



Department
of Health &
Social Care

Post-Implementation Review of Tobacco Legislation

The Tobacco and Related Products Regulations 2016

Published March 2022



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The Tobacco and Related Products Regulations 2016

Presented to Parliament
by the Secretary of State for Health and Social Care
by Command of Her Majesty

March 2022



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1. Executive Summary

- 1.1 Smoking is one of the main causes of both preventable and premature deaths, and a leading cause of disabilities and preventable illnesses. It is also one of the leading causes of health inequalities in the United Kingdom.
- 1.2 Over recent years a range of legislation has been introduced in the UK to discourage young people from taking up smoking or vaping, encourage existing smokers to quit, and to protect others from the harmful effects of cigarette smoke. This suite of tobacco control legislation, which is amongst the most comprehensive in the world, has contributed to smoking rates declining to their lowest ever on record. The UK has a reputation as a world leader on the development and implementation of tobacco control policies.
- 1.3 Under the Small Business, Enterprise and Employment Act 2015, the Government is required to conduct and publish a review of legislation when it has an impact on businesses. This requirement is included in the legislation within the review clause(s). These reviews are called Post-Implementation Reviews (PIR). This report presents the findings of a PIR for The Tobacco and Related Products Regulations 2016 (TRPR). This review has been conducted in accordance with the Regulatory Policy Committee's (RPC) [guidance on PIRs](#).
- 1.4 A wide range of evidence from a variety of sources has been used to inform the review. This includes commissioned evidence, published peer reviewed evidence, a public consultation, and a review of key indicator data. The review also puts into consideration that this regulation is part of a wider legal framework which includes other legislation, such as the Standardised Packaging of Tobacco Products Regulations 2015 (SPoT), which is being reviewed in parallel.
- 1.5 On balance, considering the range of evidence received and reviewed, it is the Department of Health and Social Care (DHSC) view that the TRPR regulations have met their original objectives and they could not be better achieved through alternative regulatory measures.
- 1.6 However, it is important to recognise that there have been some unintended consequences. For example, on the characterising flavour ban, some consultation respondents suggested that the ban was ineffective because smokers were using other products to flavour their cigarettes.
- 1.7 It is also not possible to directly attribute all of any positive changes in the key indicators since the introduction of the regulations, such as the reduction in adult smoking prevalence, to TRPR. As a result, the impact of TRPR should not be overstated.

- 1.8 Some consultation respondents also suggested other areas the Government could consider further action in the future. For example, respondents commented that whilst the advertising restrictions on electronic cigarettes (e-cigarettes) were discouraging use amongst young people, the packaging of e-cigarettes makes them attractive, particularly to young people. Also, on e-cigarettes, some respondents suggested that the Government should increase awareness of the health benefits of switching to e-cigarettes. The consultation responses also suggested that the regulations on novel tobacco were well balanced as similar numbers of respondents suggested the regulations should be relaxed as those who said they should follow the same restrictions as tobacco.
- 1.9 DHSC has received a fit for purpose opinion from the RPC on this post-implementation review which is available at:
<https://www.gov.uk/government/collections/rpc-opinions>
- 1.10 DHSC recommends that the regulations should remain in force based on the evidence reviewed. However, the Government will consider further regulatory reforms to TRPR as part of its plans towards meeting its Smokefree 2030 ambition, and to protect future generations from the harms of tobacco. This includes those reforms suggested by respondents to the consultation. Any proposed changes will be based on robust evidence and support improvements to public health.

2. The Context: Recent approach to tobacco control (UK)

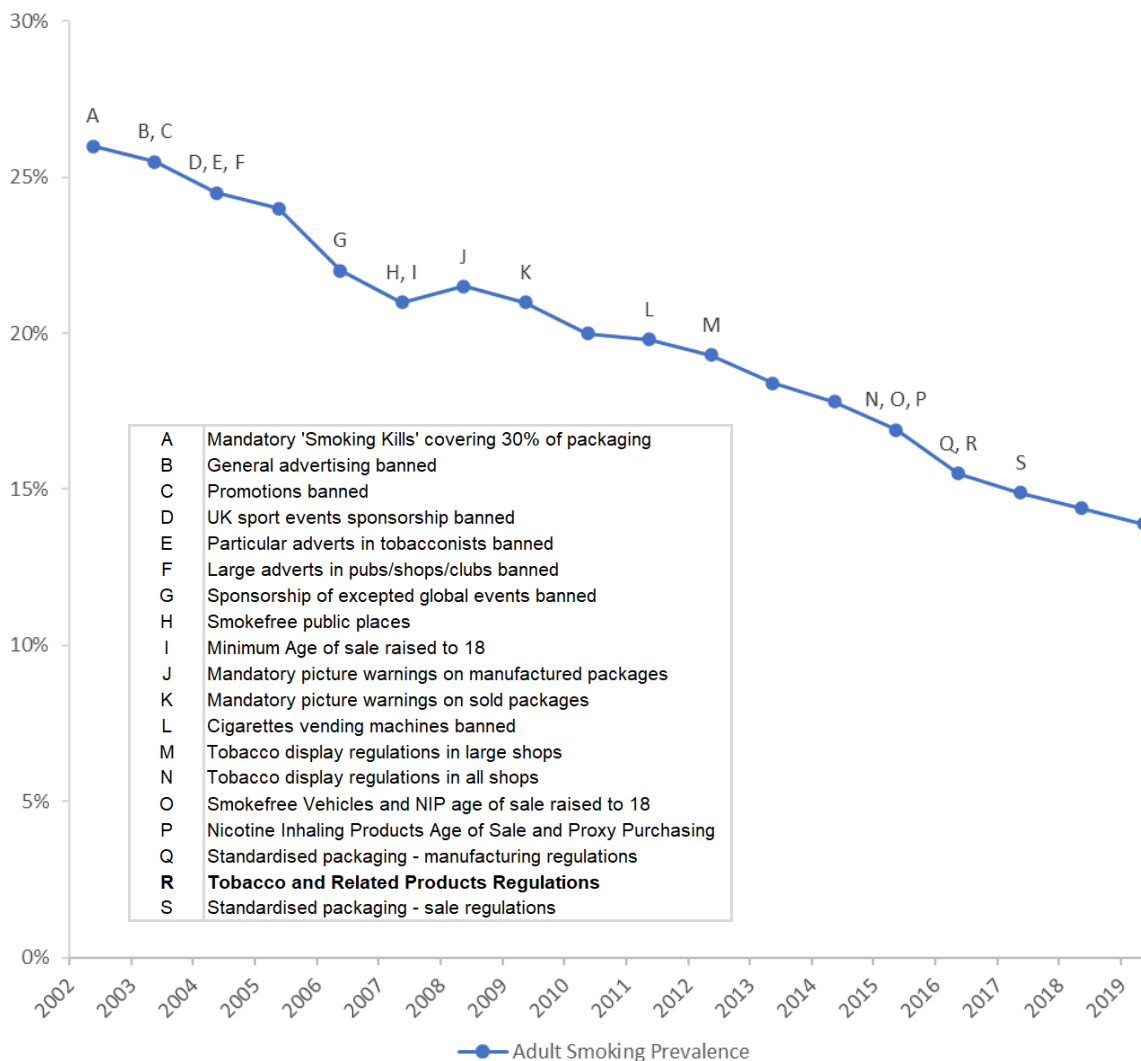
- 2.1 Smoking rates are at their lowest ever on record in the UK. Despite this positive news, smoking still remains one of the biggest causes of death and disability across the UK, and is one of the leading causes of health inequality.
- 2.2 The UK is a global leader in tobacco control and our legislative framework is regarded as one of the most comprehensive in the world¹. In the last 20 years we have introduced a suite of tobacco control policies (as illustrated in Figure 1 below).
- 2.3 This has included a ban on advertising, establishing smoke-free places, introduction of prominent graphic health warnings, a ban on proxy purchasing of cigarettes and e-cigarettes, and a ban on smoking in cars with children, as well as the introduction of standardised packaging and the point-of-sale display ban. Evaluations of some of these regulations² have found them to be effective in reducing smoking prevalence amongst young people and adults.
- 2.4 More recently, Parliament has further strengthened tobacco control by introducing the Tobacco and Related Products Regulations 2016 (TRPR), which regulate the product standards, requirements, notification and presentation of tobacco and e-cigarettes, along with the Standardised Packaging of Tobacco Products Regulations 2015 (SPoT) which introduced standardised packaging for cigarettes and hand rolling tobacco (HRT).
- 2.5 TRPR was introduced to transpose provisions from the European Union's (EU) Tobacco Products Directive (TPD) (2014/40/EU) in UK law. The previous EU Directive contained rules which were out of date and did not reflect new market, scientific, and international developments. The TPD aimed to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens. The Directive entered into force on 19 May 2014 and became applicable in the EU Member States on 20 May 2016, when TRPR came into force.

¹Tobacco Control Scale: Monitoring the implementation of tobacco control policies systematically at country-level across Europe. Available here: <https://www.tobaccocontrolscale.org/>

² A Post-Implementation Review report of tobacco legislation coming into force between 2010 to 2015: <https://www.gov.uk/government/publications/tobacco-legislation-coming-into-force-between-2010-and-2015-post-implementation-review>

2.6 This review is covering TRPR and a separate review is taking place in parallel on SPoT regulations. It must be noted that both regulations set requirements on packaging.

Figure 1: Adult smoking prevalence between 2002 and 2019 (Source: ONS Adult Smoking Habits in the UK), and tobacco control policies



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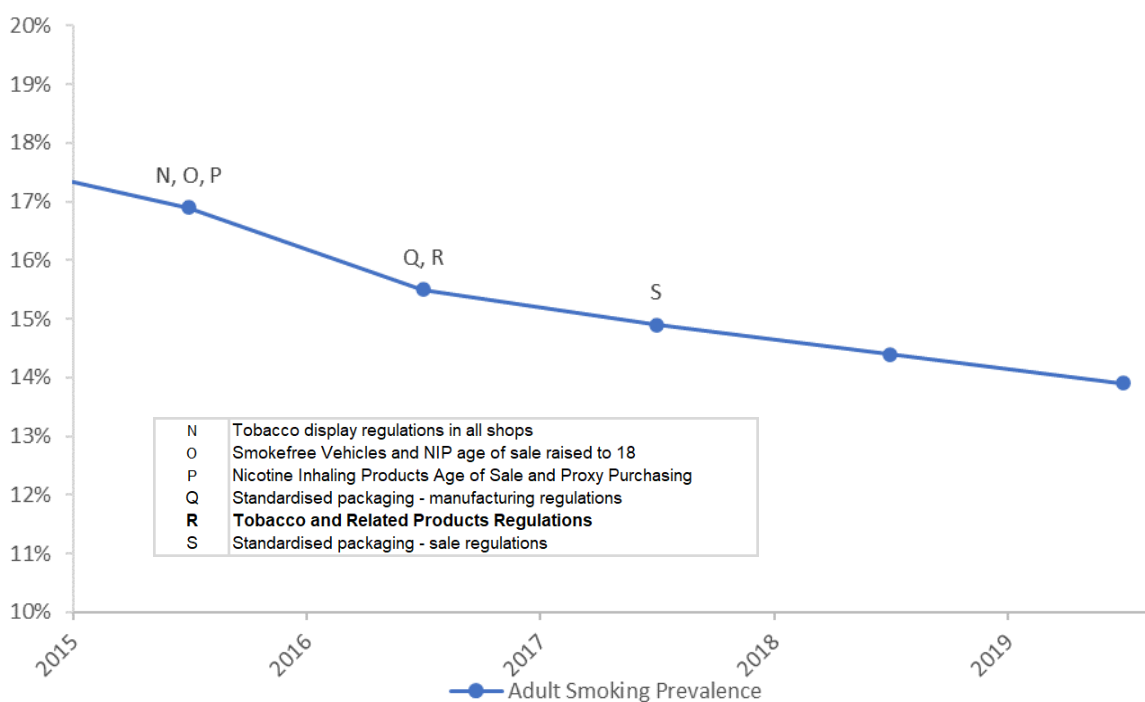
Context around TRPR

2.7 The aim of tobacco control policies in the UK has been to reduce youth uptake of smoking, and encourage and support quitting amongst smokers.

³ The interventions are representative of England only, and vary across constituent countries in terms of what has been implemented and when.

2.8 The TPD was formulated to update existing European Union tobacco control rules as well as to introduce harmonised rules for novel tobacco, herbals products and e-cigarettes. The Directive also aimed to prevent distortion of the market as member States consider their implementation of the global World Health Organization Framework Convention on Tobacco Control (WHO FCTC), and improve the function of the internal market, whilst maintaining a high level of health protection. These changes were expected to have a positive impact on both reducing youth uptake of smoking, and encourage and support quitting amongst

Figure 2: Adult smoking prevalence between 2015 and 2019, since the introduction of SPoT (Source: ONS Adult Smoking Habits in the UK)



smokers.

3. Regulation Objectives

3.1 The Tobacco and Related Products Regulations 2016 (TRPR) included:

- Changes to the labelling requirements of tobacco products
- Introduced a ban on certain emissions, additives and ingredients, including a ban in characterising flavourings for cigarettes and roll your own tobacco
- Reporting and notification requirements around tobacco products
- Specific requirements for herbal products for smoking
- Introduction of new product and labelling requirements, including warnings for e-cigarettes
- Reporting and notification requirements around e-cigarettes
- Restrictions on advertising of e-cigarettes
- Specific requirements on cross-border distance sales of tobacco products and e-cigarettes
- Penalties and enforcement for a breach of the regulations

3.2 The regulations came into force on 20 May 2016 and allowed for a 12-month sell-through period for stock that was manufactured before May 2016.

3.3 TRPR was amended by The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020. This was to ensure tobacco control continued effectively in Great Britain and Northern Ireland after the end of the transition period on 1 January 2021, from which point Great Britain no longer had to comply with the TPD.

3.4 The objectives of TRPR were to transpose the TPD into UK law. The objectives of the TPD were:

- 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 e-cigarettes

- Prevent distortion of the market as Member States consider their implementation of the WHO FCTC
- Improve the function of the internal market whilst maintaining a high level of health protection

3.5 TRPR was expected to have a positive impact on both reducing youth uptake of smoking, and encouraging and supporting quitting amongst smokers. For example, the provisions of TRPR to ban characterising flavourings for cigarettes and roll your own tobacco was expected to reduce their palatability to minors. While among other provisions, increasing the size of health warnings on tobacco product packaging was to help better inform people of the health risks of tobacco products.

3.6 The full legislation is available at:
<https://www.legislation.gov.uk/ukxi/2016/507/contents>

Commitment to review

3.7 TRPR contains a review clause which requires the Secretary of State to carry out a review of the provisions in the legislation and set out the conclusions of the review in a report. The Government also wants to understand how effective TRPR has been in protecting people from the harms of tobacco and in ensuring we continue to learn from, and improve, the regulatory framework in the UK.

3.8 The aim of this review is to:

- set out the objectives of these regulations,
- assess the extent to which those objectives have been achieved, and
- assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

3.9 When undertaking the review, regard has been taken as to how the TPD is implemented in EU Member States. In May 2021 the EU published a report into the progress of the TPD⁴ which included UK input. In its conclusion summary it states "The TPD has enhanced tobacco control and its validity was upheld in courts. It strengthened rules, e.g. enlarged combined health warnings, the track

⁴ Report from the Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee of The Regions on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products [EUR-Lex - 52021DC0249 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/lexUri.do?uri=CELEX:52021DC0249:EN)

and trace system, banning characterising flavours, the ingredients database, the regulation of electronic cigarettes, all of which have established their position as part of a comprehensive EU tobacco control policy. The TPD achieved the 2% reduction target of the impact assessment with decreased smoking prevalence among youths. The Directive also implemented relevant WHO FCTC provisions."

- 3.10 As TRPR was enacted to protect the public's health, we have reviewed both health and economic impacts, in accordance with the RPC's [guidance on PIRs](#).
- 3.11 The review only considers the aims set out above and the costs and benefits of the legislation that were set out in the original impact assessment. This report should be used in conjunction with, and as additional evidence for, the formal PIR reports which are included in Annex D.
- 3.12 The report does not address any regulatory gaps beyond the original objective of TRPR. Emerging policy considerations, public opinion, and business environments outside the remit of the regulation are also outside the scope of the review. Proposals and concepts for regulatory considerations to widen the remit of TRPR are also outside the scope.
- 3.13 The report was written by officials at DHSC with input from Other Government Departments and Devolved Administrations, the RPC, Ministers and Parliament. DHSC also liaised with external and independent experts, considered the evidence, and drew conclusions from this broad evidence base.

4. How the review was conducted

4.1 This part of the report sets out the methods we have used to assess the impact of TRPR on the objectives stated above, and the extent to which the objectives could be achieved with a system that imposes less regulation. Consistent with Government guidance and in consultation with the Better Regulation Authority and the RPC, this assessment considered a wide range of sources including information collected from stakeholder consultations, peer reviewed evidence, other publicly available data and estimates of costs and benefits from [TRPR's original Impact Assessment](#).

4.2 The key questions for the PIR were:

- To what extent have policy objectives been achieved?

the extent to which expected / additional benefits were achieved.

the extent to which expected / additional costs were incurred.

- Were there any unintended consequences?
- Could these objectives be achieved in another way which involves less onerous regulatory provision to reduce the burden on businesses?

4.3 Five years is insufficient for the full long-term impacts, such as reductions in lung cancer, to be seen. We used a more practical approach for this PIR, concentrating on the short and medium-term impacts, together with the other key questions identified above.

4.4 Given the breadth of information used for this review it was necessary to consider the various strengths and quality of evidence reviewed. All evidence presented has been fully referenced and annotated.

Public Consultation

4.5 DHSC ran a public consultation on TRPR to gather views from a range of stakeholders. Over 5,000 responses were received, and the results of this are presented in this report.

4.6 Results from the consultations should be considered in the context of the consultation process and the information supplied by respondents. There are limitations associated with the consultation, such as not being representative of the whole of the UK.

Peer-reviewed Evidence

- 4.7 DHSC considered findings of studies undertaken across the UK in relation to TRPR regulations published in peer-reviewed journals. Where appropriate, international evidence and comparisons were considered.
- 4.8 In order to fill specific evidence gaps, DHSC commissioned a study into particular aspects of TRPR. This was a qualitative study of small retailers by The King's Fund, assessing the impact of SPoT and TRPR on small businesses.

Health Indicators

- 4.9 The results sections contain a review of the various publicly available metrics (published by the Office for National Statistics (ONS), NHS Digital, Public Health England (PHE) and others) that are relevant to this regulation. Where available, the data for England, Scotland, Wales, and Northern Ireland are all presented.
- 4.10 Despite these data sources forming a large evidence base, it is still difficult to attribute any changes in trends directly to any single event or intervention. There are a variety of factors which may influence the objectives outlined in the review. This is discussed in the results section of the review.
- 4.11 Where appropriate, this report discusses the effect on medium and longer-term health indicators to see if there have been any changes to health outcomes due to TRPR. However, it should be noted that we were not expecting to see or assess the effect on health outcomes beyond the five-year period covered by this review.

Economic Impacts

- 4.12 This section includes evidence on the economic impact of TRPR, including a detailed review of the assumptions made in the Impact Assessment for the regulation in terms of both the costs to businesses and the health benefits anticipated.
- 4.13 We have attempted to assess whether the realised costs were in line with the estimates in the original Impact Assessment. To do this we have updated the calculations using post-implementation data obtained through our own searches and responses to the consultation.

5. Evidence and analysis to inform the post-implementation review

5.1 This section covers the quantitative and qualitative evidence available to assess TRPR, including the DHSC's public consultation, studies commissioned by the Department, a review of the peer reviewed evidence and the key indicator data, and a review of the costs and benefits associated with the regulations.

Summary of findings

- 5.2 The public consultation, which received over 5,000 responses, provided a mixed view on the regulations. Individuals, who made up the majority of the responses (97.3%) were generally polarised, either in favour of the regulations and agreeing they had achieved the objectives, or disagreeing with the implementation of the regulations and the impact they might have had. Public sector bodies, including public health stakeholders, were strongly in favour of the regulations, providing evidence to support their views.
- 5.3 Limited peer reviewed evidence was available on the impact of TRPR. The studies we did identify were mainly based on international evidence and related to specific provisions in the regulations. The studies suggested that the health warnings for e-cigarettes introduced by TRPR have reduced the willingness and likelihood of smokers purchasing e-cigarettes. At the same time, the evidence suggested that the changes to the pictorial warning labels for tobacco products required by TRPR has increased the impact they have on smokers' desire to quit.
- 5.4 Key indicators that were expected to be affected by TRPR all showed positive trends: there were reductions in adult and youth smoking prevalence and a sustained trend in the proportion of those attempted to quit that succeeded. In addition, they show that e-cigarette use has increased since the introduction of TRPR. These indicators were also reviewed for the PIR of SPoT. Although these positive trends therefore reflect the impact of both of these regulations and other changes in the tobacco landscape, it further suggests that TRPR had no negative effects.
- 5.5 Compliance with the regulations was found to have improved over time to a relatively high level.
- 5.6 The review of the latest evidence has not changed the estimated impact of the regulations on smoking prevalence. However, there were significant reductions in smoking prevalence prior to the implementation of TRPR, such that the baseline for measuring the impact of the regulations is lower. The lower baseline means the

impact on sales is less than expected, and the monetised costs and benefits of the regulations are estimated to have been lower, compared to the estimates in the original Impact Assessment.

