EXPLANATORY MEMORANDUM TO

THE TOBACCO PRODUCTS AND NICOTINE INHALING PRODUCTS (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. 41

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

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

2. Purpose of the instrument

2.1 The purpose of this instrument is to remedy deficiencies in UK legislation relating to tobacco and nicotine inhaling products, or failures of that UK legislation to operate effectively, which would arise from the withdrawal of the UK from the European Union ('EU'), in the event of no deal. It also amends one piece of related EU tertiary legislation and revokes four pieces of related EU tertiary legislation which will no longer have any application to the UK after withdrawal. 'EU tertiary legislation' refers to delegated acts and implementing acts made under powers contained in EU legislation (such as regulations or directives). The instrument is made under powers in the European Union (Withdrawal) Act 2018.

2.2 As a responsible government, we will continue to proportionately prepare for all scenarios, including the unlikely outcome that we leave the EU without any deal in March 2019. This purpose of this Statutory Instrument is to ensure that, in the unlikely scenario that the UK leaves the EU with no deal, there will continue to be a functioning statute book on exit day which maintains continuity in relation to tobacco control policy and legislation.

Explanations

What did any relevant EU law do before exit day?

2.3 The two main pieces of EU legislation in relation to tobacco and related products are Directive 2014/40/EU (the 'Tobacco Products Directive') and Directive 2003/33/EC (the 'Tobacco Advertising Directive').

2.4 The Tobacco Products Directive requires EU Member States to introduce advertising restrictions for e-cigarette products and also regulates the following areas for tobacco products, herbal products for smoking and e-cigarette products:

- product standards (such as ingredients and emissions);
- packaging; and
- notification requirements prior to the placement of products on the market.

2.5 The Commission has made several pieces of tertiary legislation under powers in the Tobacco Products Directive which provide detailed requirements in each of these areas, such as specifying:

- a process for determining whether products have a characterising flavour,

- requirements for the layout of tobacco product packaging, and
- the process and format for notifications of tobacco and e-cigarette products.

2.6 The Tobacco Advertising Directive requires Member States to prohibit almost all forms of tobacco advertising in the EU.

2.7 Other pieces of legislation amended by this instrument include provisions implemented to comply with Directive 2000/31/EC (the 'E-Commerce Directive'), Directive 2001/83/EC (the 'Directive on medicinal products') and Commission Recommendation 2003/361/EC concerning the EU definition of micro, small and medium-sized enterprises.

Why is it being changed?

2.8 As noted above, the amendments contained in this instrument are necessary to ensure that tobacco control legislation will continue to function after exit day. In particular they allow for necessary changes to the picture warnings on tobacco products and the process by which tobacco products and e-cigarettes are notified to Public Health England (PHE) and the Medicines and Healthcare Products Regulatory Agency (MHRA), respectively. The legislation being amended also contains a number of references that will no longer be appropriate once the UK withdraws from the EU, such as references to arrangements to which the UK has access as an EU Member State, and minor references to the European Union (EU), the European Economic Area (EEA), the Commission and EU law. The European Commission also has a number of powers under the Tobacco Products Directive (such as the ability to update regulations in line with scientific developments), which it will no longer exercise on the UK's behalf following exit.

What will it do now?

2.9 The amendments and revocations made by this instrument will ensure that there is minimal disruption to tobacco control policy as a result of the UK's withdrawal from the EU. The detailed breakdown of the various types of changes which this instrument will bring about is included in section 7. It will make the following changes:

- Amend or omit EU/EEA/Member State references
- Revoke EU obligations and reciprocal arrangements that will no longer be relevant to the UK
- Transfer relevant Commission powers under the Tobacco Products Directive to the Secretary of State (all of which are detailed in paragraph 7.14)
- Allow for the establishment of new Notification Systems for tobacco products and e-cigarettes
- Allow for the use of Australian picture warnings to replace the ones which are owned by the Commission
- Introduce a fee-making power

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The instrument, at regulation 6(18)(b), omits paragraph (b) of regulation 26 of the Tobacco and Related Products Regulations 2016 (S.I. 2016/507). In its Twentieth Report of Session 2016-2017 the Joint Committee on Statutory Instruments reported

an amendment to this provision under the Tobacco and Related Products (Amendment) Regulations 2016 (S.I. 2016/1127) for defective drafting.

3.2 The Joint Committee on Statutory Instruments reported two other items in the Tobacco and Related Products (Amendment) Regulations 2016 (S.I. 2016/1127) for defective drafting in its Twentieth Report of Session 2016-2017, but the vires do not exist under European Union (Withdrawal) Act 2018 powers to correct these errors.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.3 The territorial application of this instrument varies between provisions.

