from the current message and is clear and action oriented.

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each of these. This gives estimates of 8.46 grams of tobacco for cigarette or HRT smokers and 6.4 grams per day for cigar or pipe smokers

<sup>88</sup> ONS General Household Survey 2011 is the latest data available

### Labelling/packaging costs for pipe tobacco and cigars

263. Option 1 exploits the flexibility allowed by the TPD2 in requiring a less onerous labelling regime (i.e. smaller labels without pictures) on tobacco products other than cigarettes, HRT and water pipe tobacco (i.e. cigars, pipe tobacco etc.) on the basis that these products are generally not attractive to children. However, under Option 2, the Government will adopt the lesser labelling regime for individually wrapped cigars and cigarillos. The Government will also adopt the lesser labelling regime for cigars weighing above 3g.
264. Individually wrapped cigars and cigarillos are exempt from the stricter labelling regime as it is difficult to apply the full labelling to these small packs and full labelling could diminish the impact of health warnings. Limiting the derogation to these products is also in line with the current regulation of these products in the UK implementation of TPD1, which also applies less stringent labelling to these products.
265. The exemption from the stricter labelling regime also applies to cigars weighing above 3g. The derogation of these products aims to reduce the cost burden of relabelling on UK distributors in the handmade cigar market, whilst providing a requirement that is easy to enforce. This aims to address the concern that the costs of adhering to the full labelling regime (annual rotation of picture warnings covering 65% of the front and back surfaces) would fall disproportionately on small and medium sized importers of handmade cigars in the UK because of the large number of low selling SKUs in this market. The definition of cigars above 3g is expected to capture 99.5%<sup>89</sup> of the handmade cigar market. It may also capture a small proportion<sup>90</sup> of machine made cigars sold in packs. Any costs incurred by manufacturers or distributors of machine-made cigars are estimated assuming their adherence to the stricter labelling regime (see below).
266. There is a danger that the derogation of these products implies that they are safer than other tobacco products, which is not the case. However, the approach taken still represents a strengthening of current labelling and health messages on these products.
267. There is therefore an additional requirement for picture warnings and cessation information for tobacco products excluding cigarettes, HRT, individually wrapped cigars and cigarillos, and cigars weighing above 3g under Option 2.
268. The costs incurred will be higher than under Option 1. 90% of the UK cigar market consists of machine-made cigars, sold by large tobacco companies (Imperial, JTI and Scandinavian Tobacco Group). The production process in this sector is likely to be similar to that of cigarettes therefore a relabelling cost per SKU is applied, using estimates from the RAND Europe study. Using Nielsen data we have estimated that these companies sold 69 different SKUs. Applying the cost for a minor relabelling<sup>91</sup> (as rebranding is still not required) gives a one-off cost of £170,000 the same as under Option 1. There is an additional one-off cost for applying pictorial warnings. The RAND study estimated this to be £220 to £1,300. Applying the mid-point of this, £780, to the 51 SKUs which are not individually wrapped gives an additional one-off cost of £40,000 over Option 1.
269. The requirement for pictorial warnings, and the requirement that individually wrapped cigars carry text warnings for the first time, will give a further recurring annual cost. The RAND study estimates the recurring annual cost of text warnings for cigars to be £150 to £300. Applying the midpoint, £220, to the 18 individually wrapped SKUs gives a recurring annual cost of £4,000, the same as under Option 1. The RAND study estimates the recurring annual cost of pictorial warnings for cigars to be £170 to £370.

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<sup>89</sup> Figure provided by industry and is consistent with stock keeping unit data which was also provided.

<sup>90</sup> Information from industry suggests this is around 3% of the cigar market.

<sup>91</sup> Previously estimated as £2,500 under Option 1 relabelling costs section

Applying the midpoint, £270, to the 51 SKUs that are not individually wrapped gives a recurring annual cost of £14,000 over Option 1.

270. There is therefore an additional one-off cost of £40,000 and an additional recurring annual cost of £14,000 for Option 2 over Option 1.
271. Beyond this, 9.2% of the market is machine-made cigars imported and sold by smaller distributors. According to information gathered in consultation, currently the foreign manufacturers take responsibility for ensuring packs meet labelling requirements. However costs will still be incurred due to relabelling. As under Option 1 some manufacturers will no longer supply certain low volume SKUs under the new requirements leading to a loss of profits for UK based distributors and retailers. However the loss of profits on these SKUs is expected to be offset by increased profits on others in the same industry, therefore no cost is included in EANDCB or NPV.
272. There will be a cost due to expected write off of non-compliant stock not sold during the sell-through period. Evidence from the same distributor was used to estimate this cost. However the estimate provided did not account for the exemption for individually wrapped cigars and cigarillos. The Nielsen data shows that approximately 37% of cigar SKUs are individually wrapped<sup>92</sup>. Therefore the estimated increased costs for complying with the full labelling regime that were provided are reduced by 37% to reflect this exemption. Therefore this will result in a one-off cost of £150,000 over Option 1.
273. The remainder of the UK cigar market (0.8%) consists of premium hand-made cigars. The exemption of cigars weighing above 3g from the stricter labelling regime under Option 2 aims to reduce the cost burden on UK manufacturers and distributors in this sector of the cigar market, the majority of which tend to be small and medium sized businesses. Therefore, this IA considers the costs incurred by distributors and manufacturers of hand-made cigars outside of this category (in other words, for cigars weighing 3g and under) meeting the stricter labelling requirement.
274. The costs associated with the stricter labelling regime for all hand-made cigars would be incurred for printing new plates and expanding current health warning application facilities, amongst others. The entire cost of this exercise is expected to fall on UK businesses, as the foreign manufacturers of premium handmade cigars tend to delegate responsibility for labelling of these products to the importers and distributors. An estimate of the costs expected to be incurred by individual businesses in this sector were provided by the same distributor during consultation. These costs assumed no exemptions so are reduced by 99.5%<sup>93</sup>, an estimate of the proportion of handmade cigar products that weigh above 3g provided by the same distributor. This results in an expected initial cost of £9,200 and a recurring annual cost of £4,300 over Option 1.
275. Pipe tobacco will be subject to the stricter labelling requirements under Option 2. Though the market for pipe tobacco is similar to that of hand-made cigars, with small-scale distributors and retailers dealing with many low-volume SKUs, there is less variation in shapes and size of packaging. As under Option 1, we therefore scale the estimated cost of all hand-made cigars being subject to the stricter labelling regime, to estimate the cost of re-labelling for pipe tobacco. Data provided in the consultation identifies 893 cigar SKUs and 509 pipe tobacco SKUs. The cost of relabelling for pipe tobacco is therefore estimated to be 57% (509/893) of that for handmade cigars<sup>94</sup>,

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<sup>92</sup> Nielsen ScanTrack data misses out many smaller specialist retailers. It is possible that these stores may have a higher proportion of individually wrapped cigars SKUs. This is explored in the sensitivity analysis

<sup>93</sup> Note this 99.5% figure includes the exemption for individually wrapped cigars.

<sup>94</sup> The reduction to account for individually wrapped cigars and cigars weighing over 3g are not applied as all pipe tobacco will be subject to the full requirements

giving an initial cost of £1 million and an annual recurring cost of £490,000 over Option 1.

#### Notification costs for novel tobacco products

276. The TPD2 provides for Member States to implement either a notification scheme or a prior authorisation scheme for NTPs. An authorisation scheme would introduce significant costs for both the industry and any organisation charged with administering the scheme.
277. The Government intends to adopt a notification scheme as the protections this provides are likely to mean that the additional benefit of a prior authorisation scheme would be outweighed by the cost it imposes. Option 2 is therefore identical to Option 1.
278. Consultation responses largely supported this choice as it is consistent with the treatment of normal tobacco products and therefore avoids implying that NTPs are safe, as an authorisation scheme might.
279. The costs and benefits are unchanged from Option 1.