- 5.7 Despite changes in e-cigarette prevalence since the implementation of TRPR, as discussed in the Key Indicator section, the estimated costs to the e-cigarette industry as a result of TRPR have not changed since the Impact Assessment. In addition, any other impacts of people switching to e-cigarette have not been quantified.
- 5.8 Overall, the estimated benefits of TRPR still significantly outweigh the estimated costs.

Peer reviewed evidence

- 5.9 We have completed a review of literature to assess the impact TRPR has had on smoking prevalence and e-cigarettes. The literature available on the attributable impact of TRPR on smoking prevalence and e-cigarettes is limited. The section below summarises an evaluation by the EU on the impact of the TPD and several studies on the impact of particular aspects of TRPR, specifically e-cigarette warning messages, tobacco product warning messages and the prohibition of flavours in cigarettes.

EU evaluation of the TPD

- 5.10 In May 2021, the EU published a report on the application of the TPD⁵, to examine the progress of the Directive in achieving its objectives, similar to a PIR.
- 5.11 The report found that the TPD has improved public health. The provisions that the report identified as benefitting public health included labelling and packaging provisions and prohibition of characterising flavours in cigarettes and hand rolled tobacco. However, despite this finding the report was not able to quantify the direct impact that the TPD had on reducing smoking prevalence or the use of tobacco and other related products.
- 5.12 The report also highlighted that since the implementation of the TPD illicit trade and smuggling has declined. The report was not able to identify the proportion of the decline in illicit trade and smuggling that is attributable to the TPD.

⁵ Support study to the report on the application of Directive 2014/40/EU: Final report
<https://op.europa.eu/en/publication-detail/-/publication/9ce15083-b931-11eb-8aca-01aa75ed71a1/language-en>

- 5.13 In terms of the costs to businesses, stakeholders reported that they faced significant costs to implement the TPD, particularly in relation to redesigning packaging and testing to meet reporting obligations. However, due to a lack of evidence provided by businesses, the EU were not able to quantify the costs businesses incurred to implement the TPD and consider them against the benefits described above.
- 5.14 Overall, the report concluded that the TPD had met its intended objectives and created minimum standards in areas that had previously been problematic, such as, emissions levels, ingredients, packaging and labelling, flavouring, traceability, and security features.

E-cigarette warning messages

- 5.15 A 2018 study⁶ examined the effect of the changes to e-cigarette warning messages due to the TPD.
- 5.16 The study found that there was a statistically significant reduction in the willingness and likelihood of purchase of e-cigarettes when they contained the warning messages introduced as part of the TPD, compared to when there was no message or a message explaining the reduced harm of e-cigarettes compared to tobacco products.
- 5.17 However, the study only contained smokers, meaning it may also mean that the e-cigarette warning messages has led to fewer non-smokers trying e-cigarettes and becoming addicted to nicotine.

Tobacco product warning messages

- 5.18 Graphic health warnings were perceived as more effective than text-only warnings⁷.
- 5.19 A study⁸ in 2020 reviewed the effectiveness of tobacco warning labels before and after implementation the changes of warning labels due to the TPD. Smokers from

⁶ Messages matter: The Tobacco Products Directive nicotine addiction health warning versus an alternative relative risk message on smokers' willingness to use and purchase an electronic cigarette
<https://www.sciencedirect.com/science/article/pii/S235285321830138X>

⁷ A systematic review of the perceptions of adolescents on graphic health warnings and plain packaging of cigarettes
<https://pubmed.ncbi.nlm.nih.gov/30654833/>

⁸ Effectiveness of tobacco warning labels before and after implementation of the European Tobacco Products Directive—findings from the longitudinal EUREST-PLUS ITC Europe surveys
<https://pubmed.ncbi.nlm.nih.gov/32918822/>

Germany, Greece, Hungary, Poland, Romania and Spain were included in the study.

- 5.20 Although the study did not include smokers from the UK it provides evidence that the changes to the pictorial warning labels as required by the TPD2 increased the impact of the health warning messages. It did not find any clear increases in behavioural changes.

Menthol and other flavoured products

- 5.21 TRPR banned the characterisation of flavours in cigarettes and hand rolling tobacco (2016), including menthol cigarettes (2020). A 2020 study⁹ reviewed cessation behaviours among smokers of menthol and flavoured cigarettes (MFCs) following this change. The study included MFC smokers from England, Germany, Greece, Hungary, the Netherlands, Poland and Romania.
- 5.22 The study showed that the decline in MFC prevalence was mainly driven by MFC smokers switching to unflavoured tobacco products, as opposed to MFC smokers completely quitting. In addition, this study did not find evidence that it changed the likelihood of MFC smokers quitting.
- 5.23 However, the study recognises that the main motivation for this aspect of the TPD was to reduce the appeal of cigarettes amongst young people, whereas this study only considered the impact on adult smokers.
- 5.24 Another 2020 study¹⁰ showed that the market share of menthol/capsule cigarettes began to decline after the TPD legislation was announced in all EU countries, with the exception of the UK and Poland. In both these countries there was marked growth in the market share of menthol/capsule cigarettes despite the incoming ban.
- 5.25 A further study from 2020¹¹ explains that the tobacco industry has introduced diverse new products that are not covered by the ban, such as, menthol accessories sold separately from cigarette packs and roll your own (RYO)

⁹ Cessation behaviours among smokers of menthol and flavoured cigarettes following the implementation of the EU Tobacco Products Directive: findings from the EUREST-PLUS ITC Europe Surveys
https://academic.oup.com/eurpub/article/30/Supplement_3/iii34/5904938?login=true

¹⁰ Menthol Cigarettes: Tobacco Industry Interests and Interference
[Menthol Cigarettes: Tobacco Industry Interests and Interference - TobaccoTactics](#)

¹¹ Tobacco industry tactics to circumvent and undermine the menthol cigarette ban in the UK R Hiscock et al, University of Bath (May 2020)
[Tobacco industry tactics to circumvent and undermine the menthol cigarette ban in the UK \(bmj.com\)](#)

pouches, and cigarillos with a capsule. The study also highlights that there has been an increase in the promotion of heated tobacco products since the ban.

Key indicators

- 5.26 An important element in assessing whether the objectives of the legislation have been met is tracking the key indicators the policy was expected to affect over the past 5 years. The extent to which these regulations were successful in realising benefits therefore depends on the extent to which they have influenced these indicators.
- 5.27 Any changes in these indicators may not be directly attributable to TRPR, as there are a range of factors which could have affected them, such as, other regulatory interventions (see Figure 1) and changes in taxation of tobacco products. Specifically, in this period SPoT was also introduced which was also expected to affect many of the indicators presented below. Therefore, it is likely the changes in the indicators represent at least the compound effect of both SPoT and TRPR. Despite this, reviewing how the indicators have changed since the introduction of TRPR provides further evidence on whether it has had any negative effects.
- 5.28 Due to the nature of TRPR, and there being a 12-month sell through period for stock manufactured before May 2016, we have presented the overall trend in each key indicator as well as highlighted how the figures changed between 2015 (one year pre-implementation) and 2018 onwards (at least one year post-implementation).
- 5.29 Where available, the key indicator data for each constituent country in the UK has been presented. The key indicator data has also been split to present data for adults and young people separately, outlining the relevant objectives of the regulation. The sources for the key indicators are included in the text or alongside charts and tables.

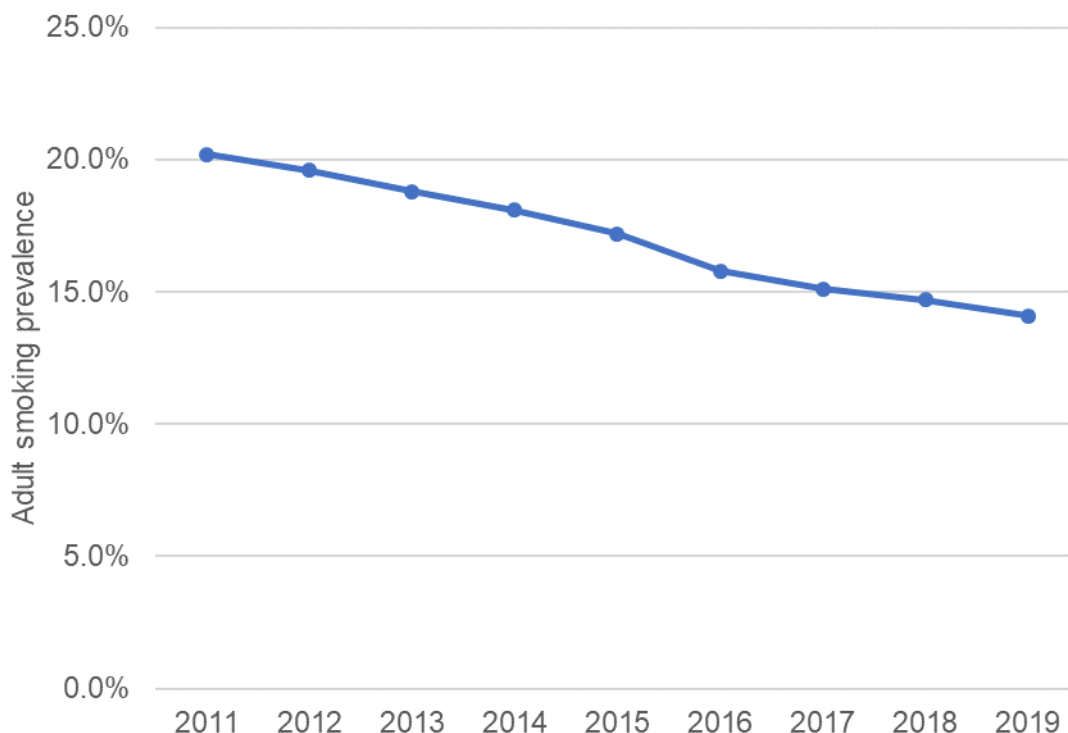
Adults

- 5.30 As explained above, the changes due to TRPR was expected to have a positive impact on encouraging and supporting quitting amongst smokers. The indicators presented below relate to adults in each country in the UK.

Adult Smoking Prevalence

5.31 Adult smoking prevalence is the proportion of the population that are smokers. This has declined across the UK, and since 2011 has fallen from 20.2% to 14.1% in 2019. In 2015, before the introduction of TRPR, adult prevalence was 17.2%. In 2018, the year after full implementation of the regulations, prevalence was 14.7%.

Figure 3: Adult smoking prevalence in the United Kingdom, 2011 to 2019 (Source: Adult Smoking Habits in the UK: 2019)



5.32 The large reduction in prevalence was seen in all countries of the UK as shown below in Table 1, with all countries experiencing a drop of almost 2 percentage points in adult smoking prevalence between 2015 and 2018:

Table 1: Adult smoking prevalence in each constituent country of the UK, 2011 to 2019 (Source: Adult Smoking habits in the UK)

Country	2011	2012	2013	2014	2015	2016	2017	2018	2019
England	19.8%	19.3%	18.4%	17.8%	16.9%	15.5%	14.9%	14.4%	13.9%
Wales	22.3%	21.0%	20.2%	19.4%	18.1%	16.9%	16.1%	15.9%	15.5%
Scotland	23.4%	21.7%	21.5%	20.3%	19.1%	17.7%	16.3%	16.3%	15.4%
N.I.	18.9%	19.2%	18.5%	18.0%	19.0%	18.1%	16.5%	15.5%	15.6%

5.33 UK adult smoking prevalence declined by less than one percentage point each year between 2011 and 2015, constituting a percentage change of between three and five percent each year. In 2016, the percentage point decrease was 1.4%, an 8.1% decrease in prevalence.

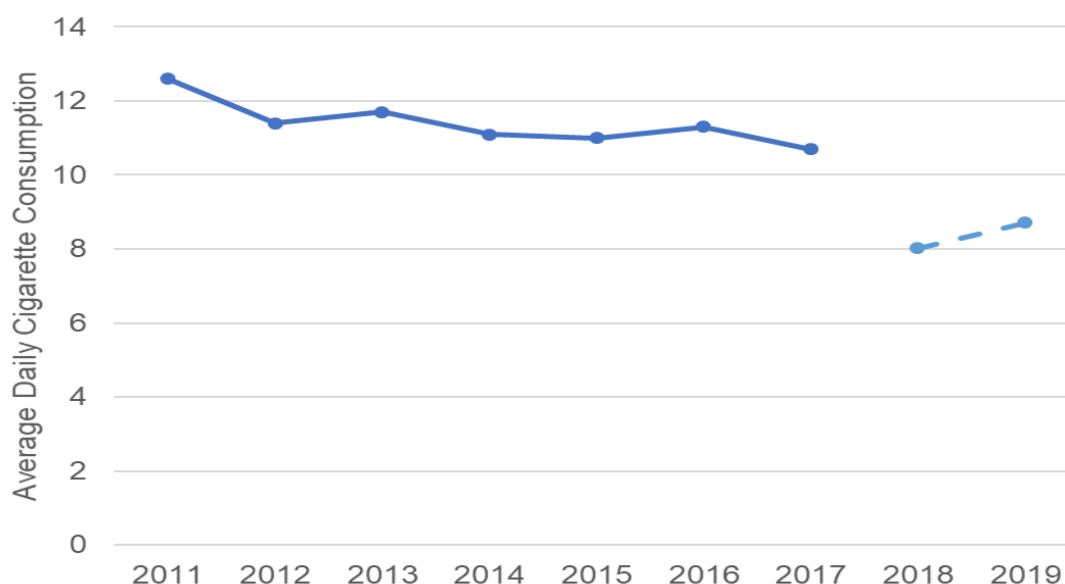
Table 2: Adult UK smoking prevalence between 2011 and 2019, and the associated percentage point and percentage change each year (Source: Adult smoking habits in the UK)

Year	UK Smoking Prevalence	Percentage point change	Percentage change
2011	20.2%		
2012	19.6%	-0.6%	-3.0%
2013	18.8%	-0.8%	-4.1%
2014	18.1%	-0.7%	-3.7%
2015	17.2%	-0.9%	-5.0%
2016	15.8%	-1.4%	-8.1%
2017	15.1%	-0.7%	-4.4%
2018	14.7%	-0.4%	-2.6%
2019	14.1%	-0.6%	-4.1%

Adult cigarette consumption

5.34 As with prevalence, cigarette consumption per smoker has fallen. The following figures are for Great Britain. The daily number of cigarettes smoked has fallen steadily over the past decade. Cigarette consumption fell from 11.0 in 2015 to 8.0 in 2018. However, there was a change in the method this data was collected in 2018 onwards, so the 2018 and 2019 figures are not directly comparable to the previous years' figures.

Figure 4: Adult average daily cigarette consumption, 2011 to 2019 (Source: ONS Adult smoking habits in the UK)



5.35 The consumption for each constituent country (where available) is displayed in Table 3. England and Scotland have both seen a steady reduction in the number

of cigarettes consumed, whereas the daily cigarette consumption in Northern Ireland has remained similar. No data for Wales was available.¹²

Table 3: Daily cigarette consumption in each constituent country of the UK 2011 to 2019 (Source: England – Adult smoking habits in the UK, Scotland – Scottish Health Survey, Northern Ireland – Health Survey Northern Ireland)

Country	2011	2012	2013	2014	2015	2016	2017	2018	2019
England	12.6	11.4	11.7	11.1	11.0	11.3	10.7	8.0	8.7
Wales	No data available								
Scotland	13.8	13.5	13.0	13.2	12.6	12.7	12.3	11.8	-
N.I.	12.9	12.0	12.9	12.0	11.4	11.4	10.0	11.4	-

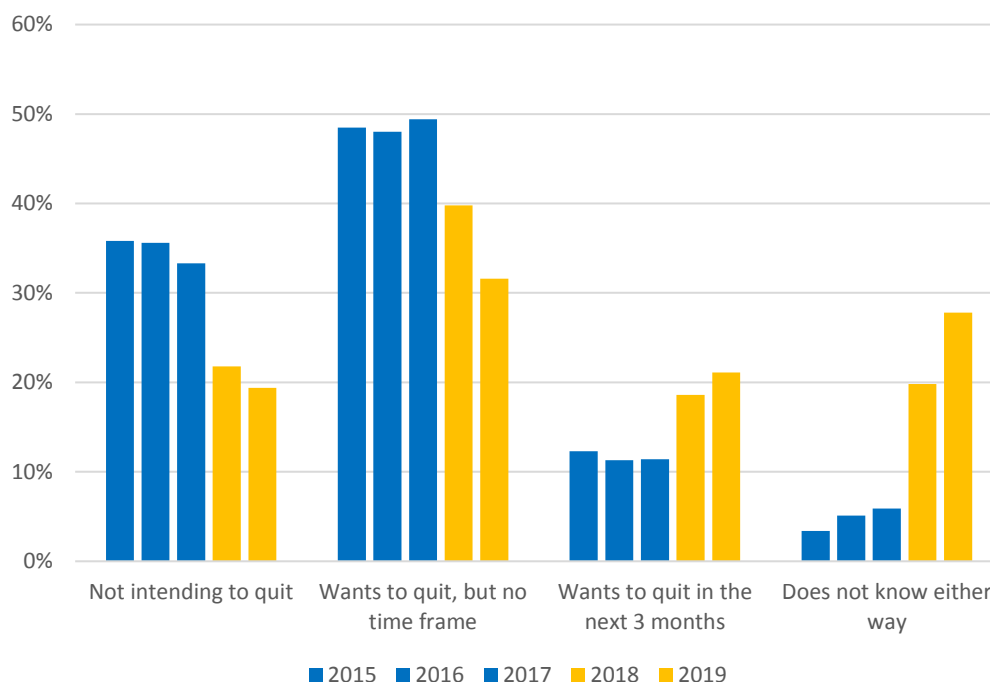
Adult smokers' intention to quit

- 5.36 An objective of TRPR was to discourage people using tobacco products, which could involve helping those who wanted to quit do so. We have an indicator to track peoples' intention to quit. The proportion of smokers that were not intending to quit fell greatly between 2017 and 2018, however due to changes in the data collection process outlined below, it is hard to determine the impact TRPR might have had on this indicator.
- 5.37 The ONS publish smokers' intention to quit. This covers smokers who are not intending to quit, those who want to quit but have no time frame, those who want to quit in the next three months, and those who don't know either way.
- 5.38 In Great Britain, between 2015 and 2017 the proportion of smokers not intending to quit fell slightly, as did those wanting to quit in the next three months. The proportion wanting to quit but had no timeframe in mind, and those who did not know either way increased slightly across the same time period.

¹² Data for England is affected by the data collection method changes as in Figure 4, moving to a telephone survey. Data for Northern Ireland is for financial years, and is calculated as the average weekly cigarettes divided by 7.

5.39 After the change in the survey methodology, moving to telephone interviews, there were large decreases in the proportion not intending to quit and the proportion who wanted to quit with no time frame. Conversely, there were large increases in the proportion wanting to quit in the next three months and those who did not know either way.

Figure 5: Smokers' intention to quit, 2015 to 2019. Change in survey method highlighted by change in colour. (Source: ONS Smoking Habits in the UK)



5.40 The data for constituent countries is not consistent, with surveys in each country asking slightly different questions around quitting. Some of these cover whether smokers had tried to quit or not. Quitting behaviour is presented below from stop smoking services across the UK.

Adult quit behaviour

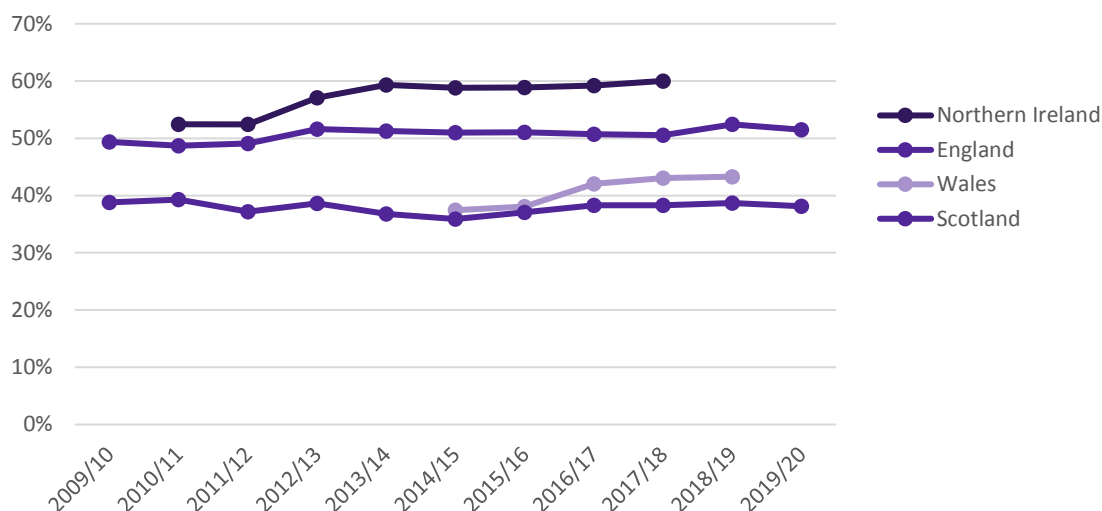
5.41 TRPR aimed to help those who wanted to quit do so. While the number of people attempting to quit each year has been steadily falling, the proportion of those quit attempts that are successful has remained stable.

5.42 Below are figures from each constituent country across the UK on the number of smokers making a quit attempt each year, and the proportion of quit attempts that are successful.

5.43 In England, between 2015/16 and 2019/20 the proportion of smokers successfully quitting (self-reported, 4 weeks) has remained broadly stable at around 50%. Further to this, the proportion of quits that were carbon monoxide (CO) validated remained broadly stable.