3.4 The territorial application of Parts 2 and 3 of this instrument is the same as the territorial application of each enactment being amended in these Parts. For the majority of the enactments their territorial application is all of the UK.

3.5 The territorial application of Parts 4 and 5 of this instrument is all of the UK.

4. Extent and Territorial Application

4.1 The territorial extent and application of Parts 2 and 3 of this instrument is the same as the territorial extent and application of each enactment being amended in these Parts.

4.2 The territorial extent and application of Part 4 of this instrument (which amends and revokes EU tertiary legislation in relation to tobacco and nicotine inhaling products) is all of the UK.

4.3 The territorial extent and application of Part 5 of this instrument is all of the UK.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State (Public Health and Primary Care), Steve Brine MP has made the following statement regarding Human Rights:

"In my view the provisions of The Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument is being made in order to ensure that legislation in relation to tobacco control continues to function in the event that the UK leaves the EU without a deal in place.

6.2 The Tobacco and Related Products Regulations 2016, parts of the Standardised Packaging of Tobacco Products Regulations 2015 (S.I. 2015/829) and relevant amendments to the Tobacco Advertising and Promotion Act 2002 were made under powers conferred by section 2(2) of the European Communities Act 1972 in order to implement the Tobacco Products Directive and the Tobacco Advertising Directive (see paragraph 2.3 above for a full description of relevant EU law).

6.3 The European Communities Act 1972 will be repealed by the European Union (Withdrawal) Act 2018, but section 2 of the European Union (Withdrawal) Act 2018 saves EU-derived domestic legislation so that it continues to have effect in domestic law on and after exit day. The legislation listed in paragraph 6.2 will therefore be preserved, but will require amendment in order to function effectively after exit day,

and so it is being amended pursuant to the power in section 8 of the European Union (Withdrawal) Act 2018.

6.4 When the Tobacco and Related Products Regulations 2016 were originally debated in parliament, there was a strong focus on e-cigarettes and some concerns were raised that the regulatory regime was too onerous and would undermine UK business innovation. The recent Science and Technology Committee report also advocates a reduction in the regulatory burdens associated with e-cigarettes. These issues fall outside the scope of this instrument as its purpose is to ensure that EU/EU-derived legislation continues to function in the event that the United Kingdom leaves the EU with no deal and it is made under powers that are limited to that purpose.

6.5 Section 3 of the European Union (Withdrawal) Act 2018 also incorporates certain categories of direct EU law into domestic law. Part 4 of this instrument revokes those items of direct EU law in relation to the regulation of tobacco and nicotine inhaling products which would be saved by the European Union (Withdrawal) Act 2018 but which it is not appropriate to have as domestic law after exit day. It also amends one item of direct EU law so that it refers to the new domestic picture library, rather than the EU one.

6.6 In addition to implementing the Tobacco Products Directive and the Tobacco Advertising Directive, some of the legislation that is amended by this instrument also contains provisions referencing or implementing other EU legislation, which are inappropriate to retain in their current form after EU exit. In particular:

- Some relevant provisions in the Tobacco Advertising and Promotion Act 2002 were inserted or substituted into that Act by the Health Act 2009 in order to give full effect to Directive 2000/31/EC of the European Parliament and Council of 8th June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market. These provisions are being amended to take account of the loss of reciprocal arrangements with other Member States under Directive 2000/31/EC.
- There is a reference in the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 (S.I. 2015/895) to the definition of the summary of product characteristics in Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use. This is being removed, as it is thought to be redundant following EU exit, where use of the UK definition will be sufficient.
- There is a reference in the Tobacco and Related Products Regulations 2016 to the definition of small and medium sized enterprises in Commission Recommendation 2003/361/EC. This is being amended so that the currency used in the definition is Sterling rather than Euros, in line with broader government policy.

7. Policy background

7.1 The EU tobacco control legislation referenced in paragraph 2.3 sets the policy and legal framework for tobacco control and e-cigarettes in relation to reporting requirements, product presentation and advertising.

7.2 Smoking causes 78,000 deaths a year in England and accounts for 16% of all deaths annually. This instrument is intended to ensure that UK tobacco control legislation

continues to apply effectively in the event of no deal. The changes contained within the instrument are simply designed to reflect the status of the UK outside the EU.

Public interest

7.3 The level of public interest in the policy area is generally high; smoking can be a contentious subject which sparks lively public debate with numerous vocal stakeholders. For a number of years, governments of different political persuasions have made tackling the public health harms associated with smoking the clear and overt aim of government policy.

What is being done and why?