#### Cross-border sales of tobacco products & e-cigarettes

280. There is the option to ban sales of tobacco products, e-cigarettes and refills that cross Member States borders e.g. internet retail sales to and from the UK or to introduce a registration scheme and age verification requirement.
281. Introducing such a ban is likely to put businesses at a competitive disadvantage compared to business in member states who do not adopt the ban.
282. We have no evidence that there is a significant amount of illicit trade on-line or that cross border sales form a significant route for the sale of cigarettes to minors. The Government is therefore minded to adopt a registration scheme and Option 2 is therefore identical to Option 1.
283. The costs and benefits are unchanged from Option 1.

#### Peer review

284. The TPD2 will bring new Member State responsibilities for banning products containing additives that have been shown to increase the toxic or addictive effect, or carcinogenic, mutagenic or reprotoxic properties of tobacco products. To aid them in making those decisions the TPD2 provides that manufacturers will be required to carry out comprehensive scientific studies into certain additives and submit their studies to Member States and to the Commission.
285. Member States have the option to require the scientific reports “to be peer reviewed by an independent scientific body, in particular as regards their comprehensiveness, methodology and conclusions.” The Government intends to adopt this provision and decide on a case by case basis whether peer review is required.
286. Consultation responses largely supported this choice as it ensures that information received is accurate and is therefore important for consumer safety.
287. It is expected that the European Commission will co-ordinate the peer review of priority additives at EU level. In most cases the Government will be satisfied with the European Commission using EU scientific committees to assess the quality of reports. As such, we do not expect that all of the expected 15 additives will require Government commissioned peer review. For this IA we assume that approximately half of the additives, 8, will require additional peer review.
288. The precise cost of peer review will depend on how robust an assessment is required. However, we can estimate the approximate order of magnitude of costs.<sup>95</sup>

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<sup>95</sup> Internal DH analysis

Government peer review would be expected to use the Committee on Toxicity (COT), Committee on Carcinogenicity (COC) and Committee on Mutagenicity (COM) as appropriate. Based on current contractor costs for preparing reviewing information and papers for the committees we estimate the cost of preparing papers for such a review by the committees to be £19,000 - £27,000. A further cost will be associated with the sitting of the three committees to discuss the findings of each peer review. We estimate the costs for attendance and reading fees for chairmen and committee members at £800 - £2,400 per review. Taking the central points of these two costs results in a total cost per additive of £25,000. Across 8 additives this results in a total cost of £200,000. Given that the government intends to take up the option to charge industry under Option 2, this cost will fall on the tobacco industry.<sup>96</sup>

289. Responses from the consultation have not suggested that this cost estimate is unreasonable and it is therefore unchanged from the consultation IA.

#### Cost to industry of charging industry<sup>97</sup>

290. The TPD2 allows for industry to be charged directly for the cost of the regulatory regime in some areas. The Government intends to charge the industry proportionate fees, which will be subject to a separate consultation exercise and agreed post-implementation of TPD2. Therefore costs for existing services, such as the verification of TNCO will continue to be borne by the UK tax payer, until a charging regime is agreed and implemented.
291. As the tobacco industry consists of large multi-national companies, charging will shift the cost from the government and therefore is likely to represent value for money for UK tax payers. The costs described here are therefore equivalent to those in the above "benefits" section, although only a portion of these are included in the NPV & EANDCB.

#### *Verification of TNCO levels in cigarettes*

292. The contract for verification of TNCO data currently costs the DH £130,000 per year, with a further cost for contract management and monitoring contact with companies, estimated at £30,000 annually. Assuming that these costs remain constant in real terms means that charging for Article 4 would produce a cost of £160,000 to industry over Option 1 where costs fall on Government.

#### *Processing and storing data from notifications*

293. As described in the Option 1 section, the cost to the government of storing and processing the data provided by tobacco manufacturers for product notification is £320,000 initially with a £42,000 recurring annual cost. There is therefore a cost to the tobacco industry of this value over Option 1 where costs fall on Government.

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<sup>96</sup> Estimates based on DH internal analysis

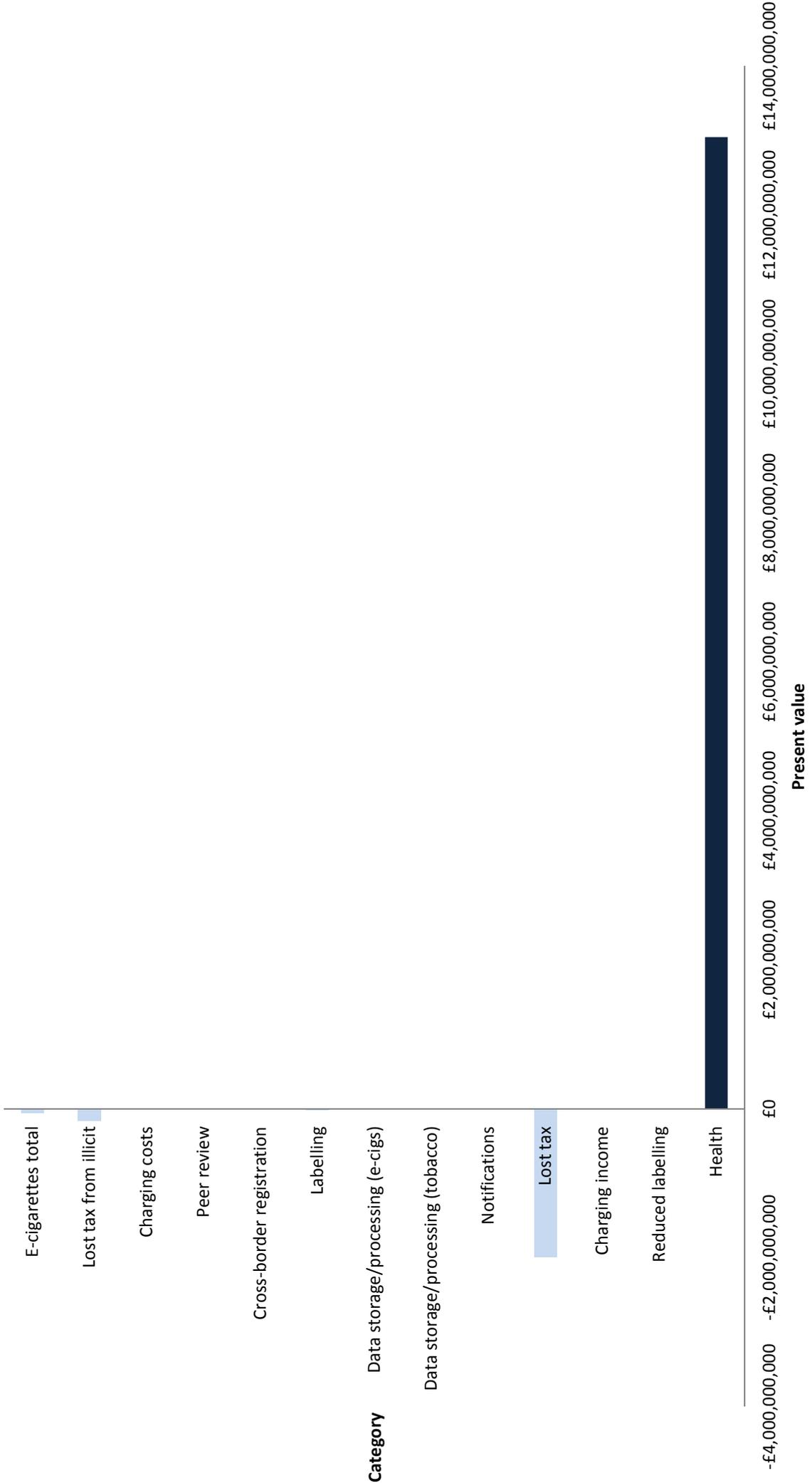
<sup>97</sup> Excluding peer review which has been estimated in the peer review section