5.44 In Scotland, while the proportion of smokers successfully quitting (self-reported, 4 weeks) was lower than in England, it has also remained broadly stable across the time period at around 38%. In Northern Ireland, the proportion of successful quit attempts remained stable at almost 60% over the same period of time. In Wales, the proportion of quits that were successful increased between 2014/15 and 2018/19 from 37% to 43%.

Figure 6: Successful quit percentages (self-reported, 4 weeks) in each constituent country across the UK, 2009/10 to 2019/20 (Sources: England - NHS Statistics on Smoking, Scotland - NHS Smoking Cessation Services Scotland, Wales and Northern Ireland - Smoking Cessation Services)



Young People

5.45 As discussed above, TRPR was also expected to have a positive impact on reducing youth uptake of smoking. Smoking prevalence in young people is presented below for each constituent country, however the data collection is generally less frequent than for adults. Most surveys are conducted every two or, in some cases, three years.

England

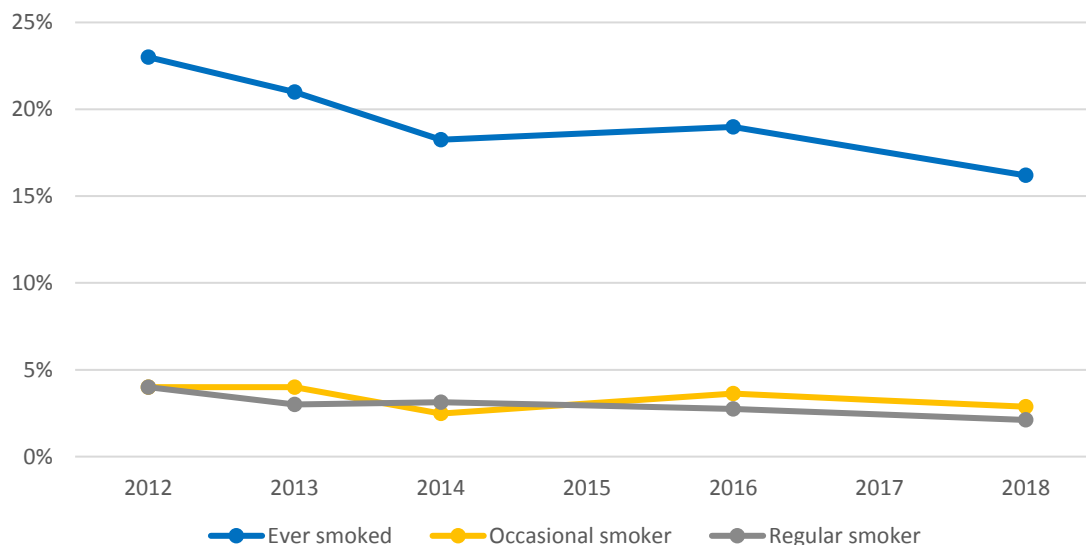
5.46 The Smoking, Drinking, and Drug¹³ use among young people tracks smoking prevalence across the ages of 11 to 15 and the category of smoking frequency that young people report¹⁴. Smoking prevalence has been falling among young people over the past decade.

¹³ From 2014 data is only available every two years due to the Smoking, Drinking and Drug use among young people switching to a biennial publication. There is no 2020 publication due to Covid-19.

¹⁴ Regular smokers defined as usually smoking at least one cigarette per week, occasional smokers defined as usually smoking less than one cigarette per week, 'ever smoked' includes 'current smokers' plus 'ex-smokers' and those who have 'tried smoking once'.

5.47 For young people aged 11 to 15 years old, 18.2% had ever smoked in 2014 (before the implementation of TRPR) compared with 16.2% in 2018. The proportion that were regular smokers also fell by one percentage point from 3.1% in 2014 to 2.1% in 2018. The prevalence of occasional smokers (those who smoke less than one a week) has seen a minor increase over the period. In 2014, 2.5% of 11 to 15 year olds were occasional smokers, compared with 2.9% in 2018.

Figure 7: Young people's smoking prevalence in England between 2012 and 2018 (Source: Smoking, Drinking and Drug use among young people in England)



5.48 Across individual age years (11 through to 15) there are very few regular smokers aged 11 and 12, so the overall decline in smoking prevalence is mainly attributed to the reduction of regular smokers who are older. 14 year olds regular smoking prevalence was 4% in 2014, which fell to less than 3% in 2018. Among 15 year olds, regular smoking prevalence fell from 8% in 2014 to 5.3% in 2018.

Scotland

5.49 The Schools Adolescent Lifestyle and Substance Use Survey (SALSUS) provides estimates of the proportion of under-16s in school who smoke. The SALSUS splits by age groups, focussing on children aged 13 and 15.

5.50 In 2018, almost all 13 year olds (97%) were non-smokers. 2% were regular smokers and 2% were occasional smokers. Smoking was more common among 15 year olds, but the prevalence was still low: 7% were regular smokers and 5% were occasional smokers. 87% of 13 year olds and 70% of 15 year olds reported never having smoked.

5.51 Smoking prevalence has decreased substantially over time, since 1996 among 15 year old boys and slightly later (since 2002-2004) among 15 year old girls and 13 year olds. However, this has levelled off in 2018, with no statistically significant changes this wave compared to 2015.

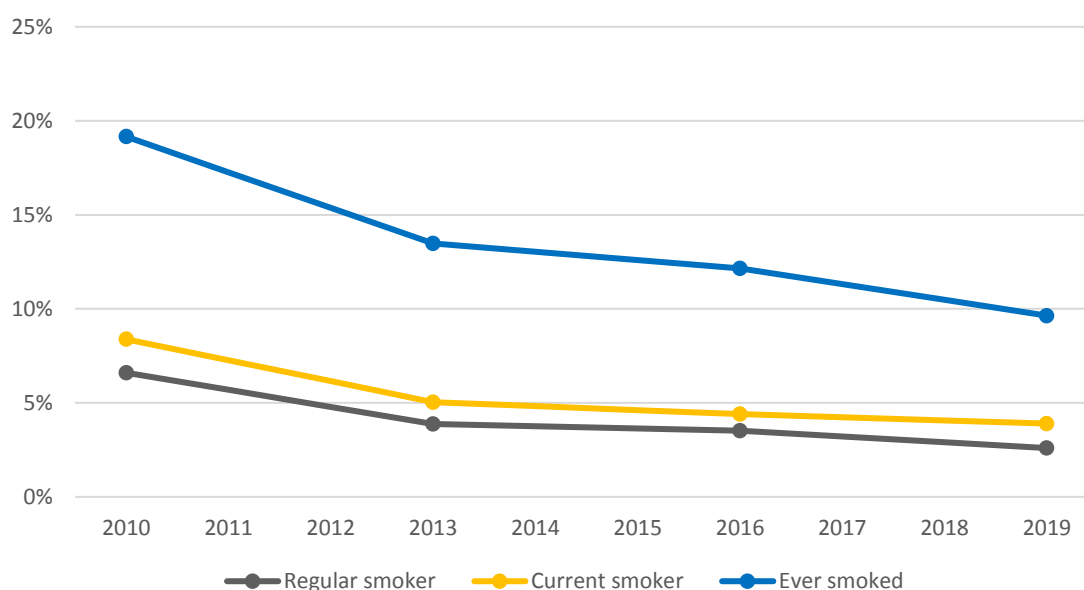
Wales

- 5.52 The Health Behaviour in School-aged children survey publishes data on smoking prevalence among 11 to 16 year olds in Wales. In 2017/18, roughly 4% of young people reported smoking weekly or daily (regular smokers) indicating no change since 2013/14. A further 2% were occasional smokers, smoking less than once a week.
- 5.53 Student Health and Wellbeing survey conducted in 2019 found similar levels of regular smokers among 11 to 16 year olds at 4%, indicating no further change. Overall, 11% of 11 to 16 year olds had ever smoked a cigarette.

Northern Ireland

- 5.54 The Young Persons Behaviour and Attitude survey publishes statistics on young people's prevalence in Northern Ireland. This survey covers 11 to 16 year olds and has been published every three years since 2010. Between 2016 and 2019, the proportion of young people who had ever smoked fell from 12% to less than 10%.
- 5.55 The proportion of young people who were regular and current smokers also decreased between 2016 and 2019. 3.5% of young people were regular smokers in 2016, compared with 2.6% in 2019. Current smokers made up 4.4% of young people in 2016, falling to 3.9% in 2019.

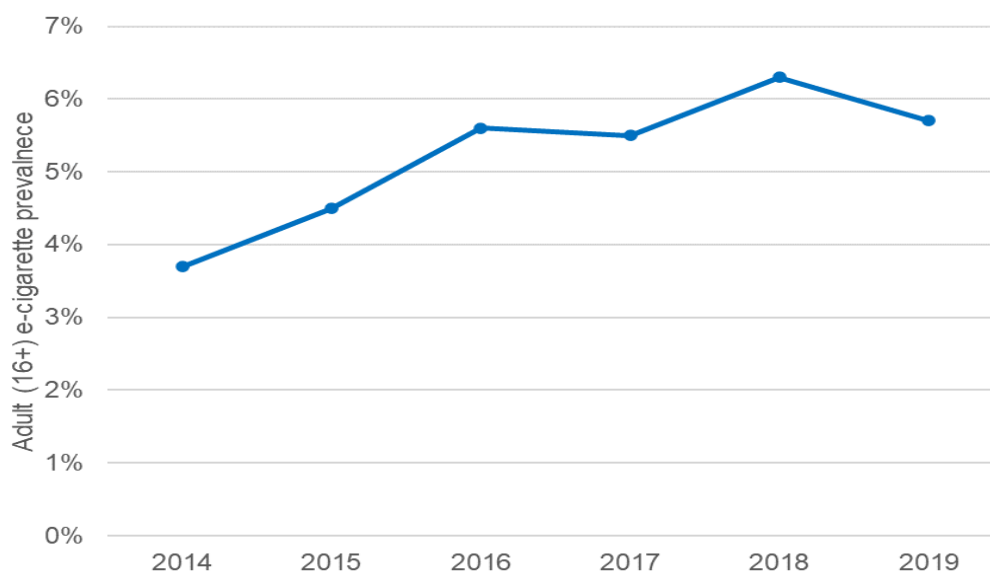
Figure 8: Young people's smoking prevalence in Northern Ireland between 2010 and 2019 (Source: Young Persons Behaviour and Attitude survey, 2019)



E-cigarette usage

- 5.56 The TRPR regulations introduced new requirements for e-cigarette manufacturers, such as warning labels, reporting and notification of products and restrictions on advertising.
- 5.57 E-cigarettes are increasingly being used by smokers to help quit smoking. In a recent evidence review¹⁵, Public Health England found that vaping poses a small fraction of the risk of smoking and that when e-cigarettes are used as part of a quit attempt, success rates are comparable with, or higher than, licensed medication alone. Welsh Government have also reported¹⁶ that the most common reason for using e-cigarettes was to help stop smoking tobacco (76% of current users).
- 5.58 In 2019 in Great Britain, 5.7% of survey respondents reported that they currently used an e-cigarette (vaped), up from 3.7% in 2014 when data collection began.
- 5.59 The prevalence of e-cigarette use across all 16+ age groups has increased since 2014, with the greatest increase being observed for persons aged 25 to 34, where it increased from 5.3% to 9.2%.

Figure 9: Adult e-cigarette prevalence in Great Britain, from 2014 to 2019 (Source: ONS Adult Smoking Habits in the UK)



- 5.60 In 2019, the proportion of vapers was highest among current cigarette smokers (15.5%) and ex-cigarette smokers (11.7%). Only 0.4% of people who have never smoked reported that they currently vape. The most common reason given for

¹⁵ Vaping in England: 2020 evidence update summary [Vaping in England: evidence update March 2020 - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/854421/vaping-in-england-evidence-update-march-2020-summary.pdf)

¹⁶ Adult smoking and e-cigarette use (National Survey for Wales): April 2018 to March 2019 <https://gov.wales/adult-smoking-and-e-cigarette-use-national-survey-wales-april-2018-march-2019>

vaping was as an aid to stop smoking, with approximately half (50.6%) of vapers reporting using e-cigarettes for that purpose in 2019.

- 5.61 Data on e-cigarette use from a survey of secondary school pupils in England¹⁷ (mostly aged 11 to 15) found that there had been a small increase in the number ever using e-cigarettes from 22% in 2014 to 25% in 2018, despite legislation which introduced a minimum age of sale of 18 for e-cigarettes and prohibited the purchase of these products on behalf of someone under the age of 18.
- 5.62 Current e-cigarette use increased with age; from less than 1% of 11-year olds, to 11% of 15-year olds. Regular e-cigarette users were most commonly given them by friends (38%). Other common sources were to buy them from the internet (29%), friends or relatives (29%), or from someone else (26%). 17% said they bought them from e-cigarette shops.
- 5.63 Buying from any kind of shop fell from 37% in 2016, to 29% in 2018. Buying from the internet increased from 23% to 29% over the same period.

Summary

- 5.64 Adult smoking prevalence across the UK continues to decline year on year, with significant reductions over the past five years. Along with it, average daily consumption of cigarettes has been falling slowly across the UK. Smokers' intention to quit has been high over the last five years, and while the number of quit attempts has generally decreased since a decade ago, the percentage of quit attempts that are successful has remained high.
- 5.65 Smoking prevalence has declined among young people in England and Northern Ireland. The proportion of young people trying cigarettes has fallen significantly, and the proportion of young people smoking regularly is also very low. Prevalence in Scotland and Wales has remained broadly stable since 2015, showing no increase.
- 5.66 The trends in these indicators have occurred despite the tobacco industry introducing a number of new products in response to the ban on menthol products, as explained in the Peer Reviewed Evidence section.

¹⁷ Smoking, Drinking and Drug Use among Young People in England 2018 - NHS Digital Aug 2019
<https://digital.nhs.uk/data-and-information/publications/statistical/smoking-drinking-and-drug-use-among-young-people-in-england/2018>

- 5.67 E-cigarette use by all 16+ age groups in Great Britain and secondary school pupils in England has increased in the same period. E-cigarettes are increasingly being used by smokers to help quit smoking.
- 5.68 The overall trends in the key indicators have shown positive changes since the implementation of TRPR regulations. The exact contributions of TRPR towards these positive trends is hard to quantify, mainly due to the large number of other changes in the tobacco and e-cigarette landscape both before and since the implementation of TRPR, including the introduction of SPoT. As discussed above, the peer reviewed evidence identified also did not provide further information on how much of the change in these indicators can be attributed to TRPR.

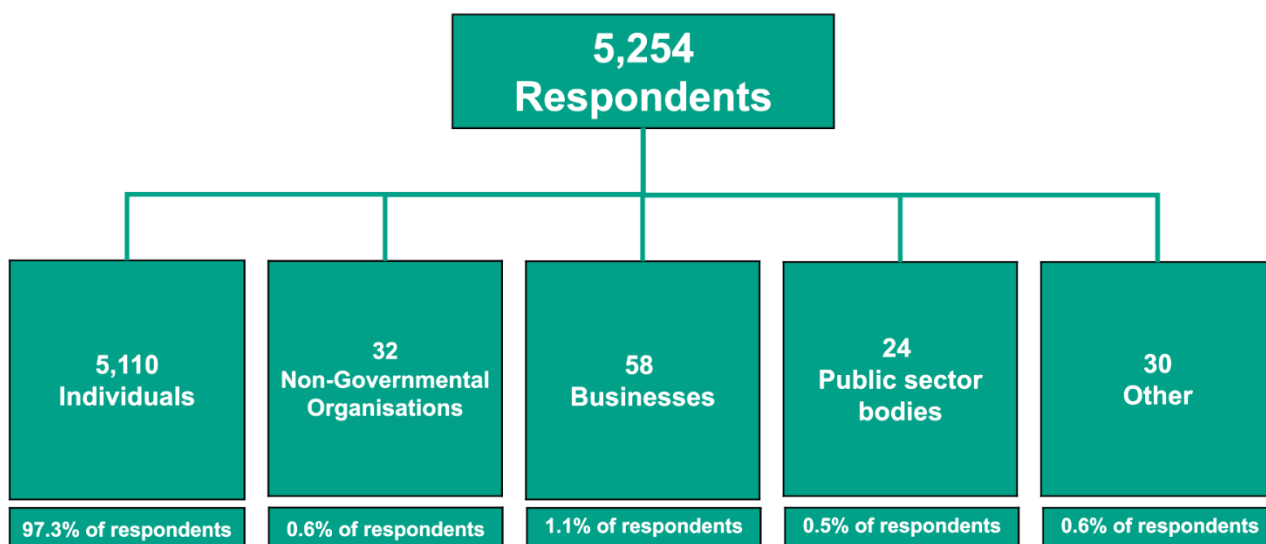
Public Consultation

5.69 A public consultation on TRPR ran from the 29th January 2021 to the 19th of March 2021.

Consultation demographics

5.70 5,254 responses were received in total, across a range of different stakeholders. The demographics of the consultation are based on how respondents identified themselves, such as individuals, non-governmental organisations (NGOs), businesses, public sector bodies, and no adjustments were made here. Figure 10 below shows the number of responses received to the consultation by the capacity of the response.

Figure 10: Breakdown of consultation responses by stakeholder group



Consultation analysis methodology

5.71 Analysis of the consultation responses outlines the proportion of respondents who answered 'Strongly Agree/Agree/Don't Know/Disagree/Strongly Disagree' to the questions (e.g. "How far do you agree or disagree that the prohibition of characterising flavours has helped smokers quit smoking?"). Some questions only had options for Agree/Disagree/Don't know.

5.72 Alongside this, the consultation offered respondents the opportunity to provide reasons and/or evidence to support their view. These free-text fields were considered individually and classified into specific themes which were summarised to draw general conclusions. Many respondents used these free text fields to include references to published evidence, such as Government publications and

independent reports. These were reviewed alongside responses to inform the review.

- 5.73 There were twelve questions covering specific aspects of TRPR and a further question giving respondents the opportunity to describe anything else they felt was relevant to the regulations.

Limitations of the consultation results

- 5.74 Results from the consultations should be considered in the context of the consultation process and the information supplied by respondents.

- The consultation was commissioned to review the legislation through the PIR process. Respondents were those who wished to express a view to the Government and therefore is not representative of the whole of the UK
- DHSC received views from both individuals and organisations. All contributions were analysed equally. For example, a response from a micro-business¹⁸ was given equal weight to that of a large business for both the quantitative and qualitative aspects of the consultation
- The capacity in which responses were submitted (e.g. as an individual, as a business, as a public sector body) was self-reported, and therefore statistics may not accurately reflect the views of each group of respondents
- Ratings of regulation impact should be treated with caution. Many individuals expressed a personal opinion, but did not provide evidence to support their view

- 5.75 In reviewing consultation responses, no further judgements were made about the credibility of respondents. All analysis has been based around attempts to classify responses into broader themes, whereby responses were analysed equally.

Summary of the consultation results

- 5.76 The consultation questions have been grouped into sections where relevant and discussed together. In the table summaries, 'Strongly Agree' and 'Agree' and 'Disagree' and 'Strongly Disagree' have been combined into one column. Respondents were not required to answer every question. Those that did not answer have been grouped in a column with those that responded 'Do not know'. Percentages may not sum correctly due to rounding.

¹⁸ Micro-businesses are those that employ less than 10 people

- 5.77 Across all respondents, attitudes towards the regulations were mixed. However, the overall response is skewed by the large number of individuals who provided an opinion on the regulations and does not provide an accurate picture for the response of different stakeholder groups.
- 5.78 Other stakeholder groups such as public sector bodies (including public health organisations) generally provided a clearer opinion on the regulations and generally favoured the regulations, suggesting they were meeting the intended objectives. Businesses and NGOs often provided mixed responses, though did provide clear opinions to certain questions.
- 5.79 A general summary for each question is presented below, and the overall response rates to each question, however it is necessary to consider the context in which the questions are summarised as the majority of responses are from individuals. Further information on stakeholder opinions is included in Annex A.

Health text and picture warnings

- 5.80 The questions below have been grouped together as they discuss health text and picture warnings and the impact they have had.

How far do you agree or disagree that the requirements on the packaging and labelling of tobacco products have been an effective way to protect young people from taking up smoking?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	29%	24%	42%	5%

How far do you agree or disagree that the introduction of rotating combined (photo and text) health warnings on cigarette and hand rolling tobacco has encouraged smokers to quit?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	25%	28%	32%	15%

Should all tobacco products have a combined (photo and text) health warning on their packaging?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents				

All Respondents	47%	25%	22%	5%
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- 5.81 Of those that agreed the introduction of combined health warnings had encouraged smokers to quit, the main reasons were that they provided increase awareness of the health consequences of smoking, and that the images put people off smoking. Some respondents explained that other factors had encouraged smokers to quit alongside the health warnings, such as the cost of cigarettes and available alternatives.
- 5.82 Of those that disagreed, the main reasons were that smokers ignore the packaging as they already know the risks. Some suggested that people had become desensitised to the warnings or that they can just be covered up.
- 5.83 In terms of protecting young people from taking up smoking, the main comment from respondents was that they will smoke regardless of any warnings on the packaging.
- 5.84 On extending the regulations to all tobacco products, many suggested the combined health warning should only be on cigarettes and hand rolling tobacco, and a small number suggested there should not be any combined health warnings at all.

Prohibiting characterising flavours

- 5.85 The questions below have been grouped together as they discuss the prohibition of characterising flavours and the impact it has had.

How far do you agree or disagree that the prohibition of characterising flavours has helped smokers quit smoking?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	17%	22%	46%	15%

How far do you agree or disagree that the prohibition of characterising flavours has deterred young people from taking up smoking?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	15%	27%	36%	22%

- 5.86 On the prohibition of characterising flavours, the majority of respondents disagreed that they had helped quit smoking. The reasons they gave were that smokers had

just switched to non-flavoured cigarettes, and that smokers were using other products to flavour their cigarettes.