7.4 As referenced in Section 6 of this memorandum, this instrument is being made in order to correct deficiencies in UK and EU legislation, to ensure that tobacco regulation continues to function following the UK's withdrawal from the EU.

7.5 Amendments are being made to the following pieces of UK legislation:

- the Tobacco Advertising and Promotion Act 2002;
- the Tobacco Advertising and Promotion (Brandsharing) Regulations 2004 (S.I. 2004/1824);
- the Standardised Packaging of Tobacco Products Regulations 2015;
- the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015; and
- the Tobacco and Related Products Regulations 2016.

7.6 The following pieces of EU legislation that will be saved by the European Union (Withdrawal) Act 2018, are being amended or revoked:

- Commission Implementing Decision (EU) 2015/1842 of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking is being amended;
- Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules with regard to the procedures for determining whether a tobacco product has a characterising flavour is being revoked;
- Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers is being revoked;
- Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products is being revoked; and
- Commission Implementing Decision (EU) 2016/786 of 18 May 2016 laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour is being revoked.

7.7 Examples of the deficiencies addressed by these amendments and revocations are listed below.

Reciprocal arrangements that will no longer exist or are no longer appropriate

7.8 Several amendments in this instrument are being made in connection with reciprocal arrangements that will no longer exist following exit, or that are no longer appropriate.

7.9 For example, the amendments to the Tobacco Advertising and Promotion Act 2002 reflect the fact that the UK will no longer benefit from or be under obligations in relation to arrangements with the other EU Member States regarding tobacco advertising under the Tobacco Advertising Directive.

7.10 In particular, there is an obligation under the Tobacco Advertising Directive for EEA Member States to prohibit companies established in their Member State from advertising tobacco products into other EEA Member States. Following EU exit, there will no longer be an obligation on EEA Member States to prohibit their tobacco companies from advertising into the UK. This instrument therefore removes the reciprocal obligation to prohibit UK companies from advertising into the EEA.

EU obligations that will no longer be relevant

7.11 In some cases, we are removing EU obligations that will no longer be relevant or appropriate. For example, this instrument removes the obligations in regulations 26 and 34 of the Tobacco and Related Products Regulations 2016, which require the Secretary of State to report to the European Commission and competent authorities of other Member States certain information submitted to them regarding tobacco and e-cigarette products. This reporting obligation was part of the implementation of the Tobacco Products Directive.

EU references which are redundant or inappropriate

7.12 There are a number of minor amendments being made by this instrument to take account of EU references which will be redundant or inaccurate. For example, in both the Tobacco and Related Products Regulations 2016 and the Standardised Packaging of Tobacco Products Regulations 2015, references to 'other Member States' or 'any member State other than' have been amended, as they would not function correctly when the UK is not an EU Member State. Similarly, references to the revoked EU tertiary legislation have also been removed from the Tobacco and Related Products Regulations 2016, as they are now redundant.

Transfer of Commission Powers

7.13 There are a range of powers currently held by the European Commission under the Tobacco Products Directive, which allow the Commission to do such things as updating regulation in line with scientific developments. This instrument inserts into the Tobacco and Related Products Regulations 2016 similar powers for the UK government to update tobacco legislation in response to emerging threats, changing safety and quality standards, and technological advances. These updating powers are likely to have minimal impact on industry. Their purpose is to make sure that the UK is still able to make technical changes after we leave the EU, where needed.

7.14 Full detail of the powers in Tobacco and Related Products Regulations 2016 which will transfer to the United Kingdom Government is included below.

- New Regulation 5A (power to amend the health warnings on tobacco products, taking into account scientific and market developments)

- New Regulation 7(5) (power to amend the information message on tobacco products for smoking, taking into account scientific and market developments)
- New Regulation 8(10) (power to amend the position of general warning and information messages on hand rolling tobacco marketed in pouches, taking into account the different shapes of pouches)
- New Regulation 9(12) (power in relation to the labelling of large cigars and individually wrapped cigars and cigarillos)
- New Regulation 10(5) (power to amend the health warning on smokeless tobacco products, taking into account scientific developments)
- New Regulation 13(3) (power to decrease the maximum emission levels of cigarettes, based on internationally agreed standards)
- New Regulation 14(5) and (6) (power to modify the methods of measurement and verification of emission levels, based on scientific and technical developments or internationally agreed standards)
- New Regulation 15(3) (power to determine that a flavour is a characterising flavour)
- New Regulation 16(4) (power to determine whether a tobacco product contains additives in quantities that increase the toxic/addictive effect or the carcinogenic, mutagenic or toxic properties of the tobacco product, which means the product should therefore be prohibited)
- New Regulation 16A (power to establish procedures for determining whether a tobacco product has a characterising flavour or contains certain additives)
- New regulation 20A(6) (power to amend the priority list of additives).
- New Regulation 36(11) (power to amend the technical standards for the refill mechanism in e-cigarettes).
- New Regulation 37(10) (power to amend the health warning on e-cigarette products).