**Summary table – Option 2**

Category	Sub-category	Marginal cost over Option 1 (millions)	In EANDCB	In NPV	Para.
<b>Charging</b>		<b>£2</b>	<b>0%</b>	<b>100%</b>	<b>241-245</b>
<b>TOTAL BENEFIT</b>		<b>£2</b>	<b>£0</b>	<b>£2</b>	
<b>Labelling</b>	"Big 3" Cigars	£0.16	5.8%	10%	268-270
	Other cigar/pipe	£5.5	100%	100%	271-275
	<b>Total</b>	<b>£5.6</b>	<b>£5.5</b>	<b>£5.5</b>	<b>263-275</b>
<b>Peer review</b>		<b>£0.2</b>	<b>8.1%</b>	<b>10%</b>	
<b>Charging</b>		<b>£2</b>	<b>8.1%</b>	<b>10%</b>	
<b>TOTAL COST</b>		<b>£7.9</b>	<b>£5.7</b>	<b>£5.7</b>	

Note: Numbers may not add up due to rounding.

**Graph 2 – Option 2 Net Present Value**



## Changes to Analysis Following Consultation

294. After further research and consideration of the consultation responses received, the following changes to the analysis of the impact of TPD2 have changed since the consultation IA was published.
- The timing of the expected reduction in prevalence has been adjusted to reflect that the ban on menthol cigarettes will only apply from 2020.
  - The methodology used to estimate the costs of the labelling requirements on other tobacco products for smoking (cigars & pipe tobacco) has been updated to incorporate concerns expressed by the industry in consultation responses. Evidence supplied by the industry is used to estimate the cost under both Option 1 and Option 2.
  - Additional costs relating to an expected increase in the illicit tobacco trade have been included. This results in reduced profits to business and further losses in tax revenue to the exchequer.
  - The cost of notifying novel tobacco products has been estimated.
  - The cost of reporting on the list of priority additives has been changed to reflect concerns expressed during the consultation that the IA had underestimated this cost.
  - A full assessment of the cost to the e-cigarette industry due to TPD2 has been made.
  - The impact of restricting advertising of e-cigarettes has been estimated.
  - The cost of registering for cross-border sales of tobacco and e-cigarettes and verifying the age of customers has been estimated.
  - The estimate of the cost to government (and to business) of processing and storing the data provided by the tobacco and e-cigarette industry has been refined.
  - The charging the e-cigarette industry for the cost of processing and storing data provided is no longer considered to be gold-plating and is therefore part of Option 1.
  - Estimates of the proportion of economic activity that is UK based for cigars & e-cigarettes have been changed to reflect new information & the consultation responses.
  - An illustrative estimate has been made considering the benefits of applying the full labelling regime to cigars & pipe tobacco (excluding individually wrapped cigars & cigarillos and cigars weighing over 3g).
  - Estimates have been updated to reflect 2015 prices and latest figures where possible.

## Equivalent Annual Net Direct Cost to Business

295. This section assesses the regulatory costs imposed on business by TPD2. Only direct costs to UK business are included, as shown in the table below<sup>98</sup>.
296. This gives an EANDCB of £15.7 million under Option 1. This is out of scope of OITO as it implements EU regulation at the minimum cost to business. It is shown here to illustrate the regulatory burden imposed by the EU.
297. There is an EANDCB of £0.63 million for the gold-plating included in Option 2. This is in scope of OITO as it involves costs to business as a result of the gold-plating of EU regulations.

### Summary table - EANDCB

	Category	Present value of cost to business
<b>Option 1</b>	Reduced labelling (benefit)	£530,000
	Profit loss	£130,000,000
	Notifications	£800,000
	Data cost (e-cigs)	£160,000
	Labelling	£4,600,000
	Cross-border distance sales	£39,000
	E-cigarettes	£9,000,000
	<b>Total</b>	<b>£141,000,000</b>
<b>Option 2 (marginal)</b>	Charging	£160,000
	Peer review	£16,000
	Labelling	£5,500,000
	<b>Total</b>	<b>£5,700,000</b>

Note: numbers may not add up due to rounding.

<sup>98</sup> Reduced profits attributable to the impact of banning menthols were assessed over a different time frame due to this aspect of the policy only applying from 2020. However to calculate the EANDCB this cost is assumed to occur concurrent with the other costs. This means the EANDCB will be larger as these costs are discounted less than they should be.

## Sensitivity Analysis

298. There are three main findings from the IA.
- a) NPV for Option 1 or Option 2 compared to Option 0 are very large and positive.
  - b) EANDCB for Option 1 is positive and around £16 million.
  - c) EANDCB for Option 2, incremental on Option 1 is positive and around £0.63 million (£16.4 million in total).
299. All of the costs and benefits estimated above are subject to uncertainty. We therefore conducted sensitivity analysis around the value of certain key variables to determine the degree of certainty surrounding these three findings.

### NPV

300. The most sizable benefits of this policy are the health benefits driven by reduced smoking prevalence. The only cost of a similar magnitude is the cost to the exchequer due to lost taxes, again driven by reduced smoking prevalence. Therefore, the key variable included in the analysis is the 1.9% reduction in smoking prevalence that is expected as a result of TPD2. This figure was based on the estimate made in the EU impact assessment which is derived from the impacts of similar policies around the world. Such an estimate will always be subject to considerable uncertainty due to the difficulty of isolating and measuring the impacts of policies.
301. Other considerations such as the impact of changes in the illicit market and the market for e-cigarettes may also impact upon prevalence. It is estimated that over 1 million people are using e-cigarettes, having completely stopped smoking<sup>99</sup>. The regulations on e-cigarettes included in TPD2 may reduce their attractiveness to smokers and could therefore have a negative impact on smoking prevalence. This would detract from the overall reduction in prevalence expected as a result of TPD2. Whilst we do not expect this to happen, the sensitivity analysis considers the impact of TPD2 if the reduction was less due to this or other uncertainties.
302. As part of the uncertainty around the estimate of reduced prevalence provided in the EU IA is a result of sampling, we base our estimate of this uncertainty on the confidence intervals from the ONS Integrated Household Survey, 2014.<sup>100</sup> This measures smoking prevalence in the UK and is representative of the surveys that will have been used to measure the impacts of previous tobacco policies and therefore estimate the expected reduction in prevalence due to TPD2. The confidence interval is equal to 0.21 percentage points above and below the central estimate. We increase this by 50%, to 0.32 percentage points, to reflect the other uncertainties, besides sampling. For example, the uncertainty surrounding what would have happened without the intervention.
303. If the change in prevalence was 0.32 percentage points larger there would be higher health benefits but also higher tax losses. Under this scenario the NPV is equal to around £20.6 billion under Option 1 & Option 2
304. If the change in prevalence was 0.32 percentage points smaller there would be lower health benefits but also lower tax losses. Under this scenario the NPV is equal to around £1 billion under Option 1 & Option 2.
305. This shows that the finding of a large and positive NPV is robust. The NPV only becomes negative if the change in prevalence is 2.2% or less of the expected value.

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<sup>99</sup> ASH estimates - Methodology: Calculations are by ASH and King's College London. We applied the proportions of e-cigarette use by smoking status in the 2015 YouGov survey to the most recent available ONS mid-year GB population estimates (2012).