- 5.87 Of those that felt the prohibition had helped smokers quit, they said that it helped smokers move to alternative products (such as e-cigarettes) where those flavours were still available.
- 5.88 On young people, similar reasons were suggested for both those who agreed and disagreed that the prohibition of characterising flavours had deterred them from taking up smoking.

E-cigarettes

- 5.89 The questions below have been grouped together as they discuss the respondent's views on current e-cigarettes regulations and the impact they have had.

How far do you agree or disagree that the current regulations on e-cigarettes have been proportionate in protecting young people from taking up use of these products?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	37%	22%	28%	13%

How far do you agree or disagree that the current regulations have ensured that e-cigarettes are available for those smokers who wish to switch to these products?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	67%	13%	15%	6%

What effect do you think the regulations have had on smokers considering switching to e-cigarettes?

	Encouraged	Neutral	Discouraged	Don't Know/No answer
All Respondents	40%	35%	15%	10%

Do you consider the restrictions on e-cigarette advertising to be an effective way to discourage young people and non-smokers from using e-cigarettes?

	Yes	No	Don't Know/No answer
All Respondents	32%	40%	28%

- 5.90 Common themes from those who felt the regulations were too severe were that both tank and refill bottle sizes should be bigger, and some suggested the allowed nicotine strength of e-cigarettes should be increased.
- 5.91 Amongst respondents that felt they should be more severe it was suggested that the packaging encourages (young) people to use e-cigarettes, and that allowed nicotine strength should be decreased.
- 5.92 On helping smokers switch to e-cigarettes, many responses suggested that tank size, refill bottle sizes, and nicotine strength should be increased. Related to restrictions on advertising, it was suggested that to help smokers switch, the restrictions on advertising should be relaxed to increase the awareness of the positive health benefits of switching. However, in regard to young people, many felt that the restrictions on e-cigarette advertising were working to discourage them from using e-cigarettes.

Novel Tobacco Products

How far do agree or disagree that the requirements of TRPR on novel tobacco products are proportionate?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	13%	30%	15%	42%

- 5.93 The response to the question on novel tobacco products was mixed. Many people did not provide an answer or neither agreed or disagreed that the requirements were proportionate.
- 5.94 The number of respondents that either agreed or disagreed the regulations were proportionate was similar, and very little was provided in the free text boxes on either of these.
- 5.95 A small number suggested that the regulations should be relaxed for novel tobacco products. However, a similar number of respondents suggested novel tobacco products should follow the same restrictions as regular tobacco.

Enforcement

Do you agree or disagree that the penalties for a breach of the regulations are an effective deterrent to ensure compliance with the regulations?

	Agree	Disagree	Don't Know/No answer
All Respondents	34%	22%	44%

- 5.96 When asked about penalties for breaching the regulations, more respondents agreed they were an effective deterrent than disagreed.
- 5.97 Of the stakeholder groups that responded, businesses were most likely to suggest the penalties were an effective deterrent to ensure compliance.
- 5.98 Comments on the severity of the penalties were mixed. A similar number of people suggested that the penalties should be more severe to those who suggested penalties should be less severe (or removed entirely). No businesses felt the penalties should be more severe, however, some, along with many other respondents felt there should be more compliance checks in regard to the regulations.

Economic impact of TRPR

How far do you agree or disagree that there has been an economic impact of TRPR, either positive, negative, or both?

	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	21%	30%	4%	45%

- 5.99 Responses agreeing there had been an economic impact provided various reasons. Of those that felt there had been a positive economic impact, this was due to the health benefits from the regulations. This was supported by many public sector bodies, as well as some businesses and NGOs.
- 5.100 Many felt there had been a negative economic impact. Some of the reasons provided were that the regulations had had a negative impact on switching, and that the financial cost to comply had increased and/or was too high. This was supported by businesses.
- 5.101 A small number of respondents felt that there had been both positive and negative economic impacts due to the implementation of TRPR.

Anything else on TRPR

Is there anything else you would like to share on negative or positive impacts the regulations have had on topics not covered above?

- 5.102 When providing any additional information on TRPR, many respondents commented on particular aspects of the regulations. There were suggestions that both the refill bottles and tank sizes for e-cigarettes should be bigger, and that the

allowed nicotine strength of e-cigarettes should be increased. A small number of responses suggested e-cigarettes should have stronger regulations in place to deter use, including youth use.

- 5.103 There were a large number of responses both suggesting that the regulations were fair and proportionate, and suggesting that they should be relaxed as e-cigarettes are less harmful.

Compliance rates

- 5.104 Chartered Trading Standards Institute (CTSI) have reviewed product compliance with TRPR regulations. In May 2018 CTSI found that almost a quarter of all products examined were found to be non-compliant with the regulations, the majority for multiple reasons including labelling issues, lack of health warnings and information leaflets¹⁹.
- 5.105 A second report in August 2018 found that there was 84% compliance of e-cigarette products and 80% compliance for refill containers, an improvement on the compliance rates found during the first review²⁰.
- 5.106 The CTSI Tobacco Control Survey England²¹ showed that the proportion of councils undertaking activities relating to TRPR reduced from 63% in 2018/19 to 49% in 2019/20.
- 5.107 For tobacco products, 2,918 visits were made by 42 councils to assess compliance with TRPR, 9% of visits found non-compliant tobacco products. For most tobacco products, except for cigars and shisha products, non-compliant products were mainly found in convenience stores and grocers. The survey showed that no non-compliant tobacco products were found at large retailers or online.
- 5.108 For nicotine inhaling products 889 visits were made by 63 councils to assess compliance with TRPR, 18% of these visits found non-compliant nicotine inhaling products. Over half of non-compliance for e-cigarette refill products were found in specialist e-cigarette suppliers, while non-compliance for e-cigarette products were

¹⁹ Rapid Review of Nicotine Inhaling Product Compliance with the with the Tobacco Product and Tobacco Product and Related Products Regulations - CTSI May 2018

[Microsoft Word - RR1 phase 3 final report for DHSC \(tradingstandards.uk\)](#)

²⁰ Rapid review 2: product compliance tobacco and related product regulations: 2016 phase 3: nicotine inhaling products CTSI Aug 2018

[Microsoft Word - RR2 Nicotine Inhaling Products compliance 2018 \(tradingstandards.uk\)](#)

²¹CTSI Tobacco Control Survey England 2019/20 [ctsi-tobacco-report-2019-20.pdf \(tradingstandards.uk\)](#)

most commonly found in convenience stores and grocers. The survey showed that no non-compliant e-cigarette or refill products were found in newsagents.

- 5.109 Analysis of e-cigarette advertising expenditure by Cancer Research UK in 2019 showed that 99.9% of spend reported occurred in media channels where e-cigarette advertising was permitted under TRPR, suggesting good compliance with this aspect of TRPR²².
- 5.110 Results from the study indicate that the TRPR has prevented further increases in youth noticing e-cigarette marketing in prohibited channels in England. However, despite relatively stable levels of noticing e-cigarette marketing in prohibited channels, there was an overall increase in young people reporting noticing things that promote e-cigarettes between 2017 and 2019 through permitted channels.
- 5.111 Among adults (aged 18 and over) who currently or formerly smoked or vaped, there was a significant decrease in noticing e-cigarette marketing on television, radio, posters, billboards, newspapers and magazines between 2016 and 2018 in England. However, as posters and billboards are permitted channels in England and were also included in the measure, it is not possible to conclusively determine whether the overall decrease was attributable to TRPR prohibitions.

²² E-cigarette marketing in the UK - Cancer Research UK
[E-cigarette marketing in the UK \(actbr.org.br\)](https://actbr.org.br)

Economic impacts

5.112 The implementation of TRPR was expected to have a significant economic impact. Research was commissioned to explore the impact of the regulations on small business due to the large proportion of tobacco estimated to have been sold in small and micro businesses (46%²³), and the costs and benefits estimated in the original Impact Assessment have been reviewed.

The King's Fund: Qualitative assessment of the effect of TRPR on small businesses

- 5.113 The implementation of TRPR was expected to have a particularly large impact on small and micro businesses, specifically retailers, due to the large proportion of tobacco estimated to have been sold by businesses of this size (46%²⁴).
- 5.114 To explore the impact of the SPoT and TRPR regulations on small businesses that are retailers of tobacco and related products²⁵, DHSC commissioned research by The King's Fund.
- 5.115 This research was designed to inform this PIR through the illustrative experience of small businesses. Some of the questions posed to retailers were based on concerns raised by the industry at the time of the Impact Assessment (such as purchasing habits and an increase in time taken to sell tobacco). Some of the qualitative evidence below is used to inform the review of the Impact Assessment.
- 5.116 20 semi-structured interviews were conducted between November and December 2020. Interviewees received payment in recognition of their time. Larger retailers such as supermarkets and petrol stations were deemed outside the scope of this research. The final sample of interviewees were selected to ensure a mix of representation from rural, urban, suburban, and coastal areas. The full demographic breakdown can be found in Annex B.
- 5.117 The findings for TRPR only are summarised here, with illustrative quotes italicised throughout to provide examples of particular points.

²³ "Cigarettes in the United Kingdom", Euromonitor 2011

²⁴ "Cigarettes in the United Kingdom", Euromonitor 2011

²⁵ The Kings Fund: Qualitative assessment of the impact of Standardised Packaging of Tobacco and Tobacco and Related Products Regulations on small business, 2021:

<https://www.york.ac.uk/healthsciences/research/health-policy/research/health-policy-projects/prepare/reports/>

Sales of tobacco products

- 5.118 Many Interviewees did comment on a significant reduction in the sales of tobacco products, though some did suggest they had increased slightly or more substantially. The general feeling was that the impact of specific regulations was hard to pin down, but that all the changes together were noticeable over time:

"...we evaluated it after, like, six months ... slowly, slowly [finding] people were drifting off and moving on to other things. So it's hard to specify one particular thing that contributed the most to it."

- 5.119 Of the requirements in TRPR, the perception was that the ban on characterising flavours had had more of an impact than other requirements, such as larger health warnings.

- 5.120 Beyond tobacco, the wider trends included a growing preference for e-cigarette use and this was felt to be due to the increase in cost of tobacco as well as ban on characterising flavours:

"And I think a lot of people who have gone from smoking to vaping are doing it purely and simply because the cost of smoking is just becoming untenable for them"

Changes to e-cigarette and refill sales

- 5.121 There was limited awareness of specific e-cigarette related requirements due to TRPR among interviewees, even when prompted by the interviewer. There was an inability to recognise how or when the regulations came into place, and therefore were unable to comment on any impact on sales. Specifically on reporting requirements, one interviewee said:

"I don't understand what are the regulations you're referring [to]. So I don't understand the question."

- 5.122 Some of those interviewed did think the TRPR regulations had made positive steps in removing less reputable or potentially harmful products. Specifically on the strength of nicotine in liquids, and legitimacy:

"Because I knew, before, you used to get really strong stuff that you could add to [e-liquids] so that, I believe, has gone."

"I think a lot of [e-liquid product] has been made, no offence, in the back of a shed, by some people. And the regulations kind of stamped out on that a lot, so it did, because it was unregulated."

- 5.123 Similarly, interviewees implied that the introduction of health warnings due to TRPR had in some way legitimised the products. The regulations were seen to have created a differential between e-cigarettes and conventional tobacco due to the difference in requirements of health warnings and packaging.
- 5.124 Across many interviewees, there was the feeling that e-cigarette use was more popular among young people. However, most smokers (especially older smokers) were not changing habits towards e-cigarette use.

Effects on business and income

- 5.125 Due to interviewees limited knowledge of the requirements of TRPR for tobacco products, and the inability to differentiate between the various regulations that have been introduced, the overall impact on business and income was felt to be limited. Any impact was likely to have been incurred when the regulations were first implemented, and before customers changed any purchasing habits:

"Like I say, I don't think [the introduction of the regulations] has had an effect on the income coming into the business."

- 5.126 Some interviewees that considered the regulations had had a limited impact on income noted that the profit margin on tobacco products was very small to begin with.

"Tobacco [sale] has decreased slightly, but the big thing about tobacco is there's not much margin to be made on it. So we haven't been keeping that much of an eye on it."

"But to be honest, yeah, I make a bigger profit selling jelly babies than I do with cigarettes."

- 5.127 A minority of interviewees did note that even incremental effects of TRPR were important for business and that the regulations had had a negative impact. Specifically on e-cigarette and related products it was suggested that warnings being on both the packaging on bottle meant old stock had to be disposed of at cost.

- 5.128 Shops where e-cigarettes were a sizeable seller for the retailer felt the shift towards e-cigarettes were positive due to the larger profit margin on these products compared to tobacco products:

"The e-cigarette does tend to there's a lot more mark-up on them, so we can make more on that. So if the likes of our cigarette smokers move across to e-cigarettes, then it's a win-win for us."

- 5.129 However, some interviewees noted that their sales of e-cigarette products were low despite stocking them, suggesting that consumers would rather go to specialist stops. It was not clear from these interviews whether the shift to e-cigarettes meant customers were moving to other retailers constituting a loss for these businesses, and how much of this was due to the regulations.

Customer feedback and circumvention of regulations

- 5.130 In regard to TRPR, measures such as the increase in size of health warnings or the requirements of health warnings were not picked up on by customers. Other restrictions that were significant such as the flavouring ban for cigarettes and hand rolling tobacco did produce negative feedback from customers. This was around the time of implementation, and decreased over time:

"It's gone back to normal because they know they can't [get 10-packs]... most people will come in the shop, they know they can only get 20 fags now. And they know they can't get the menthol fags."

- 5.131 Particularly in response to the flavour ban, interviewees commonly said manufacturers had gotten around the regulations by selling products separately to cigarettes and hand rolling tobacco. These included flavoured cards, rolling papers, and filters.

"So like your tobacco companies and everyone, they're looking at ways of how to keep mentholated products going but not making them an actual mentholated product. So like your flavour cards, your liquids what you can add to your pack of cigarettes."

- 5.132 On health warnings, some interviewees said that customers would often ask for packs to be sold face down to avoid seeing them, or asking for warnings that did not really apply to them.

- 5.133 In regard to e-cigarettes, a small number of those interviewed said customers could often get around the e-cigarette regulations that were implemented by various means. This included purchasing online, or making their own e-liquids.

"You can still buy the big tanks online, you can still buy the great big bottles of oil online, you know?"

Summary

- 5.134 The specific contributions of TRPR to any impact on business are hard to quantify. Across tobacco products, there were some parts of TRPR that had had greater impact than others. For e-cigarettes and related products, the regulations were

viewed somewhat positively by retailers. Costs to business due to TRPR were felt to be limited by retailers in this study, with any costs being incurred when the regulations were first implemented.

- 5.135 These findings are based on the illustrative experience of a small number of tobacco retailers and are considered alongside other sources of evidence. The findings are also used to review certain elements of the Impact Assessment.

TRPR Impact Assessment

5.136 The Impact Assessment considered the costs and benefits associated with the implementation of regulations. Below, we explore the changes in the tobacco landscape since the Impact Assessment was produced and review the costs and benefits associated with the implementation of standardised packaging in line with new data. In the main review we present only the changes to previously quantified costs. Further information on all costs and benefits originally considered in the Impact Assessment can be found in Annex C.

Summary

5.137 Based on the review of the Impact Assessment, the economic impact remains dominated by the health benefits of the regulations. The costs to business remain small relative to these benefits. Prior to the implementation of the regulations there were significant changes to certain key indicators such as smoking prevalence and tobacco sales. These changes were not accounted for in the Impact Assessment due to the data not being available at the time. The review of the evidence suggested no other changes are necessary. While the impacts attributable to the regulations remains the same, when applying them to lower baseline figures for certain key areas, the monetised costs and benefits are lower than originally anticipated.

5.138 The costs and benefits for each stakeholder were included in either the Net Present Value (NPV), the Equivalent Annual Net Direct Cost to Business (EANDCB), or both. Table 4 below presents the original estimates for both compared with the estimates using new data. The full breakdown of which elements are included in each is presented in Annex C and is the same as for the original Impact Assessment.

Table 4: NPV and EANDCB of the regulations as estimated in the Impact Assessment compared with the PIR estimates

	IA Estimate	PIR Estimate
Net present value		
Benefits	£13bn	£12.2bn
Costs	£2.2bn	£2.1bn
Total NPV	£10.8bn	£10.1bn
EANDCB		
EANDCB	£16.4million	£16.1million

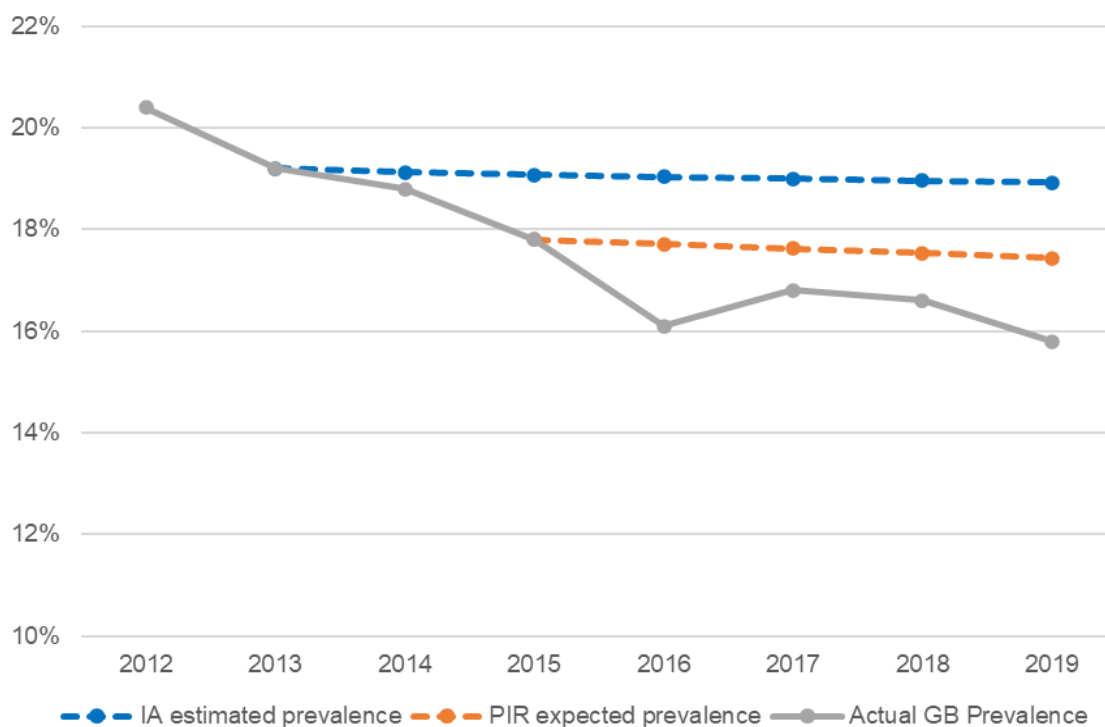
Overview of changes since implementation

5.139 The Impact Assessment used the data available at the time to estimate the likely impact of the regulations. Since the Impact Assessment was conducted and since implementation, we have more recent data to revise the estimates. Two of the main changes are to the estimations of smoking prevalence and sales figures.

Changes to smoking prevalence estimates

- 5.140 At the time the Impact Assessment was conducted, data on smoking prevalence from 2013 onwards was not available. Therefore, smoking prevalence was forecasted between 2013 and implementation. This forecast accounted for decreases in prevalence as a result of other regulations, such as the display regulations, however prevalence fell much faster than anticipated, and by the time the regulations were implemented prevalence was much lower than expected.
- 5.141 Many of the estimated impacts of TRPR were based on an expected relative reduction applied to forecasted 2014 baseline prevalence. When reviewing the Impact Assessment estimates, the baseline has been adjusted in line with actual data to more accurately reflect any impact of TRPR, displayed in Figure 11 below. Further to this, the actual prevalence over the years is displayed, demonstrating the difference between the new estimated impact of TRPR and how much further prevalence declined beyond this.
- 5.142 The impact of TRPR, which was expected to occur between 2015 and 2019, makes up around 10% of the fall in actual prevalence (0.2 percentage points of the 2.0 percentage point fall between 2015 and 2019).
- 5.143 Considering and accounting for the display regulations that were introduced around the same time, the total impact of all of these including TRPR, would make up around 18% of the fall in actual prevalence (0.36 percentage points of the 2.0 percentage point fall between 2015 and 2019). Smoking prevalence is affected by more than just regulatory interventions, such as increases in tax, and the estimated impact does not constitute a fall greater than what was seen in actual data over the review period. It is therefore considered a reasonable estimate.

Figure 11: TRPR Impact Assessment estimated smoking prevalence vs PIR estimated and actual GB prevalence (Source: TRPR IA, TRPR PIR Estimates, ONS Adult Smoking Habits in the UK)



Changes to tobacco clearance estimates

- 5.144 Tobacco clearances are the volume of duty paid tobacco cleared for legal consumption. The Impact Assessment calculations used forecasts from the Office for Budget Responsibility (OBR). The Economic and Fiscal outlook 2014 reports²⁶ covered the expected clearances of tobacco up until 2020, whereby the general trend in cigarette clearances was applied to the 2020 figure to estimate the clearances up to 2025 (covering the 10-year appraisal period).
- 5.145 Similar to the changes in prevalence, the actual clearances of cigarette sticks and hand rolling tobacco (sourced from the HMRC tobacco bulletin²⁷) were significantly lower in the years following the implementation of the regulations compared to the forecasts. Table 5 below shows the OBR forecasts for tobacco clearances from 2014/15 to 2018/19, compared with the actual clearances.
- 5.146 Many of the expected impacts of TRPR were based on these clearances. When reviewing the Impact Assessment estimates, the 'baseline' has been adjusted in line with revised data to reflect any impact of TRPR more accurately.