Notification System

7.15 In the event of no deal, the UK will need to develop its own domestic notification systems to enable notification of new tobacco products and e-cigarettes to continue when the UK no longer has access to the EU notification system. This instrument removes the obligation to submit information via the Commission's data system and in the Commission's required format, and provides the Secretary of State with the power to issue guidance on new notification procedures (new Regulations 25(2) and 33(2) of the Tobacco and Related Products Regulations 2016).

Picture warnings

7.16 In the event of no deal, the UK will no longer hold copyright for the EU picture library that is included in the Tobacco Products Directive 2014/40/EU, as amended by Commission Delegated Directive 2014/109/EU. The UK has reached an agreement to use pictures from the Australian government in order to ensure that tobacco products sold in the UK continue to have packaging which is designed to be as unappealing as possible. This instrument repeals the requirement to use the EU set of picture warnings and introduces the new set of picture warnings as Schedule A1. This instrument requires all products produced from exit day to include the new picture

warnings. There is also a sell through period for products produced before exit day, which means they can legitimately be sold for 12 months after exit day.

Fee making power

7.17 New Regulation 53A (Fees for determining characterising flavour, toxicity, addictiveness or Carcinogenic, Mutagenic, Reprotoxic properties) of the Tobacco and Related Products Regulations 2016, provides the Secretary of State with the power to charge fees in connection with the exercise of its functions listed at paragraph 7.14.

Application to Northern Ireland

7.18 This instrument amends some provisions in the Tobacco Advertising and Promotion Act 2002 and the Tobacco and Related Products Regulations 2016 which relate to a transferred matter for Northern Ireland by virtue of not falling within a description specified in Schedule 2 or Schedule 3 of the Northern Ireland Act 1998. The UK Government remains committed to restoring devolution in Northern Ireland. This is particularly important in the context of EU Exit where we want devolved Ministers to take the necessary actions to prepare Northern Ireland for exit. We have been considering how to ensure a functioning statute book across the UK including in Northern Ireland for exit day in the absence of a Northern Ireland Executive. With exit day less than one year away, and in the continued absence of a Northern Ireland Executive, the window to prepare Northern Ireland's statute book for exit is narrowing. UK Government Ministers have therefore decided that in the interest of legal certainty in Northern Ireland, the UK Government will take through the necessary secondary legislation at Westminster for Northern Ireland, in close consultation with the Northern Ireland departments. This is one such instrument.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. The instrument is also made under the power in paragraph 1 of Schedule 4 to the European Union (Withdrawal) Act 2018 in order to introduce a power for the Secretary of State to charge fees in relation to the exercise of powers being granted to the Secretary of State under this instrument. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 This Statutory Instrument does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 A short technical consultation took place with the tobacco and e-cigarette industry, representative groups and other stakeholders during October. The consultation asked for comments in relation to the two significant practical changes that that this instrument will introduce: the change of the picture library and the introduction of new domestic notifications systems for tobacco products and e-cigarettes.

10.2 There were 32 responses to the consultation. There was support for tying the notification systems as closely as possible to the existing EU arrangements, and responses also emphasised the need to be informed about UK's new system in good time.

10.3 There were also concerns raised around timing and costs in relation to switching to the Australian picture warnings. Whilst these concerns are noted, if the UK leaves the EU in March 2019 without a deal in place, we will no longer be able to require use of the current picture library, so in order to maintain the current standards of tobacco control it is necessary to have other arrangements in place. Given this, we do not feel the responses justify changing our policy as set out in the regulations.

10.4 Relevant guidance on the new notification system and picture warnings will be issued to the tobacco and e-cigarette industry by January 2019. This guidance will take account of the consultation responses.

10.5 Scotland, Wales and Northern Ireland have been engaged in ongoing consultation in relation to the changes included in this instrument. The instrument has been adapted to incorporate changes and comments that Devolved Administrations have proposed. Scotland, Wales and Northern Ireland have all provided their consent to this instrument being made by the Secretary of State insofar as it makes provisions that could otherwise fall within devolved competence.

11. Guidance

11.1 Guidance will be issued by January 2019 in relation to the change of the picture library and the introduction of new domestic notifications systems for tobacco products and e-cigarettes. This guidance will be developed in response to the feedback received from the consultation in September. The main audience for this guidance are businesses involved in the production of tobacco products and e-cigarettes.