<sup>100</sup> Note that this survey was not used to estimate prevalence in earlier sections because it does not include 16 & 17 year olds, however it provides an example of the level of uncertainty involved in measuring prevalence, and similarly, impacts of policies on prevalence

306. Although the key variable is the change in smoking, this is not to say that this is the only variable that would have an impact. For example, there is uncertainty in the value of smoking prevalence in May 2016. However this is very small when considered against the importance of the uncertainty in the change in prevalence created by TPD2.
307. It should be noted that as well as the uncertainty in the numbers included in this IA there is uncertainty in how these numbers are constructed and modelled. For example, the extent to which “fewer smokers” is modelled from fewer starters and more quitters. Similarly there is uncertainty surrounding variables that are not included in the model. For example, there are other benefits and costs from reduced smoking e.g. the UK having a healthier more productive workforce or those quitting losing the enjoyment of smoking (if they had any beyond sustaining their addiction). These omitted details are much lower than those of health benefits and tax considered here. However, ever more realistic models come at various costs and the impact on the main finding is considered small enough that including them would be considered disproportionate.

***EANDCB under Option 1***

308. Graph 3 below highlights which costs have most impact on the final EANDCB value for Option 1.

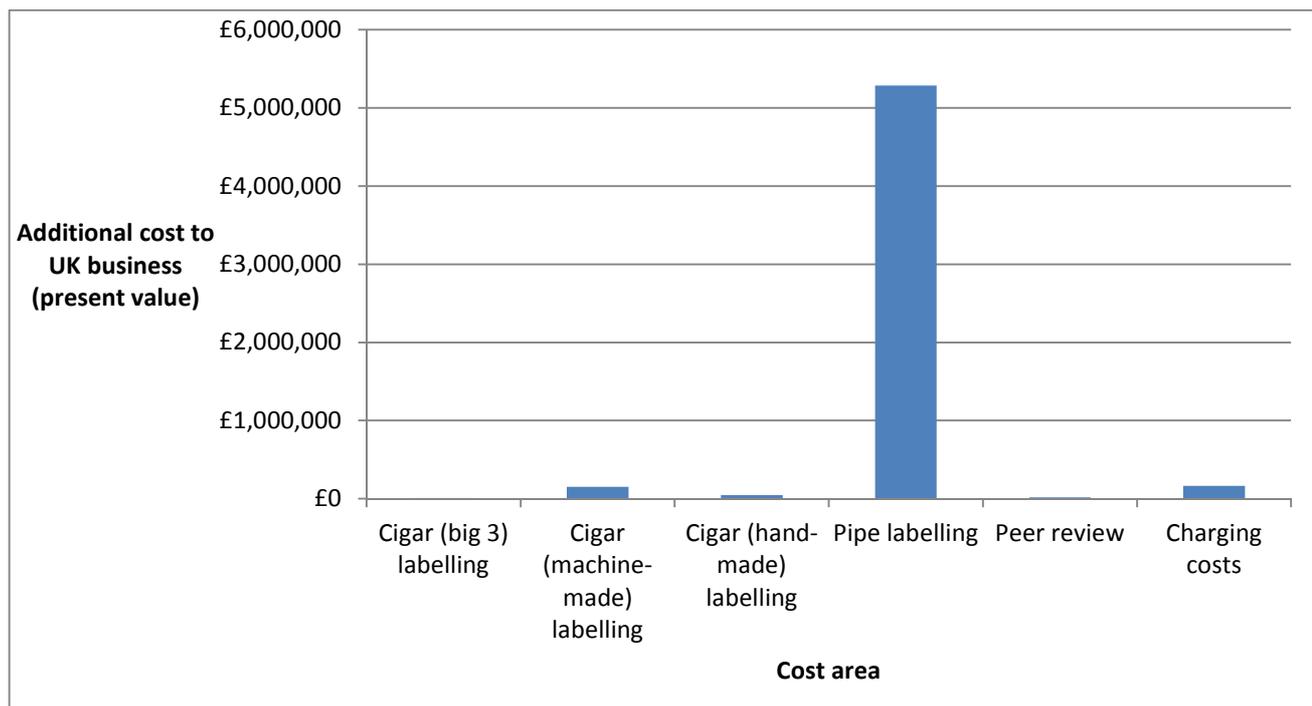


309. The largest contributor to the EANDCB is the loss of profits due to reduced tobacco consumption, particularly to retailers. The other large costs are the loss of profits to advertising agencies due to restrictions on e-cigarette advertising and, to a lesser extent, the costs to the e-cigarette industry for toxicology test and labelling requirements. We explore the uncertainty around these key costs in this sensitivity analysis.
310. There is some uncertainty surrounding the profit losses to retailers, wholesalers and manufacturers due to reduced tobacco consumption. The key variable in these estimates is the expected reduction in smoking prevalence as a result of TPD2. We therefore consider a high estimate where the change in prevalence is 0.32 percentage points greater and a low estimate where it is 0.32 percentage points smaller (as explained above).
311. There is considerable uncertainty surrounding all the estimates relating to the e-cigarette industry, as described in the “E-cigarettes” section under Option 1 and in Annex B. High and low estimates have therefore been made for each of these costs, shown in more detail in Annex B. In addition to this there is uncertainty in the proportion of the total costs that will fall on the UK. We therefore adjust this proportion to be 50% higher in our high estimate and 50% lower in the low estimate.
312. Using all the higher estimates described above the value of the EANDCB for Option 1 increases to £29 million.
313. Using all the lower estimates described above the value of the EANDCB for Option 1 decreases to £2.6 million.

#### ***EANDCB under Option 2***

314. Graph 4 below highlights which costs have the most impact on the marginal EANDCB value for Option 2 over Option 1.

**Graph 4 – Additional costs to business under Option 2**



315. The largest additional costs are to the sector of pipe tobacco industries selling products with lower volume sales, for complying with the full labelling requirements of TPD2 (compared to the less onerous regime under Option 1). We explore the uncertainty around these key costs in this sensitivity analysis.
316. These estimates rely on evidence provided in the consultation by an importer and distributor in the cigar market. One of the key uncertainties was the factor that the cost estimates provided needed to be increased by to estimate the cost to the entire industry. Therefore for a high estimate we increase this by 50% whilst for a low estimate we decrease it by 50%.
317. There are additional uncertainties around the cost estimates provided by industry. For example, there was no detailed evidence on this particular point from the consultation specifically from the pipe tobacco industry. As there is less variation in the size and shape of the packaging of pipe tobacco<sup>101</sup>, the costs of re-labelling are expected to be lower than the costs facing the handmade cigar industry, were all handmade cigars subject to the stricter labelling regime. However, there is no further information to draw upon to help quantify the extent of these uncertainties. To illustrate this uncertainty for our high estimate we increase the costs provided by 25% whilst for a low estimate we decrease it by 25%.
318. Using all the higher estimates described above the value of the EANDCB for Option 2 over Option 1 increases to £1.5 million.
319. Using all the lower estimates described above the value of the EANDCB for Option 2 over Option 1 decreases to £0.32 million.

## Specific Impact Tests

### Small and Micro Business Assessment (SaMBA)

<sup>101</sup> See paragraph 275 of the IA .