²⁶ [Economic and fiscal outlook - March 2014 - Office for Budget Responsibility \(obr.uk\)](https://obr.uk/economic-and-fiscal-outlook-march-2014/)

²⁷ HMRC Tobacco bulletin: <https://www.gov.uk/government/statistics/tobacco-bulletin>

Table 5: Forecasted cigarette stick clearances compared with revised clearances (Source: OBR Fiscal and Economic Outlook, 2014 and HMRC Tobacco bulletin, July 2021)

Year	2014/15	2015/16	2016/17	2017/18	2018/19
Cigarette stick clearances, millions					
OBR Forecast	36,700	35,100	33,800	32,400	31,100
Actual clearances	32,661	30,971	28,246	26,948	26,289

5.147 While cigarette clearances were forecasted to fall, clearances of hand rolling tobacco were forecasted to increase. The same OBR reports were used for forecast figures of hand rolling tobacco. The forecasts for hand rolling tobacco were again higher than the actual clearances as shown in table 6 below. Again, the revised data has been taken in account when reviewing the Impact Assessment estimates.

Table 6: Forecasted hand rolling tobacco clearances compared with revised clearances (Source: OBR Fiscal and Economic Outlook, 2014 and HMRC Tobacco bulletin, July 2021)

Year	2014/15	2015/16	2016/17	2017/18	2018/19
Hand rolling tobacco clearances, million kgs					
OBR Forecast	6.7	6.9	7.1	7.3	7.5
Actual clearances	6.1	6.1	6.0	6.1	6.4

5.148 Among other things, this reduction in clearances and expected clearances reflects the findings of the key indicators. There are in general fewer smokers, and average consumption has fallen slightly.

5.149 The costs and benefits as calculated in the Impact Assessment are affected by these changes. Generally, where costs and benefits have changed, this is a reduction compared to the original Impact Assessment estimates.

5.150 The changes in smoking prevalence outlined above reduce the monetised health benefits associated with the regulations. This is due to the impacts being measured as a percentage reduction in prevalence, and when applying these to a lower baseline it results in a smaller change in prevalence. This also has an impact on some costs. For instance, where the number of fewer smokers was used to estimate a loss in profit, a reduction in the number of fewer smokers produces a lower loss in profit.

5.151 The clearances of tobacco are significantly lower. The costs associated with this are those regarding profits to certain stakeholders, as well as the tax revenue. The changes in clearances are significant and would suggest large costs have been incurred. However, only a portion of these are likely attributable to TRPR, with the remainder due to other measures and interventions prior to the implementation of TRPR. The estimated impact of TRPR on clearances also remains unchanged, however as with prevalence, when applied to a lower baseline the monetised costs are estimated to be lower than in the Impact Assessment.

- 5.152 Evidence on other costs and benefits associated with the regulations was identified through searches of available datasets and studies, including from academics and industry. Additionally, the consultation did provide an opportunity for respondents to provide details and evidence on the economic impact due to TRPR. However, evidence on other costs and benefits of TRPR was limited. For example, while some consultation responses noted particular costs (such as reporting costs), no figures or evidence were included in these responses. Where no evidence was identified through our searches or received through the consultation, the assumptions used in the Impact Assessment have been used.
- 5.153 Full details of each cost and benefit described in the original Impact Assessment can be found in Annex C. Below is a general overview of the changes in monetised costs and benefits to each of the major stakeholders identified in the original Impact Assessment.

Changes in impact

5.154 Given the changes outlined above, the costs and benefits have been revisited. The original calculations have been updated with the new data outlined above, and the changes in the estimated costs and benefits are summarised below. Further details are included in Annex C, including more detailed methodology used in the original calculations as well as that used to update them.

Health Benefits

5.155 The reduction in smoking prevalence TRPR was estimated to generate was expected to result in large health benefits to the general population of smokers, quitters, and non-smokers. These were in the form of health gains due to fewer smokers, from those who quit each year.

5.156 The changes in prevalence described above result in a slight reduction in the estimated benefits attributed to TRPR. The number of people who quit and the number who did not take up smoking were based on a percentage reduction applied to the 2014 prevalence. While the estimated percentage reduction in prevalence due to TRPR has not changed, when applying this percentage reduction to the lower baseline it provides a lower estimate for the number of adult quitters. This means that although the estimated impact on prevalence of TRPR is the same, the monetised health benefits are lower than they were in the original Impact Assessment.

Impact	IA estimate (£m)	PIR estimate (£m)
Health gain - reduced smoking in adults	13,047	12,170

Reduced labelling costs

5.157 TRPR removed a requirement for cigarette packages to contain printed TNCO (emission levels for tar, nicotine, carbon monoxide and other yields) labelling. This was expected to provide a cost saving for manufacturers of tobacco products.

5.158 No further evidence has been identified or received through the consultation for this PIR in relation to this cost, therefore it is assumed to have remained the same.

Impact	IA estimate (£m)	PIR estimate (£m)
Reduced labelling	6.6	6.6

Charging income and costs

- 5.159 Under TRPR the Government could charge industry to cover some costs of the regulatory regime. The Government decided to charge industry fees to verify TNCO levels in cigarettes and processing and storing data from notifications.
- 5.160 In the Impact Assessment this was described as a benefit to Government and an equivalent cost to businesses.
- 5.161 The estimated income to Government and cost to businesses in the Impact Assessment was £2 million over the appraisal period.
- 5.162 No further evidence has been identified or received through the consultation for this PIR in relation to this benefit and cost, therefore it is assumed to have remained the same.

Impact	IA estimate (£m)	PIR estimate (£m)
Charging income	2.0	2.0
Charging costs	-2.0	-2.0

Lost tax

- 5.163 HMRC and taxpayers were estimated to see a reduction in the amount of tax and duty paid as a result of the regulations.
- 5.164 This cost could be seen as a transfer payment due to this reduction in spend on tobacco likely to be at least partially offset by spending on other goods and services in the economy. However, it is a transfer of spending from higher taxed goods to lower taxed goods. This means that if the Government wanted to maintain public spending additional tax revenue would have be raised, which would impose a cost on the public. Therefore, in the Impact Assessment this transfer of spending from higher taxed goods to lower taxed goods was considered a cost of this policy.
- 5.165 The Impact Assessment considered the reduction in taxes because of the regulations due to there being fewer smokers purchasing tobacco and a potential increase in illicit trade.
- 5.166 The reduction in the number of quitters and tobacco clearances relative to estimates in the Impact Assessment means the estimated loss in tax due to TRPR is also estimated to be lower than in the Impact Assessment. Although the reduction in tax remains significant, however it does not outweigh the expected benefits of the regulations presented above. In addition, the evidence from the

HMRC 'tobacco tax gap estimates'²⁸ and an EU study²⁹ suggests that the illicit market may not have grown by as much since the implementation of TRPR as assumed in the Impact Assessment. However, as it has not been possible to attribute the changes in the illicit market identified by these studies solely to TRPR, it has not been possible to update this assumption.

Impact	IA estimate (£m)	PIR estimate (£m)
Loss in tax due to fewer smokers	-1,989.3	-1,851.5
Loss in tax due to increase in illicit sales	-164.5	-155.0

Lost profits

- 5.167 TRPR was expected to reduce the profits for retailers, wholesalers and manufacturers of tobacco products. This was due to both the expected reduction in the number of smokers and increase in the consumption of illicit tobacco. Although as mentioned above the evidence suggests that the illicit market may not have changed by as much as originally assumed in the Impact Assessment. This means that the lost profits may be lower than originally estimated.
- 5.168 These costs were based on forecasted sales data and estimated profit margins. As a result, the estimates of these costs have decreased in line with the reduction in overall tobacco clearances. The estimated lost profits to retailers are borne by all retailers of tobacco. In 2020, it was estimated that there were 46,955 shops in the UK, of which 72% were independent retailers³⁰. Although a large number of these retailers will be small and micro businesses the lost profits would be spread across all retailers of tobacco products and mostly realised over a 10-year appraisal period, meaning the impact on individual small and micro retailers is likely to be small.
- 5.169 Additionally, The King's Fund research, described above, did not provide any evidence to update the estimated lost profit for retailers or that retailers incurred any additional costs that were not considered in the Impact Assessment.

Impact	IA estimate (£m)	PIR estimate (£m)
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²⁸ HMRC Measuring Tax Gaps: <https://www.gov.uk/government/statistics/measuring-tax-gaps>

²⁹ Support study to the report on the application of Directive 2014/40/EU

Final report <https://op.europa.eu/en/publication-detail/-/publication/9ce15083-b931-11eb-8aca-01aa75ed71a1/language-en>

³⁰ ACS Local Shop Reports 2020 available at:

https://www.acs.org.uk/sites/default/files/acs_local_shop_report_2020.pdf

Loss in profit due to fewer smokers	-194.8	-175.1
Loss in profit due to increase in illicit sales	-27.4	-26.6

Tobacco notification

- 5.170 TRPR included a provision requiring manufacturers of tobacco products, novel tobacco products, herbal products for smoking to report varying degrees of information on their products. This included a comprehensive study on any additives placed on a priority list covering emissions, toxicological and flavouring characteristics.
- 5.171 The estimated cost to businesses of this requirement in the Impact Assessment was based on information from industry on the cost of producing the reports and the number of formulations that were expected to require a report.
- 5.172 No further evidence has been identified or received through the consultation for this Post-Implementation Review in relation to this cost, therefore it is assumed to have remained the same.

Impact	IA estimate (£m)	PIR estimate (£m)
Tobacco notification	-9.8	-9.8

Peer review

- 5.173 As described above, TRPR requires manufacturers of tobacco products, novel tobacco products, herbal products for smoking to submit a comprehensive study on any additives. In addition, TRPR includes a provision for these studies to be peer reviewed. The Government charged industry for these peer reviews.
- 5.174 The estimated cost in the Impact Assessment was based on information on the cost at the time of having this type of study peer reviewed.
- 5.175 No further evidence has been identified or received through the consultation for this PIR in relation to this cost, therefore it is assumed to have remained the same.

Impact	IA estimate (£m)	PIR estimate (£m)
Peer review	-0.2	-0.2

Tobacco cross-border registration and age verification costs

- 5.176 The regulations required any UK retailers selling tobacco products to EU Member States to register and provide an age-verification system for any cross-border transactions.
- 5.177 At the time of the Impact Assessment very few UK tobacco retailers were expected to register for cross-border sales. Demand for tobacco from UK retailers from EU Member States was expected to be low due to duty on tobacco being higher in the UK relative to EU Member States. For the UK retailers that were expected to register, they were only required to provide minimal information. Therefore, the cost of the registration requirement was expected to be zero.
- 5.178 The estimated cost for any UK retailers providing age-verification checks was based on the number of estimated cross-border transactions and an estimated cost of each age-verification check.
- 5.179 No further evidence has been identified or received through the consultation for this PIR in relation to either of these cross-border costs for tobacco products, therefore it is assumed to have remained the same.

Impact	IA estimate (£m)	PIR estimate (£m)
Tobacco cross-border registration costs	0	0
Tobacco cross-border age verification costs	-0.04	-0.04

Data storage/processing (tobacco)

- 5.180 The information TRPR requires tobacco manufacturers and importers to provide is stored and processed by DHSC. The regulations allowed the Government to charge tobacco manufacturers and importers fees to cover this cost.
- 5.181 No further evidence has been identified or received through the consultation for this PIR in relation to this cost, therefore it is assumed to have remained the same.

Impact	IA estimate (£m)	PIR estimate (£m)
Data storage/processing (tobacco)	-0.6	-0.6

Labelling costs

- 5.182 As described above, TRPR removed a requirement for cigarette packages to contain printed TNCO labelling, which provided a cost saving to tobacco manufacturers. However, TRPR also included provisions that required manufacturers of cigarettes, hand rolling tobacco, cigars, pipe tobacco and herbal products to redesign packaging. For example, it required cigarette packages to include larger health warnings.
- 5.183 The estimates of these costs in the Impact Assessment were based on the estimated number of products that would need to be repackaged and estimates of the costs of redesigning cigarette packaging.
- 5.184 No further evidence has been identified or received through the consultation for this PIR in relation to this cost, therefore it is assumed to have remained the same.

Impact	IA estimate (£m)	PIR estimate (£m)
Labelling costs	-18.6	-18.6

E-cigarette costs

- 5.185 As set out above, TRPR included a number of provisions relating to e-cigarettes. These provisions were expected to impose costs on a range of stakeholders.
- 5.186 TRPR was expected to impose costs on e-cigarette manufacturers and importers due to the requirements to:
- display a warning message and information about ingredients on e-cigarette packaging;
 - submit annual data on sales volumes, consumer preferences, modes of sale and executive summaries of any market surveys undertaken;
 - submit a notification to the competent authority of any products they intend to place on the market;
 - undertake toxicology and emissions tests as part of the notification process; and
 - ensure e-cigarettes and refill containers are child resistant and tamper evident.

- 5.187 For e-cigarettes, the information provided by e-cigarette manufacturers and importers is processed and stored by Medicines & Healthcare Products Regulatory Agency (MHRA). Although MHRA do not charge e-cigarette manufacturers and importers to do this, in the same way DHSC does for tobacco products, MHRA is funded by businesses meaning the cost ultimately falls on e-cigarette manufacturers and importers.
- 5.188 E-cigarette retailers were also expected to incur costs due to TRPR requiring any retailers selling e-cigarettes to EU Member States to register and provide an age-verification system for any cross-border transactions. This was the same as the requirement described above for UK tobacco retailers.
- 5.189 There were also expected to be costs for the e-cigarette industry as a whole. This was due to the time the industry was expected to need to familiarise themselves with the new regulations and to rebrand any e-cigarettes that may potentially lead to consumers to believe that they are “lite” or similar, are healthier, or safer than alternative brands of e-cigarettes.
- 5.190 TRPR also restricted advertising of e-cigarettes. In the Impact Assessment this was not expected to have an impact on the e-cigarette industry but was expected to reduce profits for advertising agencies.
- 5.191 Despite there being an increase in the number of people using e-cigarettes since the introduction of the regulations, as highlighted in the Key Indicator section, no further evidence has been identified or received through the consultation for this PIR in relation to any of the costs related to e-cigarettes.
- 5.192 The section above on compliance also highlighted that by August 2018 around 80% of e-cigarette products and refill containers were compliant with TRPR. However, no evidence has been identified or received to estimate how this may have changed the costs to the e-cigarette industry estimated in the Impact Assessment.
- 5.193 Overall, the costs in relation to e-cigarettes estimated in the Impact Assessment have assumed to have remained the same.

Impact	IA estimate (£m)	PIR estimate (£m)
E-cigarette costs	-143.3	-143.3

- 5.194 The Impact Assessment did not consider how changes to e-cigarette sales or prevalence due to changes in consumers behaviour resulting from the new regulations may affect e-cigarette retailers, wholesalers and manufacturers profits.

- 5.195 Additionally, it did not consider the health impacts associated with the use of e-cigarettes to quit smoking. Data in the previous section on Key Indicators has shown that there was an increase in e-cigarette use, possibly driven by their use as an aid to quitting.
- 5.196 Therefore the Impact Assessment did not quantify the potential health benefits from consumers switching between tobacco products and e-cigarette products.
- 5.197 We have not received or identified any evidence to allow us to quantify these impacts as part of the PIR.

6. Conclusions and recommendations

- 6.1 The conclusions and recommendations of the review are presented below. Evidence on whether to remove, replace, amend, or retain the regulations are summarised below followed by the final recommendation of this review.

Summary on whether to remove or replace the regulations

- 6.2 The regulations should not be removed or replaced. As estimated in the impact assessment, and included in the review, a complete removal of TRPR would mean a loss of the benefits that the regulations provide, which are clearly far greater than the costs of these regulations. Based on the review of the Impact Assessment, the economic impact remains dominated by the health benefits of the regulations. The costs to business remain small relative to these benefits.

Summary on whether to amend (relax or strengthen the regulations)

- 6.3 The regulations should be retained but the Government will consider amendments in the future. Responses to the consultation varied, with respondents suggesting amendments to e-cigarette packaging to promote them to be less harmful than smoking, increase bottle sizes of nicotine liquid, tank size increases and nicotine strength. With others wanting a strengthened TRPR to have for example more powers over packaging designs and colours to deter youth use. If the regulations were relaxed, there would be an expected decrease in the health benefits seen from the TRPR. The regulations, although seen as strong given the low youth use of smoking and e-cigarette use, still has areas to strengthen not covered under these regulations to help the 7 million UK smokers quit and deter future generations from entering smoking.

Summary on whether to retain the regulations

- 6.4 The Department believes the objectives of TRPR set out in Chapter 3 have been met and regulations should be retained. The benefits of TRPR have been demonstrated throughout the review, and were overwhelmingly reflected in the key indicator data and peer reviewed research. Generally, respondents to the consultation were supportive of the regulations and agreed they has achieved their objectives. Based on the review of the Impact Assessment, the economic impact remains dominated by the health benefits of the regulations. The costs to business remain small relative to these benefits. However, there are still 7 million smokers in the UK, and the Government is mindful to consider strengthening its regulatory framework to encourage more smokers to quit, prevent future generations from smoking, and protect youth and non-smokers using e-cigarettes.

6.5 Throughout this report we have documented evidence and views from individuals and organisations that identified several unintended consequences that may be a result of these regulations. The main ones included:

- (a) Menthol ban: Since TRPR prohibited the characterisation of flavours in cigarettes and hand rolling tobacco, tobacco manufacturers have introduced new ranges of tobacco products with menthol such as cigarillos (small cigars) with a flavour capsule, and heated tobacco with a wide range of flavours. Some respondents felt the prohibition of the characterising of flavours should be extended to these products as well to stop what they regarded was a loophole in the regulations to help smokers quit. The industry has also introduced new tobacco accessories not covered by TRPR such as flavour infusion cards to insert into tobacco products. Some respondents argued that this circumvented the rules on the cigarette menthol ban.
- (b) E-cigarettes: Some stakeholders raised concerns that the nicotine strength limits were not high enough to help some smokers switch permanently to just e-cigarettes and help the government achieve its Smokefree 2030 ambition. In addition, many from industry, other organisations and vapers felt the tank size limits, and bottle sizes should be increased as they were inconvenient.

In terms of the TRPR requirements for e-cigarette warning messages, a study suggested that they may deter smokers from switching to e-cigarettes.

At the same time, some stakeholders thought the non-nicotine vaping industry should be regulated in the same way as e-cigarettes. This would improve standards and consumer safety, and ensure regulation was coherent. Some responses also said the regulations did not go far enough on e-cigarettes in terms of restricting the packaging and descriptor names to protect youth from using these products.

- (c) Nicotine pouches: These products, and other novel nicotine products, have appeared on the UK market over the past two years and there has been criticism from some that TRPR should be more flexible and include these products under its framework. This would protect consumers and build more confidence in smokers moving to these products to help them to quit.

6.6 Overall, despite these developments that may be due to the regulations, the evidence does not presently indicate they have significantly reduced the benefits of the regulations and prevented the main objectives from being met. The Government has made a commitment for England to be Smokefree by 2030 and is exploring a broad range of regulatory measures to support this for its future Tobacco Control Plan. As part of this process, we will monitor the evidence and keep these unintended consequences under close review.

Recommendation

- 6.7 Overall, it is DHSC's position that the evidence presented above provides a strong argument for the retention of the regulations. There are some areas of tobacco and nicotine products that the regulations did not cover, with some suggesting they should do, for example, including non-nicotine vapes and nicotine pouches under the TRPR regulatory framework. In addition, some argue that TRPR should be strengthened further to include additional measures which restrict tobacco use and prevent youth and non-smokers from using e-cigarettes. This needs to be carefully balanced in supporting efforts to enable adult smokers to switch to e-cigarettes as a less harmful alternative.
- 6.8 Despite these suggested amendments, they do not provide evidence of significant issues with the regulations and removing them would likely result in all the health benefits being lost. The Government will consider the suggestions for changes to the regulations, and a range of other regulatory reforms, to help support its Smokefree 2030 ambition.

7. Annex

Annex A: Public consultation details

7.1 The public consultation received over 5,000 responses across a range of stakeholders. While the main report included broad findings across all stakeholders, the consultation was reviewed in detail and the findings of this review, including breakdowns by stakeholder groups and the opinions they held, are below.

Health text and picture warnings

7.2 The questions below have been grouped together as they discuss health and picture warnings, and the impact they have had.