12. Impact

12.1 There is some impact on businesses. There is no impact on charities or voluntary bodies.

12.2 There is no significant impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because the cost impact has been assessed as lower than the £5m threshold. The impact of this instrument on businesses will be low. The only key impacts are in relation to the picture warnings and the notification process.

12.4 Producers of tobacco products will need to amend production processes to incorporate new picture warnings for all tobacco packaging that is produced from exit day onwards. We estimate the impact on business will be small. There will be a one-off transition cost of moving to pictures selected from the Australian library, but some of these costs may be recovered in the medium-term by savings from the end of the requirement to rotate picture warnings each year, as exists currently with the EU library.

12.5 Manufacturers of tobacco products and e-cigarettes will need to submit notification information on new systems for any new products that they wish to sell in the UK. Information requirements will remain very similar to those in place before EU exit

and the systems for submitting information are being designed to minimise the immediate burden. Once a system is set up for the UK, there is potential for it to diverge from the established EU system, which might lead to additional costs to businesses that trade in both the UK and the EU, as they would need to submit to two systems under different specifications. This potential cost to business is difficult to estimate: it is currently costed in the Regulatory Triage Assessment (RTA) as £6,970 per annum in the tobacco market and £11,620-£20,910 per annum in the e-cigarette market.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 To minimise the impact of the requirements on small businesses (employing up to 50 people), the approach taken is highlighted in paragraph 12.5 above in relation to the notification system. Some specialist tobacconists argued that there would be significant costs associated with products with a long shelf-life, although overall the burden associated with picture warnings is expected to be minimal.

13.3 The basis for the final decision on what action to take to assist small businesses is the department's own economic analysis combined with relevant responses to the consultation.

14. Monitoring & review

14.1 No specific additional monitoring arrangements are needed. Some of the pieces of legislation being amended include review provisions (the Standardised Packaging of Tobacco Products Regulations 2015; the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015; and the Tobacco and Related Products Regulations 2016). These review provisions will continue to apply following the UK's withdrawal from the EU, with the amended application as provided for by Schedule 8, paragraph 9 of the EU (Withdrawal) Act 2018.

14.2 As this instrument is made under the EU (Withdrawal) Act 2018, no review clause is required.

15. Contact

15.1 Martin Teff at the Department of Health and Social Care can be contacted with any queries regarding the instrument. Telephone: 01132546304 or email: martin.teff@dh.gsi.gov.uk

15.2 Tim Baxter at Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Parliamentary Under Secretary of State (Public Health and Primary Care), Steve Brine MP at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/ESIC
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 77	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9, and 23(1) or jointly exercising	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising clauses 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Sch 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s.2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Parliamentary Under Secretary of State (Public Health and Primary Care), Steve Brine MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 do no more than is appropriate".

1.2 This is the case because they do no more than amend or revoke tobacco legislation to correct deficiencies arising from the withdrawal of the United Kingdom from the European Union or to correct tobacco legislation where it would otherwise fail to operate effectively after the UK leaves the EU. This includes removing or revoking redundant provisions or pieces of legislation, amending references to obligations or reciprocal agreements that will no longer exist, and transferring appropriate Commission functions to the Secretary of State. Further details, including examples of all the changes included in the instrument, are detailed in Section 7 of the main body of this explanatory memorandum.

2. Good reasons

2.1 The Parliamentary Under Secretary of State (Public Health and Primary Care), Steve Brine MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 Following exit day, without amendments to the relevant legislation, tobacco control policy would cease to function effectively. This instrument seeks to remove or amend provisions in UK legislation and EU legislation saved by the EU (Withdrawal) Act 2018, in order to ensure that tobacco control policy will continue to function at the same level as prior to EU exit. In particular, the instrument introduces a new picture library and notification system, both of which would be otherwise unable to continue in the UK. It also makes a number of technical amendments, and provides the Secretary of State with powers previously held by the EU Commission which will allow the Secretary of State to update tobacco legislation in in response to emerging threats, changing safety and quality standards, and technological advances. Further details, including examples of the amendments made and reasons for making them, are set out in section 7 of the main body of this explanatory memorandum.

3. Equalities

3.1 The Parliamentary Under Secretary of State (Public Health and Primary Care), Steve Brine MP, has made the following statement:

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts."

3.2 The Parliamentary Under Secretary of State (Public Health and Primary Care), Steve Brine MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

3.3 This instrument will have no, or very limited, impact on equalities.

4. Explanations

4.1 The explanations statement has been made in paragraph 2.3 of the main body of this explanatory memorandum.