320. We do not believe that the health benefits identified, or the unquantified improvement in market functioning due to harmonisation across the EU, could be realised by exempting SMBs from the regulations as they are contingent on consistent application. It would not be possible, therefore, for the benefits to be realised if consumers could still purchase TPD2 prohibited tobacco products from SMBs.
321. Whilst most aspects of the TPD2 apply to organisations of all sizes, SMBs are exempt from the requirements of Article 6 (priority additive reporting list), if the relevant additive is being studied by another organisation. This will help to reduce costs to SMBs.
322. Not banning cross border selling is likely to be a benefit to small specialist distributors who may continue to operate in this area.
323. Allowing a sell through period until May 2017 will be a benefit to small tobacco & e-cigarette retailers.
324. Exempting individually wrapped cigars and cigarillos and cigars weighing above 3g from the full TPD2 labelling requirements will reduce the cost burden on manufacturers, distributors and retailers, some of which will be SMBs.
325. In terms of the gold-plating measures included in Option 2, taking up the option to charge industry will affect all businesses in relation to the number of products they intend to notify. This may therefore impact disproportionately on small manufacturers that produce a large range of low volume sales products. This may particularly affect businesses in the e-cigarette industry as well as the cigar and pipe industries.
326. As cigars & pipe tobacco (excluding individually wrapped cigars & cigarillos and cigars weighing above 3g) are not exempted from the full labelling requirements, there could be a large impact on the small and micro businesses in the industry. Many of the UK based importers, distributors and retailers of cigars and pipe tobacco are small businesses and are expected to face substantial costs for compliance, as described above.
327. The Imported Tobacco Advisory Council (ITPAC) is the trade body representing importers and distributors of tobacco and has 11 core members<sup>102</sup>, most of which are small and medium enterprises<sup>103</sup>. Of these members we have identified that 6 are not SMBs, giving a SMBs proportion of 45%<sup>104</sup>. As ITPAC may not represent the entire industry, and firms outside the trade body are more likely to be SMBs, we make an estimate of 60%, for the proportion of firms in the industry that are SMBs. The additional cost to SMBs due to the increased relabelling requirements under Option 2 is therefore estimated to be £3.3 million, over the assessment period.
328. Implementation of the TPD2 under Option 1 will generally impact upon the large multinational manufacturers of tobacco products. However a number of products, especially those in niche markets, may be produced by smaller businesses. DH tobacco notification data suggests that there are fewer than 5 small manufacturers of tobacco products located in the UK. There may be further producers of herbal products for smoking and electronic cigarettes in the UK, although market intelligence suggests the majority of the latter products are imports from China.
329. In recent years the big tobacco firms have acquired a large portion of the e-cigarette market (in terms of sales volumes), mainly through acquisitions and buy-outs. Many of these firms were previously regarded as being small and micro businesses, but we are now considering these as part of a large multinational firm, even though they may retain their original name and branding. We therefore consider a number of the UK

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<sup>102</sup> There are also three associate members; BAT, Imperial Tobacco and Gallaher Ltd

<sup>103</sup> ITPAC consultation response

<sup>104</sup> Where we could not identify whether a firm was a SMB (the case for 3 firms), we have assumed that they are SMBs

based e-cigarette manufacturers are part of large firms, and so not in scope of this SaMBA.

330. There may still be a significant portion of the e-cigarette market which is UK based and independently owned. Whilst many of the biggest brands are now owned by the large tobacco manufacturers, there remain a number of smaller manufacturers. It is likely that some portion of these will be classified as small or micro, and therefore will be affected by these regulations.
331. Annex B breaks down the costs to the e-cigarette industry by the size of the firm, showing how the costs facing SMBs are proportionally larger.
332. Using data from Euromonitor Passport for 2014, it is estimated that up to 57% of cigarette sales, 66% of cigar sales and 54% of smoking tobacco retail sales were from SMBs. The main effect on these retailers is likely to be due to changes in profits due to reduced tobacco consumption after the effects of the TPD2 are fully realised. Whilst this is expected to be offset by increased profits in other sectors of the economy, these benefits may not accrue to the same businesses, particularly in the case of specialist tobacco retailers.
333. There could also be an impact on retailers through lost “footfall” sales<sup>105</sup>. These sales are expected to decrease as a result of reduced prevalence and further due to the prohibition of smaller tobacco packs, which will lead to fewer trips to retailers being required. It has been estimated that the impact of lost footfall will be a reduction in annual turnover of £222 million for retailers (not just SMBs).<sup>106</sup> As above this is likely to be offset by spending elsewhere in the economy, but as SMBs rely on footfall sales for a greater proportion of their profits they are likely to be disproportionately impacted.
334. Whilst it is not valued in this IA, there will be a benefit to business from improved employee productivity as a result of fewer smoking breaks and less smoking related health problems. SMBs will receive a share of this expected benefit.

#### Equality Test

335. Neither implementation through copy-out nor any of the flexibilities are thought to impact on equalities. Overall, in its assessment of the impact on equality of this measure<sup>107</sup>, the Department of Health has concluded that the policy would not lead to any unlawful discrimination, harassment or victimisation of any particular group by gender, race, religion, ethnicity, sexuality, sexual orientation or disability. It is a wide-ranging policy which has potential to advance equality of opportunity by reducing health inequalities. The Departments Equality Impact Assessment is published alongside this IA.

#### Competition Test

336. Implementing the TPD2 as per Option 1 will impact upon competition. The TPD2 directly prohibits a number of product characteristics that could previously be used to compete. Much of the recent innovation in the tobacco industry has occurred in the areas of packaging design and product flavouring – such as the introduction of flavour capsules. These aspects of non-price competition may be replaced by further price competition.
337. The harmonisation of rules across EU Member States is intended to improve the functioning of the internal market, and as such may increase competitive pressures within the EU.

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<sup>105</sup> Sales of non-tobacco goods bought in addition to tobacco

<sup>106</sup> The Economic Impact of the Tobacco Products Directive from Reductions in Incidental Purchases, Oxford Economics Report, November 2013

<sup>107</sup> Tobacco Products Directive, Consultation Equalities Impact Assessment, DH

338. None of the flexibilities are thought to impact on competition, apart from not banning cross border sales which is likely to enhance competition and not put UK businesses at a competitive disadvantage.

Sustainability Test

339. Neither implementation of the TPD2 at a minimum nor any of the flexibilities are thought to impact on sustainability.

Environmental Test

340. The TPD2 may have a negative impact on the environment due to some of the product restrictions and packaging requirement imposed on the e-cigarette industry. E-liquid bottles will be restricted to 10ml capacity. The removal of larger capacities will mean more packaging is used for the same amount of liquid, therefore using more materials and creating more waste. However under the same logic, the removal of smaller packets of cigarettes and HRT will have the opposite impact.
341. Furthermore the requirement to include an information leaflet with e-cigarettes, along with the increased labelling requirements which may necessitate a fold-out label, will lead to more paper being used.

## Annex A

This Annex describes the method and data sources behind the estimation of:

- The discounted number of life years saved for a randomly chosen adult who quits smoking today.
- The discounted amount of money not spent per £1 spent on a 20-pack of cigarettes for a randomly chosen adult who quits smoking today. This value can be applied to find estimates such as the lost duty per adult quitter.

Estimates take account of the fact that many smokers quit during their lifetime, thus reducing the expected number of life years lost from starting to smoke in the first place, and reducing the expected number of life years gained by quitting today. There is a similar effect for monetary estimates.

The following main sources of data are used:

- Opinions and Lifestyle Survey (OLS, 2012) source data used to identify the age distribution of smokers and the relationship between age and the percentage of smokers who have quit. It is also used to estimate the average daily cigarette consumption.
- Doll, Peto, Boreham and Sutherland (2004), 'Mortality in relation to smoking: 50 years' observations on male British doctors' (BMJ 2004;328;1519) reports the impact of smoking on mortality, split by age of quitting smoking (if applicable).
- Office for National Statistics (ONS) National life tables, United Kingdom, 2010-12, report population mortality estimates used to transform the outputs of the doctors' study into life years saved.