How far do you agree or disagree that the introduction of rotating combined (photo and text) health warnings on cigarette and hand rolling tobacco has encouraged smokers to quit?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	29%	24%	42%	5%
Individual	28%	24%	43%	5%
Non-Governmental Organisation	38%	9%	31%	22%
Business	29%	21%	26%	24%
Public Sector Body	75%	0%	17%	8%
Other	33%	13%	10%	43%

How far do you agree or disagree that the requirements on the packaging and labelling of tobacco products have been an effective way to protect young people from taking up smoking?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	25%	28%	32%	15%
Individual	28%	24%	43%	5%
Non-Governmental Organisation	31%	13%	34%	22%
Business	21%	36%	24%	19%
Public Sector Body	71%	4%	17%	8%
Other	37%	13%	7%	43%

Should all tobacco products have a combined (photo and text) health warning on their packaging?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	47%	25%	22%	5%
Individual	47%	26%	22%	5%
Non-Governmental Organisation	34%	3%	41%	22%
Business	31%	22%	29%	17%
Public Sector Body	88%	4%	4%	4%
Other	40%	3%	13%	43%

- 7.3 Views on the impact of health warnings on both preventing young people taking up smoking and helping current smokers quit are largely similar. The most common responses are that health warnings have not been effective in both cases. Proportionally less responses dispute the effectiveness of health warnings deterring young people (32%) compared to helping existing smokers quit (42%).
- 7.4 The most common theme identified in individuals' responses were that rotating combined photo and text warnings were not effective, both at curbing current levels of smoking, and from protecting young people from smoking. This was also the most common theme in responses to both questions from businesses, NGOs, and the 'other' stakeholder group.
- 7.5 In both cases, the majority of public sector bodies agreed that health warnings have had a positive impact. 75% of public sector bodies agreed that health warnings helped existing smokers quit, and 71% of responses agreed that health warnings helped combat youth uptake of smoking, compared to 29% and 25% of all respondents. These views are also highlighted in the thematic analysis of text responses- the most common theme identified in this stakeholder group was that combined health warnings are effective, both for young people and for existing smokers.
- 7.6 In terms of deterring young people from taking up smoking, many respondents argued that young people will smoke anyway (671 responses), or are not influenced by packaging (206). For those already smoking, respondents argued that smokers ignore packaging (582), already know the risk (236) or are otherwise desensitised to combined warnings (164).

- 7.7 Conversely, there were also many respondents that argued that combined health warnings reduced smoking prevalence, either by increasing awareness of health consequences or the less attractive packaging/images putting people off smoking.
- 7.8 Despite many respondents' views that combined health warnings are not effective, almost half (47%) agreed that all tobacco products should carry combined health warnings on them. Agreement was lowest among businesses and NGOs (31% and 34% respectively), and highest among public sector bodies, reaching almost 90%.
- 7.9 The most common theme in the responses among individuals, NGOs, public sector bodies, and 'other' were along the theme that all tobacco products should be regulated. Public sector bodies were especially keen, with 100% of text responses in favour of regulation for all tobacco products. Businesses were the only stakeholder group with a different view, with their most common text response arguing that combined health warnings should be isolated to RYO tobacco and Factory Made cigarettes.

Prohibiting characterising flavours

- 7.10 The questions below have been grouped together as they discuss prohibiting characterising flavours and the impact it has had.

How far do you agree or disagree that the prohibition of characterising flavours has helped smokers quit smoking?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	17%	22%	46%	15%
Individual	16%	22%	47%	15%
Non-Governmental Organisation	34%	6%	34%	25%
Business	17%	21%	41%	21%
Public Sector Body	58%	8%	17%	17%
Other	23%	13%	10%	53%

How far do you agree or disagree that the prohibition of characterising flavours has deterred young people from taking up smoking?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	15%	27%	36%	22%

Individual	15%	27%	37%	21%
Non-Governmental Organisation	31%	6%	34%	28%
Business	9%	26%	41%	24%
Public Sector Body	58%	13%	17%	13%
Other	30%	10%	13%	47%

- 7.11 In terms of characterising flavours, the most common view was that it has not help existing smokers quit, with 46% of all respondents responding in this way. 17% were positive about the ban, and 22% neither agreed nor disagreed.
- 7.12 The most common arguments to support the view that the prohibition of flavours has not deterred young people or helped existing smokers quit, were that removing flavours meant smokers simply moved to non-flavoured cigarettes, or that they began using products to re-flavour their cigarettes.
- 7.13 Of the 5 groups of stakeholders, individuals and businesses most commonly responded negatively. NGOs and especially public sector bodies held a more positive view of the prohibition of flavours, with 34% of NGOs and 58% of public sector bodies that responded agreeing or strongly agreeing that it has helped smokers quit. The most common argument for the ban's effectiveness across these responses was that the prohibition of flavours has moved smokers to e-cigarettes.
- 7.14 The most common argument from individuals and businesses was that prohibiting flavours has had no impact on current smokers, or that existing smokers have moved to using non-flavoured products, but still smoke. NGOs and public sector bodies were much more positive, with the most common theme in their text responses being that of prohibiting flavours has helped existing current smokers quit. The 'other' group was split, with an equal number of responses arguing for and against the effectiveness of the prohibition on flavours.
- 7.15 Responses on how the ban has impacted young people is similar, with the largest amount of responses disagreeing that the ban on characterising flavours has deterred young people from taking up smoking. 36% of all respondents disagreed that the ban is effective, compared to 15% who agreed and 27% who were neutral. This suggests that the overall view of the ban's effects on young people is still negative, but respondents are less sure of this compared to perceived views on the effect on current smokers. Individuals and businesses were again the most negative groups, 36% of individuals and 41% of businesses disagreed that the ban deters youth smoking. Public sector bodies were again the most positive, with almost 60% of public sector bodies agreeing that the ban has been effective.

7.16 Thematic analysis on responses to this question show stakeholder groups feel young people are impacted similarly, with all groups having the most common theme being the same as it was for the question on the impact on current smokers.

E-cigarettes

7.17 The questions below have been grouped together as they discuss responses on e-cigarette regulations and the impact they have had.

How far do you agree or disagree that the current regulations on e-cigarettes have been proportionate in protecting young people from taking up use of these products?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	37%	22%	28%	13%
Individual	37%	22%	28%	13%
Non-Governmental Organisation	44%	13%	38%	6%
Business	50%	17%	21%	12%
Public Sector Body	67%	13%	17%	4%
Other	50%	0%	20%	30%

7.18 37% of all respondents agreed that regulations on e-cigarettes are proportionate, 22% were neutral, and 28% disagreed. While the proportion of individuals' agreeing, disagreeing and neutral views were in line with the totals, a higher proportion of every other group agreed that current regulations on e-cigarettes are proportionate, indicating that the majority of stakeholders are happy with current levels of regulations on e-cigarettes. 245 (5%) responses said that the current regulations are too severe, whilst 176 (3%) wished for more severe regulations.

7.19 Themes from individuals' text responses were mixed. The most common theme identified was a belief that the current levels of e-cigarette regulation is proportionate, but other common arguments were that young people will smoke e-cigarettes regardless of any regulations on tobacco, and that e-cigarettes are still attractive to young people.

7.20 The most common text responses from businesses were that current regulations were effective, and that e-cigarettes are not appealing to young people. NGOs most commonly responded with this latter view as well.

7.21 The 'other' group held mixed views, with the joint most common responses being that e-cigarettes do not appeal to young people, and that regulations need to be more severe to protect young people.

7.22 Public sector bodies most commonly responded that e-cigarettes are an effective way to stop people using tobacco products. This view was somewhat common among the other stakeholder groups as well, though not as well represented as in the public sector bodies stakeholder group.

How far do you agree or disagree that the current regulations have ensured that e-cigarettes are available for those smokers who wish to switch to these products?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	67%	13%	15%	6%
Individual	67%	13%	15%	6%
Non-Governmental Organisation	56%	13%	16%	16%
Business	53%	22%	16%	9%
Public Sector Body	88%	13%	0%	0%
Other	53%	10%	3%	33%

7.23 Responses on the availability of e-cigarettes were the clearest across all questions in the public consultation, with over two-thirds of all respondents agreeing that e-cigarettes are adequately available. At least half of all respondents agree e-cigarettes are readily available across all stakeholder groups. Included in these responses were several suggestions for changes to current regulations, such as increases to tank sizes, refill bottles, nicotine strength of e-cigarettes and that advertising restrictions should be relaxed.

What effect do you think the regulations have had on smokers considering switching to e-cigarettes?

Capacity	Encouraged	Neutral	Discouraged	Don't Know/No answer
All Respondents	40%	35%	15%	10%
Individual	40%	35%	15%	10%
Non-Governmental Organisation	28%	31%	22%	19%
Business	16%	40%	31%	14%
Public Sector Body	33%	58%	8%	0%
Other	30%	7%	13%	50%

- 7.24 75% of all responses indicated that the regulations either encourage smokers to switch to e-cigarettes (40%) or at least do not discourage smokers from doing so (35%). Individuals were the group most commonly responding that regulation encourage smokers to do so (40%). However, while businesses largely felt this was not the case with 31% of businesses' saying the current regulations discourage smokers from quitting, compared to just 15% across all respondents.
- 7.25 Individuals' text responses were around the theme that smokers can easily switch to e-cigarettes as a result of current regulations.
- 7.26 Common responses from businesses included the view that current regulations amount to government interference and that more should be done to highlight the benefit of switching from tobacco to e-cigarettes.
- 7.27 Text responses from NGOs also indicated views that the benefits of vaping should be further advertised. This stakeholder group also commonly responded that smokers can easily switch from smoking to using vaping products. These two themes were also the two most popular in the 'other' and public sector bodies stakeholder groups.

Do you consider the restrictions on e-cigarette advertising to be an effective way to discourage young people and non-smokers from using e-cigarettes?

Capacity	Yes	No	Don't know/didn't answer
All Respondents	32%	40%	28%
Individual	32%	41%	27%
Non-Governmental Organisation	38%	31%	31%
Business	40%	33%	28%
Public Sector Body	58%	21%	21%
Other	30%	30%	40%

- 7.28 Views on whether the advertising ban is an effective way to deter non-smokers from taking up e-cigarettes are more mixed compared to the other questions on e-cigarette regulations. 32% of all respondents agreed that the ban is effective, 40% neither agree nor disagree, and 28% were unsure or didn't answer. 438 responses said that restrictions on e-cigarette advertising discourages both young people and non-smokers from using e-cigarettes. 323 responses said advertising restrictions should be relaxed, and 170 said the restrictions should be tightened.

- 7.29 The most common theme from individuals' text responses to this question was that restrictions on advertising do not dissuade anyone from using e-cigarettes, though another sizeable proportion of this stakeholder group responded that the ban discourages both non-smokers and young people (603 said the former, and 415 the latter out of 1565 text responses from this stakeholder group)
- 7.30 The majority of businesses' text responses indicated a belief that the advertising restrictions are effective at dissuading both young people and non-smokers.
- 7.31 The views from NGOs showed in the text responses were mixed. 5 argued that the restrictions on e-cigarettes should be more severe, while 4 argued that restrictions were effective at dissuading non-smokers/young people, and a further 4 argued that the ban discourages current smokers from moving to e-cigarettes.
- 7.32 The 'other' group's text responses most commonly argued that advertising restrictions should be relaxed, as current smokers were being dissuaded from switching. However, a large proportion of text responses from this stakeholder group indicated the opposite view, that advertising bans need to be more severe.
- 7.33 Public sector bodies held the clearest view of all stakeholder groups on this question, with a clear majority arguing that restrictions on e-cigarette advertising should more severe

Novel Tobacco Products

How far do agree or disagree that the requirements of TRPR on novel tobacco products are proportionate?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	13%	30%	15%	42%
Individual	13%	30%	14%	42%
Non-Governmental Organisation	22%	19%	41%	19%
Business	24%	29%	24%	22%
Public Sector Body	4%	50%	25%	21%
Other	13%	13%	20%	53%

- 7.34 Responses to this question were quite neutral, with 72% of all respondents either not giving an answer, or indicating that they neither agreed nor disagreed that TRPR requirements on novel tobacco are proportionate. 13% of all respondents agreed that requirements were proportionate, while 15% disagreed.

- 7.35 60 respondents argued that the rules on novel tobacco products should be relaxed, whilst 55 argued that requirements should be more severe, 20 of which called for an outright ban on novel tobacco products.
- 7.36 Across the five stakeholder groups, views remained primarily neutral. Individuals and the ‘other’ group had a much lower response rate compared to NGOs, businesses, and public sector bodies, suggesting this latter group feels more strongly and/or more informed on the question topic. NGOs were the most negative, as 41% of responses from this group disagreed that current requirements were proportionate. Public sector bodies were less negative, but also much less likely to endorse current requirements, with only 4% agreeing that they are proportionate. Businesses' views largely aligned with individuals' and the overall response, albeit with a higher response rate.
- 7.37 Individuals' text responses were mixed, with the most common themes involving comments on e-cigarettes, or individuals responding that they didn't know the answer to the question. A similar number of individuals argued that the requirements are proportional (139) compared to those responding that requirements are not proportional (128). Businesses held similar views, with a majority theme of ‘unsure’ and an almost equal number of responses. NGOs had the most negative text responses, with 8 of 20 text responses arguing that current regulations are not proportionate, and another 5 responses arguing that we don't currently know the long-term harms of novel tobacco products. Public sector bodies were also concerned about this, with 7 of their 12 text responses touching on this in some way.

Enforcement of Regulations

Do you agree or disagree that the penalties for a breach of the regulations are an effective deterrent to ensure compliance with the regulations?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All respondents	34%	-	22%	44%
Individuals	34%	-	22%	44%
NGOs	22%	-	19%	59%
Business	43%	-	24%	33%
Public Sector Body	21%	-	33%	46%
Other	17%	-	17%	67%

- 7.38 Along with the questions on novel tobacco requirements and on the economic impact of TRPR, the question on enforcement had the by far the lowest proportion of respondents directly answering the question, with 44% of responses either left blank or stating that they didn't know.

- 7.39 Of those who answered the question directly, the majority of respondents agreed that current penalties are an effective deterrent (34% of all respondents agreed, while 22% disagreed). Support for the current penalties was highest among individuals and businesses, with 34% and 43% respectively agreeing that current penalties are sufficient. NGOs, public sector bodies and the 'other' category were less positive, with all of these groups only having around 20% of respondents arguing that current penalties are sufficient.
- 7.40 75 respondents said that penalties should be less severe, and a further 49 argued there should be no penalties at all. 122 respondents (no businesses) argued that penalties should be more severe, and 129 (including 5 businesses) said more compliance checks should be carried out.
- 7.41 All stakeholder groups except the NGOs most commonly responded that current penalties are effective deterrents. NGOs also most commonly responded that current penalties need to be more severe.

Economic Impacts of TRPR

How far do you agree or disagree that there has been an economic impact of TRPR, either positive, negative or both?

Capacity	Agree	Neither agree nor disagree	Disagree	Don't Know/No answer
All Respondents	21%	30%	4%	45%
Individual	21%	30%	4%	45%
Non-Governmental Organisation	31%	9%	3%	56%
Business	46%	17%	19%	18%
Public Sector Body	46%	29%	0%	25%
Other	37%	10%	10%	43%

- 7.42 Views on the economic impact of TRPR were broadly either neutral or agreed that there has been an economic impact. 30% of all respondents neither agreed or disagreed that there had been an economic impact, whilst 21% agreed and 4% disagreed (though it should be noted that respondents are agreeing/disagreeing that there has been an impact- not whether the impact has been positive or not).
- 7.43 Similar to the enforcement and novel tobacco requirement questions, this question had a relatively low response rate, with 45% of all respondents either not answering or stating that they didn't know the answer. Of those that answered the questions, individuals held the most neutral view, whilst the other 4 were more likely to agree that there has been an economic impact rather than disagree or hold a neutral view.

- 7.44 215 responses argued that there has been an overall positive impact, 131 citing health benefits, and 84 citing other positive economic impacts. 565 responses argued the opposite, with 388 citing negative economic impacts, 82 that there's been a negative impact on switching, 55 that the cost to comply was too high (including 7 businesses), and 40 responses citing the environmental cost. A further 52 responses commented that there had been both positive and negative economic impacts of TRPR
- 7.45 Individuals' text responses most commonly argued that TRPR has led to a negative economic impact, or that they were generally unsure as to the answer, or to what TRPR referred to.
- 7.46 Businesses also most commonly responded that the overall economic impact of TRPR is negative. Many businesses also cited that the financial costs to comply with TRPR have increased, or are otherwise too large.
- 7.47 NGOs' text responses indicated mixed views across this stakeholder group. 4 responded that there had been a positive impact, while 3 NGOs responded that there had been a negative impact, and another 3 were unsure. The 'other' group held similarly mixed views, with close-to-equal numbers responding that the economic impact has been positive/negative.
- 7.48 Public sector bodies were the only stakeholder group with a clear majority in opinion, with 12 of the 15 text responses from this stakeholder group indicating a belief that TRPR has had a positive economic impact.

Anything else on TRPR

Is there anything else you would like to share on negative or positive impacts the regulations have had on topics not covered above?

- 7.49 Respondents were only able to provide free-text answers in response to this question.
- 7.50 1,353 respondents (26%) provided a response to this question.
- 7.51 However, it should be noted that 337 respondents (6%) responded to the question but either were not aware of the regulations or did not provide any further information. Excluding these respondents, 1,019 respondents (19%) responded to this question.
- 7.52 A common topic provided in response to this question was on regulations for e-cigarettes. These included topics such as: refill bottle sizes should be bigger; tank sizes should be bigger; and the e-cigarettes are less harmful, and regulations

should be relaxed. Other common topics included regulations being fair and proportionate, that the public and professionals need to be better educated on non-tobacco alternatives, and the more evidence need to be gathered on the safety of non-tobacco alternatives.

- 7.53 The most common theme from individuals' was that current TRPR regulations are fair and proportionate. Other common responses from this stakeholder group were arguments against government intervention, and various suggestions of amendments to regulations on e-cigarette products.
- 7.54 Themes from businesses' responses to this question were quite scattered, with all the most common responses focusing around various amendments to regulations on e-cigarettes.
- 7.55 In addition, some businesses and NGOs also called for non-nicotine e-cigarette products to be captured under similar rules applied to e-cigarettes to improve product safety and to address an issue of shortfills³¹ of non-nicotine and nicotine products being mixed together. Although not covered under TRPR, the Government will review whether the non-nicotine vape regulatory framework should be strengthened to improve consumer safety and address shortfill concerns as part of future regulation considerations.
- 7.56 Responses from NGOs, individuals and businesses in relation to oral tobacco were most commonly against it being banned under TRPR. The responses often cited data on comparisons between daily smoking rates in countries such as Sweden and Norway where oral tobacco is permitted. While this is the case, tobacco use overall is higher in Norway and Sweden than in the UK. Norway have also introduced plain packaging to oral tobacco due to concerns on the youth appeal of these products. Both countries have seen a rise in the use of oral tobacco in young adults over the past several years.
- 7.57 Responses also highlighted that nicotine pouches (tobacco free), which are now available on the UK consumer market, should be regulated under a framework such as those for tobacco and related products rather than under The General Product Safety Regulations 2005. The Government will consider this and has asked the Committee on Toxicity to consider the toxicological risks from tobacco-free oral nicotine pouches during its 2021/22 work programme.

³¹ Shortfills are larger bottles of e-liquid that come without nicotine, generally a 60ml bottle filled with 50ml of e-liquid with no nicotine. These e-liquid bottles are called shortfills simply because they are not filled to the top. The space at the top is for adding a nicotine shot (or 'nic shot'). Once this is added, you shake the bottle to mix the nic shot with the flavoured e-liquid.

7.58 Both public sector bodies and the 'other' stakeholder group primarily used this question to argue for novel tobacco products to be regulated the same as smoked tobacco products.

Annex B: Commissioned studies - further details

The King's Fund sample demographics

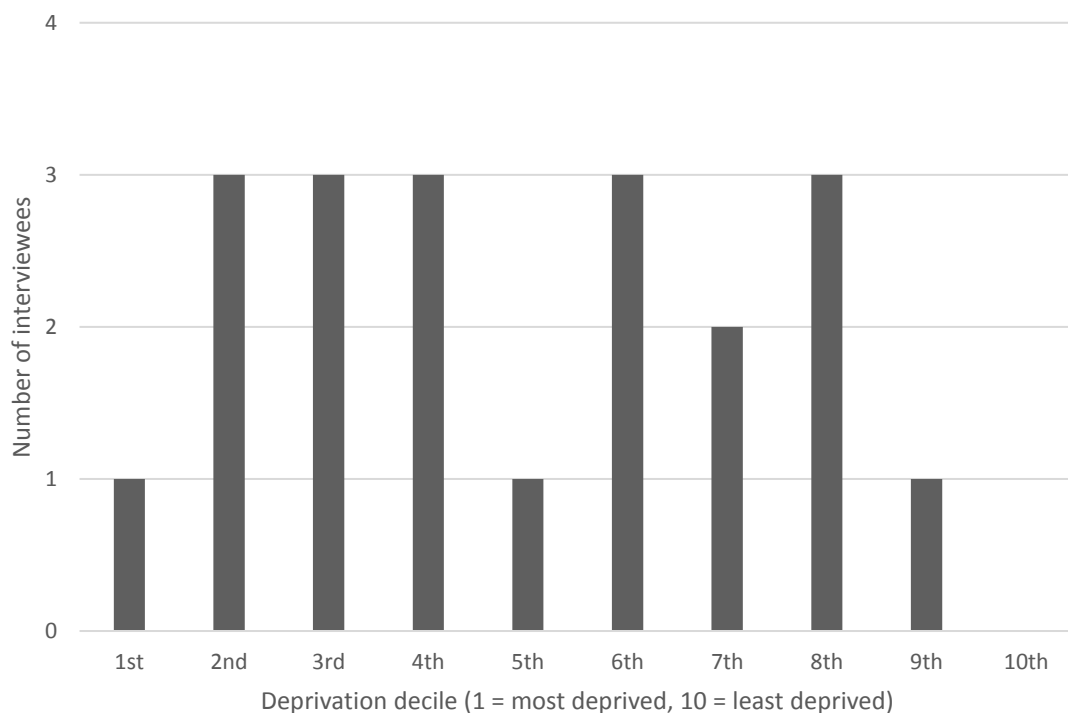
7.59 The commissioned research by The Kings Fund aimed to reach a broad range of retailers from different nations, locations, and types of businesses. The properties of the interview sample for the commissioned King's Fund research are shown below.