The following steps are followed:

- **1. Identify an estimate of the percentage of smokers who have quit by each year of age.** We use data from OLS (2012) which reports the numbers of those who have never smoked (never smokers), current smokers and ex-smokers, by single year of age. Over time, quitting behaviour results in a decline in the proportion of current smokers among those who have ever smoked (ever smokers). This percentage declines at a fairly steady and constant rate as age increases. A linear relationship was estimated between age and the percentage of ever smokers who are currently smoking<sup>108</sup>; the results imply that 35% of ever smokers have already quit by age 35, with 1.1 percentage points of ever smokers quitting in each year thereafter. This is broadly consistent with a quit rate among current smokers of 2.5% per annum, a figure used in the literature as the background rate of quitting.
- **2. Estimate the proportion of children, who take up smoking, that will quit at various ages.** We assume that children who take up smoking now will quit at the same rate as the historical data above. The results are shown below in table A1. This is important as mortality amongst ex-smokers depends on the age at which they quit. The results are collated into different age bands defined by when they quit (alongside "lifelong smokers"), described below as the "Quit age band".

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<sup>108</sup> This is done using the 75 data points from those aged 16 to 89 inclusive. Ages over 89 are excluded so this value is not overly affected by variations due to small numbers in older ages (note the linear relationship is not very sensitive to this choice).

Table A1: Proportion of children, who take up smoking, that quit in the given quit age bands, or are 'Lifelong Smokers' and never quit (note may not sum to 100 due to rounding)

Quit age band	
Under 35	35%
35 to 44	11%
45 to 54	11%
55 to 64	11%
Lifelong Smokers	33%

- 3. Estimate the proportion of smokers that will quit at various ages.** We consider 5 age bands of current adult smokers. We use the information in table A1 to produce this estimate. We note that for a current smoker to be picked at random, they need to have already reached their age category. For example a current smoker picked at random aged 55 to 64 could not have quit at 40, since that would mean they are not a current smoker, and could not have been picked. This is also taken into account for age bands with corresponding quit age bands. For example if a 35 year old smoker is picked from the age band 35 to 44 the chances they quit in the quit age band 35 to 44 is  $11\% / (11\% + 11\% + 11\% + 33\%) = 17\%$ . However, if a 44 year old was picked the day before their 45th Birthday, there is a near 0% chance they will quit in the 35 to 44 age band. Therefore, the corresponding value in table A2 of 9% is around half of 17% (when you consider rounding).

Table A2: Proportion smokers that quit in the given quit age bands, or are 'Lifelong Smokers' and never quit

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	21%				
35 to 44	13%	9%			
45 to 54	13%	18%	11%		
55 to 64	13%	18%	22%	14%	
Lifelong Smokers	40%	55%	67%	86%	100%

- 4. Identify mortality data (by year of age and sex) for lifelong non-smokers and for the five “quit age bands”.** Mortality data are taken from Doll, Peto, Boreham and Sutherland (2004, Table 5), which lists number of deaths per 1,000 people at ages 35-44, 45-54, 55-64, 65-74 and 75-84. This information is presented at these age bands for lifelong non-smokers, as well as:
  - those who have quit between age 35-44,
  - those who have quit between age 45-54,
  - those who have quit between age 55-64, and
  - those who continue to smoke beyond age 65

These categories of smoker correspond to our quit age bands (alongside an “Under 35” band). The data are converted into relative risks by dividing the number of deaths per 1,000 in each of these four categories by the equivalent number of deaths (i.e. the number of deaths in the same age band) for the lifelong non-smokers. The Doll et al. (2004) study does not report results for all ages and quit bands and so we assume:

- The relative risk of smokers aged Under 35 is 1.
- The relative risk of those in the Under 35 quit band is 1.
- The relative risk of those in the same age as quit band (e.g. a smoker aged 45-54 in the quit band 45-54) is the same as a smoker in that age band.
- The relative risk of smokers aged 85 or over is 1.

We then observe that the average mortality rate observed in the population is made up from the mortality rates of any subpopulations weighted by the size of each sub population. We also observe that we have defined relative risk, relative to never-smokers. For any year of age and sex, these observations provide us with 6 simultaneous equations and 6 unknown mortality rates. Solving these gives us the following formulae:

- $M_{ns} = M / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{qu35} = M R_{qu35} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{q40} = M R_{q40} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{q50} = M R_{q50} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{q60} = M R_{q60} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$
- $M_{ll} = M R_{ll} / (P_{ns} + R_{qu35} P_{qu35} + R_{q40} P_{q40} + R_{q50} P_{q50} + R_{q60} P_{q60} + R_{ll} P_{ll})$

Where:

- M is the mortality estimate from the ONS life tables
  - The subscripts represent the quit age bands:
    - ns for lifetime non-smoker
    - qu35 for a smoker who quits before they are 35
    - q40 for a smoker who quits between age 35-44 (i.e. around 40)
    - q50 for a smoker who quits between age 45-54 (i.e. around 50)
    - q60 for a smoker who quits between age 55-64 (i.e. around 60)
    - qll for a lifelong smoker
  - R is the relative risk of mortality compared to a lifelong non-smoker estimated using the Doll et al study
  - P is the proportion that this subpopulation represents.  $P_{ns}$  is assumed to be the simple average of this value for those aged 16-90<sup>109</sup> of 59%. The remaining 41% of the population is split by the values in table A1 to derive the other P values.
- **5. Identify the number of life years lived from now by adults (by age band and sex), and for the five “quit age bands”.** For each combination of quit age band (or lifelong non-smokers) and sex, life tables are calculated following the method of Chiang (1984). These life tables are used to model the expected number of life

<sup>109</sup> i.e. the average of the 75 data points from those aged 16 to 89 inclusive. Older ages are excluded so this value is not overly affected by variations due to small numbers in older ages (note the average is not very sensitive to this choice).

years lived per capita for each combination of sex, quit age band, and age band: Under 35, 35-44, 45-54, 55-64, and Over 65. This is done by representing the age band by approximately the median age in each of these age bands of 25, 40, 50, 60 and 70 respectively. The results for males are seen in table A3 below and the results for females are similar and are not displayed for presentational reasons, however they are considered separately throughout this analysis.

Table A3: Life years lived from now – Male

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	56.2				
35 to 44	55.0	40.8			
45 to 54	51.9	37.7	28.8		
55 to 64	50.7	36.3	27.4	19.6	
Lifelong Smokers	48.9	34.5	25.6	17.5	11.0

- 6. Identify the amount of money spent, per £1 spent on a 20-pack of cigarettes by adults (by age band and sex), for lifelong non-smokers and for the five “quit age bands”.** The life tables described above are used to estimate the expected number of packs bought each year from now per capita for each of the various combinations. Two further assumptions are needed: First, Opinions and Lifestyle Survey data is used for the average daily cigarette consumption. Secondly we assume that people in the quit age bands Under 35, 35-44, 45-54, and 55-64, quit on their 25th, 40th, 50th, and 60th birthdays respectively. The sum of these values across all future years of age equals the total number of packets bought. This value is multiplied by £1 so that a per £1 spent on a pack figure is derived. This is done so that the outputs from this model can be used to easily estimate any value that is proportionate to the number of packs bought. The results for males are seen in table A4 below and the results for females are similar.

Table A4: Money spent, per £1 spent on a 20-pack of cigarette – Male (values rounded to nearest £100)

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	-				
35 to 44	3,200	-			
45 to 54	5,300	2,100	-		
55 to 64	7,200	4,100	2,100	-	
Lifelong Smokers	10,400	7,400	5,500	3,700	2,400

- 7. Discount the numbers of year of life lived and money spent.** As the life years occur in the future, they should be discounted appropriately. The money spent discount rates used are equal to those in the Treasury Green Book<sup>110</sup>. For life years the discount rates used are equal to Green Book rates minus 2%. The ‘minus 2%’

<sup>110</sup> 3.5% p.a. reducing into the future. Green Book available at <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>

takes account of the fact that the monetary value per life-year can be expected to grow at the same rate as real economic growth. The 2% figure for this is taken from the Social Rate of Time Preference assumptions underlying the Green Book discount rates. In the short to medium term, life years are discounted at 1.5% per annum (3.5% less 2%) but this declines for survival gains occurring more than 30 years into the future. The sum of the discounted amount of money spent at each year of age equals the discounted amount of money spent by the specified combination of quit age band and sex. The sum of the discounted numbers of life years lived at each year of age equals the discounted number of life years lived by the specified combination of quit age band and sex. This gives corresponding values to those in tables A3 and A4 which are shown below in tables A5 and A6 respectively. The results for females are similar.

Table A5: Discounted life years lived from now – Male

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	38.8				
35 to 44	38.1	30.4			
45 to 54	36.5	28.5	23.0		
55 to 64	35.8	27.7	22.1	16.6	
Lifelong Smokers	35.0	26.7	20.9	15.1	9.9

Table A6: Discounted money spent from now, per £1 spent on a 20-pack of cigarette – Male (values rounded to nearest £100)

Quit age band	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	-				
35 to 44	2,500	-			
45 to 54	3,600	1,800	-		
55 to 64	4,300	3,000	1,800	-	
Lifelong Smokers	5,100	4,200	3,500	2,700	1,900

- 8. Identify the life years and money saved per quitter (by age band and sex), for the five “quit age bands”.** The difference between the life years lived for each quit age band and the life years lived if a smoker quit at their current age in table A5 is used to estimate these values. For example, table A3 suggests a 40 year old who is going to be a lifelong smoker expects to live for another 34.5 years, but if they were to quit now they would expect to live for another 40.8 years. Therefore the difference of 6.2 years is the life year gain for that quit age band. Similarly this is done for the money saved due to quitting, and repeated for corresponding discounted values as well. The results are presented in tables A7 to A10. The results for females are similar.

Table A7: Life years saved by quitting – Male

Quit age band, before intervention	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	0.0				
35 to 44	1.3	0.0			
45 to 54	4.3	3.1	0.0		
55 to 64	5.6	4.4	1.4	0.0	
Lifelong Smokers	7.4	6.2	3.2	2.0	0.0

Table A8: Discounted life years saved by quitting – Male

Quit age band, before intervention	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	0.0				
35 to 44	0.7	0.0			
45 to 54	2.3	1.9	0.0		
55 to 64	3.0	2.7	0.9	0.0	
Lifelong Smokers	3.8	3.7	2.1	1.5	0.0

Table A9: Money saved per quitter, per £1 spent on a 20-pack of cigarette – Male (values rounded to nearest £100)

Quit age band, before intervention	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	-				
35 to 44	3,200	-			
45 to 54	5,300	2,100	-		
55 to 64	7,200	4,100	2,100	-	
Lifelong Smokers	10,400	7,400	5,500	3,700	-

Table A10: Discounted money saved per quitter, per £1 spent on a 20-pack of cigarette – Male (values rounded to nearest £100)

Quit age band, before intervention	Smoker age				
	Under 35	35 to 44	45 to 54	55 to 64	Over 65
Under 35	-				
35 to 44	2,500	-			
45 to 54	3,600	1,800	-		
55 to 64	4,300	3,000	1,800	-	
Lifelong Smokers	5,100	4,200	3,500	2,700	-

- **9. Estimate the proportion of current smokers by the 5 age categories.** This is done using OLS 2012 and is used to provide an estimate of the probability of the age of a current smoker picked at random. The results are shown in table A11.

Table A11: Proportion of current smokers by age.

Smoker age				
Under 35	35 to 44	45 to 54	55 to 64	Over 65
39%	20%	18%	12%	11%

- **10. Estimate the life years and money saved per quitter and their discounted values.** Male and female estimates of life years gained and discounted life years gained are then downscaled to 65% and 61% of their calculated value respectively. This reflects the fact that the median doctor from the doctors' study smoked 18 cigarettes per day, whereas current averages for men and women are lower: 11.7 and 10.9, respectively (OLS 2012). Current smokers can therefore be expected to experience less harm and hence quitting or not starting means less health benefit. Note that the money values are not downscaled since they already use the current OLS figures. The final numbers are then calculated by weighting the downscaled values in tables A7 to A10 (and corresponding female ones) by the values in the corresponding tables A2 and A11. The male and female results are then averaged to give the following main results:
  - **The discounted number of life years saved for a randomly chosen adult who quits smoking today of 1.2 (2.0 not discounted)**
  - **The discounted amount of money not spent per £1 spent on a 20-pack of cigarettes, for a randomly chosen adult who quits smoking today of £2,700 (£4,600 not discounted)**

The following factors may bias the central estimate of benefit presented above downwards (factors a-d) or upwards (factors e-h):

- a. They do not take account of the improved quality of life that results from quitting smoking. For example, quitters may escape diseases that reduce their quality of life as well as reduce their life expectancy (such as chronic obstructive pulmonary disease).
- b. It is assumed that no harm is incurred by smoking over the age of 84. There is likely to be some harm here (which would increase the measured benefits if counted), but there is a lack of precise data. In any case, as the cohort is fairly small by this age, the results are not particularly sensitive to this assumption.
- c. It is assumed that no harm is incurred by smoking under the age of 35. Again, there is likely to be a benefit from not smoking at this age, but there is a lack of precise data. It is worth noting that means that health benefits for children who do not take up smoking, under this modelling assumption, therefore take some time to develop, and more time than an adult who quits. Therefore when

discounting this causes the discounted life years saved to be larger for adult quitters than for children who do not take up smoking.

- d. It is assumed that quitting after the age of 65 yields no health benefit. There is also likely to be a small benefit here, but again, there is a lack of precise data.
- e. By assuming that all adults who are smoking at age 65 go on to be lifelong smokers, the benefits of quitting and not taking up smoking are slightly overestimated.
- f. The Doll, Peto, Boreham and Sutherland (2004) study does not explicitly adjust for confounding factors (although it does control for social class, given that its sample consists only of doctors). For example, if smokers are also more likely to drink heavily, this may exaggerate the mortality impact of smoking. However, a similar cohort study (based in The Netherlands) does adjust for a long list of confounding factors, including socioeconomic status, alcohol use and body mass index. The authors conclude that adjusting for confounding factors reduces the estimated number of (undiscounted) life years lost due to smoking by half a year out of seven years. Given that the estimates presented in this annex are discounted and take account of future quit propensities, any reduction to take account of confounding factors would be considerably less than half a life year.

Other limitations of the estimate include:

- g. It is assumed that the same smoking mortality impacts hold for both men and women. The Doll, Peto, Boreham and Sutherland (2004) study only covers male doctors.
- h. It is assumed that the number of life years lost is linearly related to the average daily number of cigarettes smoked throughout life. The relationship is unlikely to be perfectly linear in practice.
- i. It is assumed that the average daily number of cigarettes smoked throughout life remains constant.

### **Lost tax revenues**

Using price data supplied by a cigarette manufacturer we estimate the amount of specific tax and ad-valorem duty that is charged per 20-pack of factory made cigarettes in each market segment based on 2015 tax rates. The segments defined are premium, mid-price, economy and ultra-low price (ULP). We also take the equivalent in hand-rolled tobacco (HRT) of a 20-pack of factory made cigarettes, as measured in tobacco weight. This is equivalent to 14g of HRT. The amount of duty charged for HRT is calculated using the 2015 tax rates<sup>111</sup>. This is shown in Table A20.