Nation	Number
England	12
Scotland	3
Wales	3
Northern Ireland	2

Location	Number
Urban	6
Suburban	5
Rural	7
Coastal	2

Type of Business	Number
Small/Local chain	2
Independent	11
Franchise	7

Type of Retailer	Number
Convenience store	16
Tobacconist	1
Newsagent	3



Annex C: Impact Assessment cost-benefit analysis detailed review

7.60 This annex covers the detailed review of the Impact Assessment. It includes a full breakdown of the cost and benefits estimated in the Impact Assessment, outlining if and where new data exists and how it has been used to update the original estimates of the impact of the regulations.

7.61 The following table shows the breakdown of the costs and benefits calculations made in the Impact Assessment, the categories they were assigned to the revised estimates and the proportions included in the NPV and EANDCB.

	Post-Implementation Review estimates	Impact Assessment estimates	In NPV	In EANDCB
BENEFITS	£12,178,183,495	£13,055,272,330		
Health	£12,169,607,587	£13,046,696,422	100%	0%
Reduced labelling	£6,558,557	£6,558,557	10%	8.1%
Charging income	£2,017,351	£2,017,351	100%	0%
COSTS	£2,382,892,027	£2,550,427,266		
Lost tax from reduced consumption	£1,851,532,864	£1,989,247,735	100%	0%
Lost tax from illicit	£155,045,797	£164,453,693	100%	0%
Lost profits from reduced consumption	£175,086,227	£194,768,781		
Retail lost profit	£70,226,613	£78,121,232	0%	100%
Wholesaler lost profit	£37,982,748	£42,252,630	0%	100%
Manufacturer lost profit	£66,876,866	£74,394,919	0%	8.1%
Lost profits from illicit	£26,643,202	£27,373,120		
Retailer lost profit from illicit	£10,894,584	£11,193,052	100%	0%
Wholesaler lost profit from illicit	£5,892,442	£6,053,871	100%	0%
Manufacturer lost profit from illicit	£9,856,176	£10,126,196	10%	0%
Tobacco notification	£9,816,970	£9,816,970		
Cigarette/HRT notification	£230,000	£230,000	10%	8.1%
Pipe/cigar notification	£1,160,000	£1,160,000	10%	5.8%

Herbal notification	£30,000	£30,000	100%	100%
NTP notification	£34,431	£34,431	10%	8.1%
Priority additives	£8,362,539	£8,362,539	10%	8.1%
Data storage/processing (tobacco)	£640,121	£640,121	100%	0%
Labelling	£18,611,408	£18,611,408		
Cigarette/HRT labelling	£2,572,231	£2,572,231	10%	8.1%
Herbal labelling	£802,289	£802,289	100%	100%
Cigar (big 3) labelling	£366,332	£366,332	10%	5.8%
Cigar (machine-made) labelling	£316,631	£316,631	100%	100%
Cigar (hand-made) labelling	£8,016,273	£8,016,273	100%	100%
Pipe labelling	£6,537,651	£6,537,651	100%	100%
Tobacco cross-border registration and age verification	£39,284	£39,284	100%	100%
Peer review	£196,800	£196,800	10%	8.1%
Charging costs	£2,017,351	£2,017,351	10%	8.1%
E-cigarettes total	£143,262,004	£143,262,004		
E-cigarette advertising	£47,105,964	£47,105,964	100%	0%
E-cigarette labelling	£51,633,112	£51,633,112	10%	9.5%
E-cigarette cross-border verification	£932,922	£932,922	10%	9.5%
E-cigarette cross-border registration	£475,000	£475,000	10%	9.5%
E-cigarette sales reporting	£1,067,720	£1,067,720	10%	9.5%
E-cigarette toxicology	£5,275,344	£5,275,344	10%	9.5%
E-cigarette emissions	£527,535	£527,535	10%	9.5%
E-cigarette notifications	£2,734,226	£2,734,226	10%	9.5%
E-cigarette familiarisation	£165,443	£165,443	10%	9.5%
E-cigarette tamper proof	£9,043,444	£9,043,444	10%	9.5%
E-lite branding	£22,617,292	£22,617,292	10%	9.5%
Data storage/processing (e-cig)	£1,684,002	£1,684,002	10%	9.5%
Total NPV	£10,073,331,703	£10,802,810,872		
Total EANDCB	£ 16,117,387	£16,362,620		

Detailed review of the impact assessment estimates

Health benefits

- 7.62 The monetised health benefits of TRPR come from the expected reduction in smoking prevalence in the general population, which results in life years gained for an average person who quits smoking.
- 7.63 In the Impact Assessment baseline prevalence was assumed to be 19.1% in 2014, based on forecasts available at the time. This baseline was reduced by 0.04 percentage points per year up to 2025 to account for the tobacco display ban³², introduced for large shops in 2012 and extended to all shops in 2015.
- 7.64 The introduction of TRPR regulations were expected to reduce smoking prevalence by a further 0.05 percentage points per year between 2016 and 2020 and by 0.02 percentage points per year between 2020 and 2024 when the ban on menthol cigarettes would take effect.
- 7.65 This estimated impact was based on the midpoint of the expected percentage decrease in smoking consumption due to TPD of 1.9%, which came from the EU Impact Assessment for TPD³³. This suggested that TRPR would reduce smoking prevalence by 0.36 percentage points over the appraisal period, as it was assumed consumption is linearly related to prevalence.
- 7.66 This expected decrease in prevalence was used to estimate the number of additional quitters due to TRPR during the 10-year appraisal period. It was estimated that it would lead to approximately an additional 195,450 quitters between 2016 and 2025. For each quitter, an average of 1.2 life years is saved, valued at £60,000 (£72,000 per adult quitter)³⁴. As a result, in the Impact Assessment the health benefits due to TRPR were estimated to be £13.1 billion.
- 7.67 However, between the time of the Impact Assessment and the implementation of the regulations, smoking prevalence continued to decline. This was at a rate over and above what was anticipated in the Impact Assessment. Using more recent

³² Display ban Impact Assessment, [dh_132878.pdf \(publishing.service.gov.uk\)](#)

³³ 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

³⁴ DHSC 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.

data, baseline prevalence in 2015 is 17.8%, compared to 19.1% in the Impact Assessment.

- 7.68 We have not received or identified any new evidence to update the estimated attributable impact of TRPR on smoking prevalence of 0.05 percentage points per year between 2016 and 2020 and 0.02 percentage points per year between 2020 and 2024. However, when the expected reduction in prevalence due to TRPR is applied to the updated baseline of 17.8%, the number of expected additional quitters due to TRPR reduces to around 182,311. In turn, this results in a reduction in the estimated health benefits to £12.2 billion.

Reduced labelling

- 7.69 TPD required cigarette packages to contain printed TNCO (emission levels for tar, nicotine, carbon monoxide and other yields) labelling. This requirement was removed in TRPR, which was expected to save tobacco manufacturers money.
- 7.70 The amount it was estimated to save tobacco manufacturers was based on the estimated number of individual products, known as stock-keeping units (SKUs), that would no longer need TNCO labelling and the estimated cost to relabel each SKU. Data from Nielsen Scantrack estimated that approximately 720 stock-keeping units (SKUs) per annum would no longer require TNCO labelling and a study specifically commissioned by the EU Commission from Rand Europe³⁵ estimated the cost to tobacco manufacturers of TNCO labelling for each SKU to be £1,055. This provided an estimated saving to tobacco manufacturers of £6.6 million over the appraisal period.
- 7.71 This estimate of the savings in TNCO labelling costs for tobacco manufacturers has not changed as we have not identified or received any new evidence on the number of SKUs on the market at that time, or the cost of relabelling them.

Charging income

- 7.72 The regulations allowed the Government to charge industry to cover some of the costs of the regulatory regime. The Government opted to charge industry fees to cover the cost of verifying TNCO levels in cigarettes and processing and storing data from notifications. This provision therefore provided income to Government and an equivalent cost to businesses.
- 7.73 The contract for TNCO verification cost DHSC £130,000 per year, with an additional cost of £30,000 per year for contract management and monitoring

³⁵ 'Assessing the impacts of revising the Tobacco Products Directive: Study to support DG SANCO Impact Assessment', RAND, 2011: https://www.rand.org/pubs/technical_reports/TR823.html

contact with companies. It was estimated that charging for TNCO verification would provide revenue to the Government of £160,000 per year.

- 7.74 Based on information provided by MHRA on fees for the e-cigarette industry it was estimated that the cost to Government of processing and storing data from notifications was £320,000 in the first year with an additional annual cost of £42,000.
- 7.75 In total, the estimated charging income received by Government from TRPR was £2 million over the appraisal period.
- 7.76 This estimate has not been updated as we have not received or identified any evidence to suggest the income is different to that assumed in the Impact Assessment.
- 7.77 The equivalent costs to industry of this charging regime are described below.

Other benefits

- 7.78 In the Impact Assessment there were some other benefits expected from the provisions in TRPR on e-cigarettes.
- 7.79 Requirements for childproof containers and restrictions on size and nicotine strength were expected to reduce the risk of poisonings due to consuming e-liquids. In addition, warning labels and restrictions on advertising were expected to reduce the appeal of e-cigarettes to non-smokers.
- 7.80 In the Impact Assessment these benefits were not quantified. We have not received or identified any evidence to allow us to quantify these benefits in the PIR.

Lost tax from reduced consumption

- 7.81 Reduced consumption of tobacco also reduces the tax revenue received by the Government.
- 7.82 In the Impact Assessment it was estimated that for every additional adult smoker who quits, there is an average discounted lifetime loss of tax of around £11,000. This estimate was applied to the 195,450 additional quitters due to TRPR estimated in the Impact Assessment. This provided an estimated loss in tax revenue due to TRPR of £2 billion over the appraisal period.
- 7.83 However, as explained above, the number of quitters expected due to TRPR has been re-estimated due to the change in the baseline prevalence and is expected

to be slightly lower at 182,311. The estimated lifetime loss in tax for adults has remained the same.

- 7.84 Applying this re-estimated number of quitters due to TRPR to the estimated lifetime loss in tax for adults reduces the estimated loss in tax revenue to £1.85 billion over the appraisal period.

Lost tax from illicit sales

- 7.85 In the Impact Assessment it was expected that the ban on menthol cigarettes and the introduction of minimum pack sizes would lead to an increase in illicit trade. This was expected to have a negative impact on the Government in the form of lost tax revenue.
- 7.86 The Impact Assessment estimated that TRPR would increase illicit trade by 0.75% between 2016 and 2019 and 1.5% from 2020 onward, when the ban on menthol flavoured tobacco products would take effect. This estimate was based on the mid-point of tobacco industry funded estimates³⁶ and HMRC estimates. The percentage increase in illicit sales was applied to expected sales, based on estimated cigarette clearances. At time of the Impact Assessment, total cigarette clearances between 2014/15 and 2018/19 were estimated to be 169,100 million³⁷. This resulted in an estimated 17 million packs of cigarettes and 25 million HRT pack equivalents moving into the illicit market.
- 7.87 Based on information provided through the consultation for the Impact Assessment, it was assumed an average loss of tax and VAT of £6.50 per pack of cigarettes and an equivalent loss of £3.45 per HRT pack equivalents. This was multiplied by the estimated number of packs of cigarettes and HRT pack equivalents moving to the illicit market to estimate a loss in tax and VAT of £164 million over the appraisal period.
- 7.88 The assumptions used in the Impact Assessment around the increase in illicit sales due to TRPR remains unchanged. HMRC produce 'tobacco tax gap estimates' and have noted no increase in the size of the illicit market for tobacco since the implementation of TRPR³⁸. Additionally, a report from the EU³⁹, found that that since the implementation of the TPD, illicit trade and smuggling has decreased. Although it is not possible to attribute these changes in the illicit market

³⁶ TransCrime report - <https://www.transcrime.it/en/publications/crime-proofing-of-the-new-tobacco-products-directive/>

³⁷ March 2014 Economic and Fiscal Outlook: Fiscal Supplementary Tables - <http://budgetresponsibility.org.uk/>

³⁸ HMRC Measuring Tax Gaps: <https://www.gov.uk/government/statistics/measuring-tax-gaps>

³⁹ Support study to the report on the application of Directive 2014/40/EU

Final report <https://op.europa.eu/en/publication-detail/-/publication/9ce15083-b931-11eb-8aca-01aa75ed71a1/language-en>

solely to TRPR, it does provide evidence that TRPR did not increase the size of the illicit market by more than assumed in the Impact Assessment.

- 7.89 No new evidence was identified or received through the consultation on the estimated average loss in tax and VAT per pack of cigarettes and HRT pack equivalents, as a result, these estimates have also not been updated.
- 7.90 However, as discussed above, new estimates are available for cigarette clearances between 2014/15 and 2018/19. The new estimates show a decrease from the estimates in the Impact Assessment from 169,100 million sticks to 140,818 million sticks, with a slight increase in HRT equivalents. This fall in cigarette clearances reduces the estimated number of cigarette and HRT expected to be diverted to the illicit market to 13 million packs of cigarettes and 23 million HRT pack equivalents.
- 7.91 Revising the Impact Assessment figures with the updated estimates of the number of cigarette and HRT packs moving into the illicit market reduces the estimated loss in tax revenue to £155 million over the appraisal period.

Lost profits from reduced consumption

- 7.92 The reduction in the number of smokers due to TRPR was expected to reduce the sales, and in turn profits, for retailers, wholesalers and manufacturers.
- 7.93 In the Impact Assessment the same approach was used to calculate the loss in profit for retailers, wholesalers and manufacturers. For each stakeholder the relevant profit per pack was multiplied by the estimated number of packs not sold due to TRPR.
- 7.94 As explained above, at time of the Impact Assessment total cigarette clearances between 2014/15 and 2018/19 were estimated to be 169,100 million. This estimate was used to calculate that 218 million cigarette 20 packs and 84 million HRT “20 pack equivalents” would not be sold over the appraisal period due to TRPR.
- 7.95 The estimated profit per pack for retailers in the Impact Assessment was 32 pence, based on information provided by a UK retailer on profit margins for cigarettes. For wholesalers the estimated profit per pack in the Impact Assessment was 17 pence, estimated using information from the annual reports of a UK

wholesaler⁴⁰. The estimated profit per pack for manufacturers was 30 pence, which was estimated using the annual reports of two tobacco manufacturers^{41,42}.

- 7.96 Applying the relevant profit per pack for retailers, wholesalers and manufacturers to the estimated number of packs of cigarettes and HRT not sold due to TRPR provided an estimated loss in profit over the appraisal period of £78 million for retailers, £42 million for wholesalers and £74 million for manufacturers. The overall estimated loss in profit in the Impact Assessment was £195 million.
- 7.97 As explained above, new estimates are available for cigarette clearances between 2014/15 and 2018/19. The new estimates show a decrease from the estimates in the Impact Assessment from 169,100 million sticks to 140,818 million sticks, with a slight increase in HRT equivalents. This reduction also reduces the estimated number of packs of cigarettes and HRT pack equivalents not sold due to TRPR to 184 million and 88 million respectively.
- 7.98 We have not received or identified any new evidence to update the loss in profit per pack for retailers, wholesalers and manufacturers.
- 7.99 Multiplying the relevant profit per pack by the updated estimate of the number of packs of cigarettes and HRT pack equivalents not sold due to TRPR reduces the estimated loss in profit to £70 million for retailers, £38 million for wholesalers and £67 million for manufacturers. The updated estimated total loss in profits due to TRPR is £172 million over the appraisal period.
- 7.100 The reduction in consumption was expected to have a particularly large impact on small and micro retailers, due to the large proportion of tobacco estimated to have been sold by businesses of this size (46%⁴³). Although it has not been possible to quantify the specific impact on these businesses the lost profits would be spread across all retailers of tobacco products and mostly realised over a 10-year appraisal period, meaning the impact on individual small and micro retailers is not likely to be significant.

⁴⁰ P54 Booker annual report and accounts 2014 (previously available at):

<http://www.bookergroup.com/~media/Files/B/BookerGroup/pdf/investor-centre/reposts-presentations/rp2014/booker-group-ar14-06062014.pdf?>

⁴¹ Reference in the impact assessment: Page 31 BAT Annual Report 2013 available at:

[http://www.bat.com/group/sites/uk_9d9kcy.nsf/vwPagesWebLive/DO9DCL3B/\\$FILE/medMD9HEGPT.pdf?openement](http://www.bat.com/group/sites/uk_9d9kcy.nsf/vwPagesWebLive/DO9DCL3B/$FILE/medMD9HEGPT.pdf?openement) (Link no longer available)

⁴² Reference in the impact assessment: 2nd cover page PMI 2013 report available at

<http://investors.pmi.com/phoenix.zhtml?c=146476&p=irol-reportsannual> (Link no longer available)

⁴³ "Cigarettes in the United Kingdom", Euromonitor 2011

- 7.101 At the time of the Impact Assessment the Association of Convenience Stores estimated there were 50,095 shops in the UK⁴⁴. This has decreased to 46,955 in 2020, 72% of which were independent retailers⁴⁵. Despite the decrease in the number of shops in this time, sales volumes have increased from £37.5 billion in 2016 to £44.7 billion in 2020. This indicates that the reduction in sales in tobacco due to TRPR will have been offset by an increase in the sale of other products.
- 7.102 Additionally, small businesses interviewed as part of The King's Fund research generally considered the overall impact on business and income to be limited. The reasons given included tobacco products having low margins to begin with.

Lost profit from illicit sales

- 7.103 The expected increase in illicit trade explained above was also expected to have a negative impact on retailers, wholesalers and manufacturers in the form of lost profits.
- 7.104 The estimated loss in profit was based on the same estimate of the increase in illicit trade as the estimated loss in tax revenue due to illicit trade, 0.75% between 2016 and 2019 and 1.5% from 2020 onward. Also, as with the estimated loss in tax revenue due to illicit sales, the percentage increase in illicit sales was applied to expected sales (based on the estimate of cigarette clearances referenced previously) and was estimated to move 17 million packs of cigarettes and 25 million HRT pack equivalents into the illicit market.
- 7.105 As discussed above, evidence from HMRC 'tobacco tax gap estimates' and the EU suggests that the illicit market may not have increased by as much as originally estimated in the Impact Assessment. However, as it is not possible to attribute these changes in the illicit market solely to TRPR the assumptions used in the Impact Assessment have not been changed.
- 7.106 To estimate the loss in profit for retailers, wholesalers and manufacturers due to the increase in illicit trade, the relevant profit per pack, explained above, was multiplied by the estimated number of packs of cigarettes and HRT pack equivalents moving to the illicit market. It was estimated that the loss in profit would be £11.2 million to retailers, £6.1 million to wholesalers and £10.1 million to manufactures, giving an estimated loss in profit of £27.4 million over the appraisal period.

⁴⁴ ACS Local Shop Reports 2016 available at:
https://www.acs.org.uk/sites/default/files/local_shop_report_2016.pdf

⁴⁵ ACS Local Shop Reports 2020 available at:
https://www.acs.org.uk/sites/default/files/acs_local_shop_report_2020.pdf

- 7.107 Although the assumptions used in the Impact Assessment around the increase in illicit sales due to TRPR and the profit per pack for retailers, wholesalers and manufacturers has not changed, these estimates need to be applied to the updated estimates of the number of packs of cigarettes and HRT equivalents. As described above, the fall in cigarette clearances reduces the estimated number of cigarette and HRT expected to be diverted to the illicit market to 13 million packs of cigarettes and 23 million HRT pack equivalents.
- 7.108 This reduces the estimated loss in profit due to the increase in illicit sales to £10.9 million for retailers, to £5.9 million for wholesalers and £9.9million for manufacturers. The updated estimated loss in profit for retailers, wholesalers and manufacturers due to illicit sales is £26.6 million over the appraisal period.
- 7.109 The lost profits from illicit sales was also expected to have a particularly large impact on small and micro retailers. However, for the reasons discussed above, the impact on individual businesses is not likely to be significant and the evidence suggests any reduction in sales due to illicit sales of tobacco caused by TRPR will have been offset by an increase in the sale of other products.

Tobacco notification

- 7.110 The regulations required manufacturers of tobacco products, novel tobacco products, herbal products for smoking to report varying degrees of information on their products, including a comprehensive study on any additives placed on a priority list covering emissions, toxicological and flavouring characteristics.
- 7.111 Based on information provided by industry the Impact Assessment used £560,000 as an estimate of the cost of producing a report for each additive. This was multiplied by the 15 formulations that were on the priority list adopted by the EU. This provided an estimated cost of £8.4 million.
- 7.112 In addition to producing a report for each additive, TRPR requires manufacturers to report information, other than TNCO, on emissions from tobacco products. This was estimated to cost £1.4 million for cigarette, HRT, cigar, herbal and novel tobacco products. This estimate was based on estimates from industry that a report for each formulation would cost £1,000.
- 7.113 No new evidence has been received or identified on the number of formulations and additives on the market or the cost of producing a report for each additive. As a result, the cost of £9.8 million estimated in the Impact Assessment for all types of notification, £8.4 million for additives plus £1.4 million on emissions reports, remains unchanged.

Tobacco data storage/processing

- 7.114 The information provided by tobacco manufacturers is stored and processed by DHSC. Therefore, the cost to the Government of undertaking this role was estimated in the Impact Assessment.
- 7.115 As explained above, based on information provided by MHRA it was estimated in the Impact Assessment that it would cost the Government £320,000 in the first year with an additional annual cost of £42,000, equivalent to £640,000 over the appraisal period.
- 7.116 No new evidence has been received or identified to update this estimate, meaning the estimate from the Impact Assessment for data storage and processing remains unchanged.