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<sup>111</sup> Rates from June 2015 from Tobacco Bulletin June 2015 available at <https://www.uktradeinfo.com/statistics/pages/taxanddutybulletins.aspx>

Table A20 – Price and tax projected to 2015

	Premium	Mid-price	Economy	Ultra-low	HRT (20 pack equivalent)
<b>Price incl. VAT</b>	9.31	8.43	8.14	7.47	5.11
<b>Ad-valorem duty</b>	1.54	1.39	1.34	1.23	-
<b>Specific duty</b>	3.79	3.79	3.79	3.79	-
<b>Total duty</b>	5.33	5.18	5.13	5.02	2.60

Table A21 is created by taking the above estimates for each market segment and multiplying them by the main result after stage 10 above; the discounted amount of money not spent per £1 spent on a 20-pack of cigarettes by a randomly chosen adult who quits smoking today of £2,700. This is adjusted for the amount of the market that is duty paid.<sup>112</sup> We then estimate the difference between expected VAT lost from reduced UK duty paid tobacco consumption and VAT gained from the expenditure from those smokers on other goods and services. The average VAT rate is assumed to be 13.2% compared to 20% for tobacco.

Table A21- Discounted lost duty and VAT per adult quitter for each market

	Premium	Mid-price	Economy	Ultra-low	HRT (20 pack equivalent)
Discounted lifetime lost duty per adult quitter	£12,631	£12,290	£12,174	£11,912	£4,065
Discounted lifetime spend per adult quitter	£22,075	£20,006	£19,306	£17,715	£7,987
Discounted lifetime VAT spend per adult quitter	£3,679	£3,334	£3,218	£2,952	£1,331
Discounted lifetime VAT spend per adult quitter on non-tobacco	£2,574	£2,333	£2,251	£2,066	£931
Discounted lifetime VAT loss to HMRC per adult quitter	£1,105	£1,001	£966	£887	£400

The average value is calculated by weighting the different markets by their estimated market share. First, duty loss by HRT is weighted by HMRC 2014/15 figures for market share<sup>113</sup>. Once this is accounted for the factory made cigarettes are weighted by their respective market shares (as provided by a cigarette manufacturer).

In total it is estimated that £11,000 in duty and VAT is lost per adult quitter. This is a discounted value of the course of their lifetime.

<sup>112</sup> 88% and 57% for cigarettes and HRT respectively

<sup>113</sup> Forecast for Hand Rolled Tobacco Clearances 23 April 2014.pdf available at <http://budgetresponsibility.org.uk/wordpress/docs/HRTforecastBud14.pdf>

## Annex B – E-cigarette analysis

There is great uncertainty about the number of products that will be put forward for notification, not least because we anticipate that the costs of generating notification information may deter many companies from putting all of their products through the notification process (I.e. there will be a rationalisation of existing product lines with some being withdrawn from the market). The “market effects” section of this impact assessment lists the reasons we cannot be sure of the number of products that will be on the market post TPD.

### Number of companies in the market

Responses from the consultation show that data from the Nielsen data base does not give a comprehensive view of the market. The consultation responses, alongside ECigIntelligence,<sup>114</sup> give estimates of between 800-1100 companies in the market. The consultation estimates that 90% of the market is made up of small and medium enterprises.

Number of companies	High Estimate	Consultation responses	1100
	Best Estimate	An average of the high and low	950
	Low estimate	Consultation responses	800
Number of large companies	High Estimate	10% of the high estimate	110
	Best Estimate	10% of the best estimate	95
	Low estimate	10% of the low estimate	80
Number of small and medium companies	High Estimate	90% of the high estimate	990
	Best Estimate	90% of the best estimate	855
	Low estimate	90% of the low estimate	720

### Number of products in the market

<sup>114</sup> a leading e-cigarette market analyst company

There is great uncertainty about the number of products that will be put forward for notification, not least because we anticipate that the costs of generating notification information may deter many companies from putting all of their products through the notification process (I.e. there will be a rationalisation of existing product lines with some being withdrawn from the market).

The Nielsen data shows the number of notifiable products available of the market in each category. ECITA have stated they believe this only captures 33% of the market. Therefore we have adjusted the figures accordingly, to give an estimate of 100% of the market. However please note that due to the market effects (described in the “Market Effect’s section) these estimates are subject to uncertainty.

ECigIntelligence stated that initial estimates show that there may be around 25,000 notifiable products on the market, however they also said they thought it was unrealistic to use this as a notification estimate because they expect to see a signification reduction of products in the market due to the regulations, potentially to as low as 1000 The growth rate of the market is impossible to predict with accuracy. ECigIntelligence said that between 20-30% would be a sensible estimate; however this is subject to uncertainty.

Product	Total <sup>115</sup>	Adjusted to 100%
Capsules	87	264
Cigarette	568	1721
Drops	14	42
Gel	2	6
Liquid	962	2915
Refill cartridges	81	245
<b>Grand Total</b>	<b>1714</b>	<b>5194</b>
Annual growth rate		25%

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<sup>115</sup> Nielsen data

## Cost estimates

Sales data reporting costs		Number of companies	Median Hourly wage	Number of hours spent submitting data year one	Number of hours spent submitting data years 2 onwards	Cost in year 1 (number of companies x hourly wage x hours spent )	Cost in year 2 onwards (number of companies x hourly wage x hours spent )	
Number of large companies	High Estimate	110	£11.61	10	5	£12,771	£6,386	
	Best Estimate	95	£11.61	8	4	£8,824	£4,412	
	Low estimate	80	£11.61	6	3	£5,573	£2,786	
SMEs	High Estimate	990	£11.61	16	16	£183,902	£183,902	
	Best Estimate	855	£11.61	12	12	£119,119	£119,119	
	Low estimate	720	£11.61	8	8	£66,874	£66,874	
						<b>Total high estimate</b>	<b>£196,673</b>	<b>£190,288</b>
						<b>Total best estimate</b>	<b>£127,942</b>	<b>£123,530</b>
						<b>Total low estimate</b>	<b>£72,446</b>	<b>£69,660</b>

Toxicology test costs	Number of products tested in year one	Number of products tested in year two onwards	Cost per test	Total cost of tests year one	Total cost of tests year two onwards
High Estimate (15% of the products require a test)	779	195	£5,000	£3,895,455	£973,864
Best Estimate (10% of the products require a test)	519	130	£3,500	£1,817,879	£454,470
Low estimate (5% of the products require a test)	260	65	£2,000	£519,394	£129,848

<b>Emissions test costs</b>	Number of products tested in year one	Number of products tested in year two onwards	Cost per test	Total cost of tests year one	Total cost of tests year two onwards
High Estimate (15% of the products require a test)	779	195	£550	£116,864	£29,216
Best Estimate (10% of the products require a test)	519	130	£350	£181,788	£45,447
Low estimate (5% of the products require a test)	260	65	£150	£142,833	£35,708

<b>Submitting notifications costs</b>	Number of products notified on	Median Hourly wage	Hours spent	Total cost in year 1 (number of products x hourly wage x hours spent )	Total costs on year 2 onwards (number of products x growth rate x hourly wage x hours spent )
High Estimate	5194	£11.61	18.8	£1,130,656	£282,664
Best Estimate	5194	£11.61	15.6	£942,213	£235,553
Low estimate	5194	£11.61	12.5	£753,770	£188,443

<b>Familiarisation costs</b>	Number of companies	Hours spent familiarising <sup>116</sup>	Median Hourly wage	Total cost
High Estimate	1100	20	£11.61	£255,420.00
Best Estimate	950	15	£11.61	£165,442.50
Low estimate	800	10	£11.61	£92,880.00

<b>Child/Tamper Resistant Packaging adjustments</b>	Number of products edited	Number of products tested in year two onwards	Cost per product	Total cost of tests year one	Total cost of tests year two onwards
High Estimate (15%)	779	195	£6,000	£4,674,545	£1,168,636
Best Estimate (10%)	519	130	£6,000	£3,116,364	£779,091
Low estimate (5%)	260	65	£6,000	£1,558,182	£389,545

<sup>116</sup> Estimate from the Medicines and Healthcare products Regulatory Agency