Labelling

- 7.117 The new regulations required manufacturers of cigarettes, HRT, cigars, pipe tobacco and herbal products to redesign packaging for several reasons. This included, adding larger health warnings to packages and the removal of certain claims, elements and features.
- 7.118 In the Impact Assessment the cost was estimated of redesigning all packaging that was not compliant with TRPR at that time.
- 7.119 The number of SKUs for each product that required relabelling was estimated using Nielsen data for 2015. Based on the design of the packaging at the time of the Impact Assessment, the number of SKUs that would require a major and minor redesign was estimated.
- 7.120 Evidence on the cost of redesigning the packaging for each SKU in the Impact Assessment came from a study specifically commissioned by the EU Commission from RAND Europe estimating packaging costs in the food industry. The evidence suggested a minor redesign costs approximately £1,700 to £3,400 per SKU, whilst a major redesign costs £5,900 to £7,600⁴⁶. The midpoint of these estimates was used as the estimated cost of a minor and major redesign of the packaging for each cigarette, HRT and herbal product SKU.
- 7.121 The cost of relabelling for cigarettes and HRT manufacturers was estimated by multiplying the number of SKUs that would need relabelling and the cost of a

⁴⁶ EAS, The Introduction of Mandatory Nutrition Labelling in the European Union. Impact Assessment Undertaken for DG SANCO, Brussels: European Advisory Services (EAS), 2004.

minor and major redesign. In the Impact Assessment the cost was estimated to be £2.1 million for cigarette manufacturers and £430,000 for HRT manufacturers.

- 7.122 The relabelling costs were estimated to vary between three groups of cigar manufacturers. It was estimated that for the three largest manufacturers of machine-made cigars (Imperial, Japan Tobacco International and Scandinavian Tobacco Group) there would be an initial one-off cost of £170,000 and an additional annual cost of £4,000 to include text warnings. For other manufacturers of machine-made cigars it was estimated in the Impact Assessment that there would only be a one-off cost of £160,000, based on information provided through the consultation for the Impact Assessment. For manufacturers of premium hand-made cigars, based on information provided through the consultation for the Impact Assessment it was estimated it would cost them an initial £370,000 and £210,000 annually.
- 7.123 The cost for manufacturers of pipe tobacco products was estimated in the Impact Assessment to be £210,000 in the first year and £120,000 each year thereafter. This was based on data provided through the consultation for the Impact Assessment.
- 7.124 For manufacturers of herbal products for smoking it was expected that each SKU would only require a minor redesign. This provided an estimated one-off cost to manufacturers of herbal products of £76,000. For the annual cost there were no specific estimates for these types of products. Instead the mid-point was the annual cost per SKU provided in the consultation for cigarette manufacturers and the annual cost per SKU for cigar manufacturers estimated in the RAND study mentioned above. When applied to the number SKUs of herbal products for smoking requiring a redesign, the estimated annual cost to manufacturers in the Impact Assessment was £84,000.
- 7.125 In total, the Impact Assessment estimated that relabelling would cost manufacturers of these products £18.6 million over the appraisal period.
- 7.126 No new evidence has been received or identified to suggest that more or less SKUs required relabelling, or the cost of relabelling was different to that estimated in the Impact Assessment. As a result, the relabelling costs estimated in the Impact Assessment have not been updated.

Tobacco cross-border registration and age verification

- 7.127 TRPR requires any retailers selling to EU member states to register and provide an age-verification system for any cross-border sales.

- 7.128 At the time of the Impact Assessment very few UK retailers were registered for cross-border sales, this is because tobacco duty is much higher in the UK relative to EU member states, resulting in limited demand for UK tobacco. For any UK retailers that did register they were only required to provide minimal information. It was therefore assumed in the Impact Assessment that the cost to UK retailers of cross-border registering was zero.
- 7.129 For the retailers that registered for cross-border sales the estimated cost verifying the age of customers was based on data from Euro-monitor on proportion of tobacco sales for UK retailers on the internet and an assumption that 1% of these sales were from abroad, which equated to 2 million cross-border transactions. This number was multiplied by an estimate provided through the consultation for the Impact Assessment that it costs 2.3 pence for each age verification check. This provided an estimated annual cost to UK retailers of £4,600, equivalent to around £39,000 over the appraisal period.
- 7.130 We have not received or identified any further information to update these estimates. Also, as of 2019 tobacco duty in the UK was the highest in Europe⁴⁷, suggesting that the assumption that the cost to UK retailers of cross-border registering was zero is still reasonable. As a result, the total estimated cross-border registration and age verification costs to tobacco retailers has remained unchanged.

Peer review

- 7.131 As explained above, TRPR requires manufacturers of tobacco products, novel tobacco products and herbal products for smoking to submit a comprehensive study on any additives. TRPR also includes a provision for these studies to be peer reviewed. The Government took the option to charge industry for the peer review of these studies, therefore this was a cost to the tobacco industry.
- 7.132 In the Impact Assessment it was expected that the Government would use the Committee on Toxicity (COT), Committee on Carcinogenicity (COC) and Committee on Mutagenicity (COM) for the peer review as appropriate.
- 7.133 The estimated cost at the time for preparing a review for these committees was between £19,000 and £27,000. The estimated cost for the committees to meet and discuss the findings of the review was between £800-£2,400 per review. Based on the mid-points of these estimates it was estimated that the peer review for each

⁴⁷ Tax Foundation, Cigarette Taxes in Europe: [Cigarette Taxes in the EU | European Cigarette and Tobacco Tax Map \(taxfoundation.org\)](https://www.taxfoundation.org/cigarette-taxes-in-the-eu/)

additive would cost £25,000. Therefore, the estimated cost for the 8 additives in the Impact Assessment was around £196,800.

- 7.134 We have not received or identified any further information to update the estimated peer review costs.

Charging costs

- 7.135 As explained above, the Government took the option to charge industry to cover the costs of verifying TNCO levels in cigarettes and processing and storing data from notifications.
- 7.136 The estimated costs to industry in the Impact Assessment of these charges were £2 million over the appraisal period, the same as the charging income for Government described above.
- 7.137 As above, no new evidence has been received or identified to suggest the income is different to that assumed in the Impact Assessment.

E-cigarette labelling and packaging

- 7.138 The regulations required e-cigarette packaging to display a warning message as well as information about ingredients. The regulations also required a leaflet containing information about toxicity and addictiveness to be included in the package.
- 7.139 The cost of adding a warning message to e-cigarette packaging was estimated by multiplying the estimated number of e-cigarette SKUs on the market by the estimated cost of a minor redesign of labelling costs. The Impact Assessment used the mid-point of estimates from a study specifically commissioned by the EU Commission, RAND Europe, referenced previously, that a minor redesign of labelling costs approximately £2,500 per SKU. The estimated number of e-cigarette SKUs was of 5,200 from MHRA estimates. This provided an estimated one-off cost to e-cigarette manufacturers of £13 million over the appraisal period.
- 7.140 The cost of including a leaflet with each e-liquid bottle was estimated separately in the Impact Assessment. The estimated cost of including a leaflet with each bottle in the Impact Assessment came from a range of estimates provided by e-cigarette manufacturers, the average of these estimates was 4p. This was multiplied by the estimated number of bottles sold each year. The estimated number of bottles was based on information received through the consultation from an e-cigarette manufacturer. Using this data from the consultation it was estimated that 38 million e-liquid bottles were sold in 2015 and this was forecast to increase annually to 110 million bottles by 2019, due to the expected growth in the e-cigarette market. Multiplying the 4p cost of including a leaflet in each bottle by the estimated number

of bottles sold each year provided an estimate of £39 million for e-cigarette manufacturers over the appraisal period.

- 7.141 We have not received or identified any further information to update these estimates. As a result, the total estimated costs to e-cigarette manufacturers for e-cigarette labelling and packaging of £52 million has remained unchanged.

E-cigarette advertising

- 7.142 TRPR restricted advertising of e-cigarettes. The Impact Assessment explained that although limiting the ability to advertise may reduce growth in the e-cigarette market some advertising will only grow the market share of individual firms, meaning there is no benefit to e-cigarette market as a whole. This advertising spending is effectively competitive waste and limiting the ability of e-cigarette businesses to advertise will reduce advertising spending without impacting overall consumption and profits for the e-cigarette industry. The Impact Assessment concluded that the benefit to the e-cigarette industry will be at least equal to the costs.
- 7.143 However, the Impact Assessment expected an impact from reduced profits to advertising agencies. As some advertising of e-cigarettes was still permitted under TRPR, it was assumed in the Impact Assessment that there would be a 90% reduction in annual spend and applied this reduction to expected spend in the absence of regulations to estimate the new level of advertising expenditure. Based on an estimated profit margin for advertising agencies of 11%⁴⁸, it calculated the loss of profit to equal £47 million over the appraisal period.
- 7.144 No new evidence has been received or identified on the reduction in advertising spend by the e-cigarette industry or the profit margins for advertising agencies, meaning the estimated cost to advertising agencies in the Impact Assessment has not been updated. The estimated reduction in annual spend of 90% was already a relatively high estimate. As some advertising of e-cigarettes was still permitted under TRPR the reduction may have been lower than this. Although no evidence was identified or received to change this assumption it seems reasonable to assume that the reduction was not more than 90%.

E-cigarette cross-border sales registration and verification

- 7.145 As with tobacco products described above, the TRPR regulations also required registration and age-verification of e-cigarette cross-border distance sales.

⁴⁸Top 50 ad agencies see 'lowest profit margins for seven years', Campaign:
<http://www.campaignlive.co.uk/article/top-50-ad-agencies-lowest-profit-margins-seven-years/1358676>

- 7.146 As a minimal amount of information is required, a cost of £1,000 was assumed per registration. This was based on the same information from industry as the cost per formulation for the notification costs described above.
- 7.147 Based on information from the consultation and ECigIntelligence⁴⁹ it was estimated in the Impact Assessment that there were 950 e-cigarette companies. It was assumed that 50% of these companies would wish to register for cross-border sales. This provided an estimated a one-off registration cost of £475,000 and an on-going annual cost which amounted to £930,000 over the ten-year appraisal period, for verifying cross-border transactions.
- 7.148 The on-going cost was estimated by multiplying the number of cross border transactions over the appraisal period, estimated using a baseline 1,750,000 cross-border transactions in 2014 multiplied by growth forecasts from Euromonitor, by a £0.02 unit cost⁵⁰ for verification.
- 7.149 No new evidence has been received or identified to update the costs for cross-border sales registration and verification originally estimated in the Impact Assessment.

E-cigarette sales reporting

- 7.150 The regulations required manufacturers and importers of e-cigarettes to submit annual data on sales volumes, consumer preferences, modes of sale and executive summaries of any market surveys undertaken.
- 7.151 In the Impact Assessment it was assumed that manufacturers and importers of e-cigarettes already had this information. This meant the only additional costs of the regulations was the time taken for staff to collate and submit the information.
- 7.152 This cost was estimated by multiplying the estimated number of businesses required to provide the information by the hourly wage and the hours taken. Based on the same information described above, there were an estimated 950 e-cigarette businesses. The hourly wage was based on the median UK hourly wage at the time of £11.60⁵¹. The estimated time taken to collate and submit this information came from an Industry Commercial Performance Analyst and it was estimated the time taken would vary between large and small businesses and for large businesses the time taken would halve from year 2 onwards.

⁴⁹ A leading e-cigarette market analyst company

⁵⁰ Data provided in consultation response.

⁵¹ Hourly pay - Gross (£) - For all employee jobs: United Kingdom, 2014 ONS

- 7.153 Overall, the estimated total cost to e-cigarette manufacturers and importers in the Impact Assessment was £130,000 in year 1 followed by an annual cost of £120,000 from year 2 onwards, giving a total cost of £1 million over the appraisal period.
- 7.154 No new evidence has been received or identified to update the costs originally estimated in the Impact Assessment.

E-cigarette notifications

- 7.155 TRPR required e-cigarette manufacturers and importers to submit a notification to the competent authority of any products they intend to place on the market.
- 7.156 In the Impact Assessment it was assumed that e-cigarette manufacturers and importers would already have most of the information required to submit a notification. However, companies would have to spend time completing the notification form and some companies may need to spend time requesting information from suppliers.
- 7.157 For the first year this cost was estimated by multiplying the estimated number of products requiring notification by the hourly wage and the hours taken to complete the form and submit it. Based on Nielsen data the estimated number of products requiring notification was 5,194, adjusted to account for information from ECITA (Electronic Cigarette Industry Trade Association) that the Nielsen data only covers 33% of the market. As with the estimated cost of e-cigarette sales reporting, the estimated hourly wage was £11.60. It was estimated in the Impact Assessment that it would take 15.6 hours complete this task.
- 7.158 For year 2 onwards, the calculation for year 1 was repeated with a growth rate of 25% applied to the number of products requiring notification. The estimated growth rate was based on information from ECigIntelligence.
- 7.159 This approach provided an estimated cost to e-cigarette manufacturers and importers of £940,000 in year 1, and £240,000 per year from year 2 onwards, giving a total cost of £2.7 million over the appraisal period.
- 7.160 No new evidence has been received or identified to update the costs originally estimated in the Impact Assessment.

E-cigarette familiarisation

- 7.161 It was also expected that all businesses in the e-cigarette industry would require time to familiarise themselves with the new regulations.

7.162 It was estimated that it would take 15 hours of employee time per company. This was multiplied by the estimated median hourly wage at the time, as above, to provide an estimated cost in the Impact Assessment of £170,000.

7.163 No new evidence has been received or identified to update the costs originally estimated in the Impact Assessment.

E-cigarette toxicology and emissions testing

7.164 Toxicology and emissions tests were required as part of the TRPR product notifications process.

7.165 However, in the Impact Assessment it was expected that businesses would likely already carry out some toxicology and emissions tests to ensure their products are safe in normal use before putting them on the market.

7.166 Based on a review of e-cigarette manufacturers websites⁵² on what testing they already carried out and information provided through the consultation, a best estimate of 10% was used for the proportion of products that would require additional toxicology and emissions tests. Based on the estimated number of e-cigarette products on the market, described above, this is equivalent to 519 products in year 1. It was assumed that from year 2 onwards only 10% of new products would require toxicology and emissions tests. Based on an estimated growth rate of products of 25%, explained above, the number of products requiring toxicology and emissions tests from year 2 onwards was 130.

7.167 Based on information provided through the consultation it was estimated that a toxicology test would cost £3,500. While an emissions test was estimated to cost £350, based on information provided by the Essentra Scientific Services.

7.168 Multiplying the number of products requiring tests each year by the estimated cost of each test provided an estimated cost for toxicology testing of £1.8 million in year 1 and £450,000 annually from year 2 onwards. For emissions testing the estimated cost was £180,000 in year 1 and £45,000 annually from year 2 onwards. Over the appraisal period toxicology tests were estimated to cost £5.3 million and emissions tests to cost £528,000.

7.169 No new evidence has been received or identified to update the costs originally estimated in the Impact Assessment.

⁵² Totally Wicked E-liquid Testing: <https://www.totallywicked-eliquld.co.uk/vaped/totally-wicked-e-liquid-test-results-summary/>

E-cigarette tamper evident packaging

- 7.170 TRPR required that 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.
- 7.171 ECITA provided information that suggested that the majority of e-cigarette products on the market were already child resistant and met the TRPR requirements. Based on this information, a best estimate of 10% of products was used as the proportion requiring modifying to meet the standards set by TRPR. As described above, this equates to 519 products in year 1. From year 2 onwards it was assumed only 10% of new products would require modifying. Using the same information on the expected growth rate of products described above, it was estimated that the number of products would grow by 25% per year, meaning 130 new products each year would require modifying.
- 7.172 Based on information provided through the consultation, it was estimated that it would cost £6,000 to make a container child resistant.
- 7.173 The estimated number of products requiring modifying was multiplied by the estimated cost of making a container child resistant. This provided an estimated cost for e-cigarette manufacturers of £3.1 million in year 1 and an annual cost of £780,000 from year 2 onwards. The estimated cost over the appraisal period was £9 million.
- 7.174 No new evidence has been received or identified to update the costs originally estimated in the Impact Assessment.

E-cigarette branding

- 7.175 One provision in the regulations was 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. This would require some e-cigarette manufacturers to change their branding, resulting in additional costs.
- 7.176 Using Nielsen ScanTrack data it was estimated in the Impact Assessment that 33% of the market⁵³ was made up of brands that required changes to their brand name due to the regulations.
- 7.177 The cost of rebranding this proportion of the e-cigarette market was based on the estimated advertising spend in the e-cigarette industry. As described above, information on advertising spend in the e-cigarette market came from

⁵³ Using market share based on value sales

ECigIntelligence. This estimated advertising spend was assumed to increase in proportion with expected growth in the e-cigarette market. The expected growth in the e-cigarette market was based on Euromonitor data and forecasts. It was estimated that spend on advertising in the e-cigarette market up to 2016 was £68 million.

- 7.178 This estimated spend on advertising was multiplied by the estimated proportion of the market that would need to rebrand. It was estimated that £22.6 million will need to be spent on advertising and marketing by these businesses and assumed that this entire cost is incurred in the first year of the policy.
- 7.179 No new evidence has been received or identified to update the costs originally estimated in the Impact Assessment.

E-cigarette data storage/processing

- 7.180 TRPR made the Medicines & Healthcare Products Regulatory Agency (MHRA) responsible for storing and processing the additional information TRPR required e-cigarette manufacturers and importers to provide.
- 7.181 Although the cost of this would fall directly on MHRA, as MHRA is funded by businesses the costs ultimately fall on businesses.
- 7.182 Based on information provided by MHRA, in the Impact Assessment it was estimated that this would cost £590,000 in year 1, and £140,000 annually from year 2 onwards, equating to £1.7 million over the appraisal period. The higher estimated initial cost is due to the higher number of expected notifications in the first year and IT implementation costs.
- 7.183 No new evidence has been received or identified to update the costs originally estimated in the Impact Assessment.
- 7.184 No new evidence has been received to update the costs originally estimated in the Impact Assessment.

Risks

- 7.185 The Impact Assessment noted that there is a risk of potential price increases and a reduction of choice of e-cigarettes, causing a switch back to smoking. Other risks such as a growing illicit market, false confidence in assuming e-cigarettes are medicines and uncertainty about restrictions were also cited, but none of these could be monetised in the Impact Assessment.

7.186 We have not received or identified any evidence to allow us to monetise these costs in the PIR.

Annex D: Department of Health and Social Care approved summary PIR report templates with the RPC opinion

Title: Tobacco and Related Products Regulations 2016 (TRPR) PIR No: To be allocated Original IA/RPC No: 3131 Lead department or agency: Health & Social Care Other departments or agencies: N/A Contact for enquiries: addictionspolicy@dhsc.gov.uk	Post Implementation Review
	Date: 26/01/2022
	Type of regulation: Domestic
	Type of review: Statutory
	Date measure came into force: 20/05/2016
	Recommendation: Keep
	RPC Opinion: Green

1. What were the policy objectives of the measure?

The objectives of the Tobacco and Related Products Regulations 2016 were to:

- Transpose provisions from the European Union’s Tobacco Products Directive (TPD) into UK law, including notification, labelling and advertising regulations for novel tobacco products, herbal products for smoking and electronic cigarettes.

This was expected to improve public health by:

- Discouraging young people from taking up smoking
- Support quitting among smokers who want to quit

2. What evidence has informed the PIR?

A suite of quantitative and qualitative evidence:

- Key indicator data, including adult and youth smoking prevalence, stop smoking services and e-cigarette usage
- A public consultation covering the regulations
- Independently conducted interviews of small businesses
- Peer reviewed papers published in scientific journals on the impact of the Tobacco and Related Products Regulations

3. To what extent have the policy objectives been achieved?

The impact of these regulations cannot be wholly isolated from the effects of other government regulation and interventions. However, evidence in 2 above indicates the Tobacco and Related Products Regulations 2016 have been effective in meeting its objectives:

- Smoking prevalence among adults in the UK has fallen from 17.2% in 2015 to 14.1% in 2019. Current smoking prevalence among young people in England fell from 5.6% in 2014 to under 5% in 2018.

Sign-off for Post Implementation Review: Minister

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed: ***Maggie Throup MP, Parliamentary Under Secretary of State (Minister for Vaccines and Public Health)***

Date: ***08/03/2022***

4. What were the original assumptions?

The Tobacco and Related Products Regulations 2016 were expected to deliver:

- 195,450 additional quitters between 2016 and 2025
- £13bn discounted health benefits
- Costs to businesses, including an equivalent annual net direct cost to business (EANDCB) of £16.4 million
- A reduction in tobacco duty revenue of £2.15bn.

5. Were there any unintended consequences?

There have been some unintended consequences. For example, to circumvent the prohibition of the characterisation of flavours in cigarettes and hand rolling tobacco, tobacco manufacturers have introduced new ranges of tobacco products with menthol. Despite the unintended consequences the evidence does not indicate they have significantly reduced the benefits of the regulations and the prevented the main objectives from being met. The Department will however keep them under review.

6. Has the evidence identified any opportunities for reducing the burden on business?

The main burden on businesses were the estimated lost profits due to reduced consumption and increased illicit sales. It would not be possible to reduce the burden on business in these areas without undermining the health benefits associated with the regulations.

7. For EU measures, how does the UK's implementation compare with that in other EU member states in terms of costs to business?

In May 2021, the EU published a published a report reviewing the implementation of the TPD. Although stakeholders reported that they faced significant costs to implement the TPD, due to a lack of evidence provided by businesses the EU were not able to quantify the costs businesses incurred to implement the TPD. Therefore, it has not been possible to compare the costs to businesses of the UK's implementation of TRPR against that in other EU member states.

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