EXPLANATORY MEMORANDUM TO

THE TOBACCO PRODUCTS AND NICOTINE INHALING PRODUCTS (AMENDMENT) (EU EXIT) REGULATIONS 2020

2020 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by 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 implement the Withdrawal Agreement ('WA'), in particular the Ireland / Northern Ireland Protocol ('the Protocol') to ensure the UK meets its obligations in relation to tobacco control policy under this agreement.

2.2 This instrument will ensure the requirements relating to tobacco products placed on the market before the end of the Implementation Period ('IP') are consistent with Article 41(1) of the WA around products circulating on the market after the end of the IP.

2.3 Changes are being made to the fees payable by producers when reporting information about their products in order to account for the amendments to the requirements for notifying in Northern Ireland ('NI').

2.4 These amendments will ensure tobacco control legislation continues to work effectively after the end of the IP.

Explanations

What did any relevant EU law do before exit day?

2.5 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').

2.6 The Tobacco Products Directive ('TPD') requires EU Member States to introduce advertising restrictions for e-cigarette products (nicotine inhaling products) and 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.

2.7 The European Commission has made several pieces of tertiary legislation under powers in the TPD 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.

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

Why is it being changed?

2.8 The TPD is listed in Annex 2 of the Protocol. Article 5(4) states Union law listed in Annex 2 shall also apply in NI, as long as the Protocol has the consent of the people of NI. The amendments are being made in order to implement the obligations of the Protocol in legislation.

2.9 The changes will be achieved by amendments to how the Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019, ('the 2019 instrument') laid for a no deal scenario, amends the Tobacco and Related Products Regulations 2016 ('TRPR') such that they apply for the end of the IP. The TRPR implemented the TPD.

2.10 In particular, this instrument makes necessary changes to picture warning requirements in TRPR for NI 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), for NI.

2.11 This instrument also makes an amendment to the transitional provision provided for tobacco products to reflect the provisions of the WA, allowing tobacco products carrying EU pictures placed on the market in Great Britain ('GB') before the end of the IP to circulate until they reach their end user.

2.12 TRPR contains a number of references to the UK, which are being changed in order to refer to GB or NI to reflect the obligations of the Protocol.

2.13 The implementation of the Protocol will result in two separate notification system processes for GB and NI for tobacco and related products, the Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017 and Electronic Cigarettes etc (Fees) Regulations 2016 are being amended to reflect that if a producer notifies via both the NI and GB systems, they are only required to pay one fee. If a producer wishes to notify in relation to placing products on just one of the markets, the same one fee will be payable.

2.14 The legislation will allow goods to move freely between GB and NI, subject to the tobacco picture warning requirements.

2.15 These amendments and revocations are necessary to ensure that the UK's obligations under the WA are met and that the TPD accordingly applies in NI.

What will it now do?

2.16 The legislation will maintain the high level of tobacco control measures across the UK while also reflecting the requirements of the Protocol.

2.17 The legislation will maintain product standards and packaging requirements, prohibitions of certain features of products and restrictions on advertising and require notification before products are placed on the NI or GB market.

2.18 In accordance with the WA:

- Tobacco products sold in NI will be required to feature the EU picture warnings, while tobacco products sold in GB will be required to feature the picture warnings licensed from the Australian Government.
- Producers placing products on the NI market will be required to continue using the EU Common Entry Gate (EU-CEG) system for the notification of tobacco and e-cigarette products.
- Producers placing products on the GB market will be required to notify on the GB domestic system.
- Notifiers will be required to pay one fee if they notify in relation to placing products on one of the GB or NI markets and the same one fee if they notify in relation to placing products on the two markets.
- Tobacco products featuring the EU picture warnings placed on the GB market prior to the end of the IP will be allowed to circulate in GB until they reach their end user.

2.19 The amendments will mean that references to the EU, which would have become references to the UK under the 2019 instrument, will now become references to GB. Functions that would have been transferred to the Department of Health in NI as regulation making powers to amend detailed requirements under the Tobacco Products Directive will not be transferred.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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)

3.2 The territorial application of this instrument is UK wide.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is UK wide.

4.2 The territorial application of this instrument is UK wide.

5. European Convention on Human Rights

5.1 The Minister for Health Edward Argar 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 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 Tobacco control legislation is a mixture of EU derived legislation: primarily the TRPR, and directly applicable EU tertiary legislation made under the TPD, and domestic legislation: UK wide legislation made in part to implement the TPD such as the standardised packaging legislation, and devolved legislation imposing

requirements relating to restrictions such as the age of sale for tobacco products and e-cigarettes.

6.2 The 2019 instrument was made to remedy deficiencies in retained EU and domestic legislation relating to tobacco and nicotine inhaling products (e-cigarettes), or failures of that legislation to operate effectively, which would arise from the withdrawal of the UK from the (EU, in the event of no deal. These amendments included two main changes to the requirements under TRPR:

- Allow for the establishment of new notification systems for tobacco products including novel products and herbal products for smoking, and e-cigarettes.
- Allow for the use of Australian picture warnings to replace the EU picture warnings on which the Commission holds the copyright.

6.3 This instrument amends the 2019 instrument in order to give effect to the WA and amends the amendments made in the 2019 instrument to the TRPR, for example by removing references to the UK, so that the TPD remains directly applicable in NI ensuring the Protocol is reflected in law. In particular, the new notification system for tobacco products and e-cigarettes will be used for the GB market only, and tobacco products placed on the NI market will be required to use the EU picture warnings.

6.4 As explained in paragraph 2.13, amendments are also made to the Electronic Cigarettes etc (Fees) Regulations 2016 and to the Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017 which require fees to be paid in relation to notifying placing on the market of e-cigarettes, tobacco products and herbal products for smoking and annual fees. This means that only one fee is payable when a producer is placing products on both the NI and GB market.

6.5 This instrument is being made under sections 8 and 8C of the European Union (Withdrawal) Act 2018.

7. Policy background

What is being done and why?

7.1 As referenced in paragraph 2.1 of this explanatory memorandum, this instrument is being made in order to implement the obligations of the WA.

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

- The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2019 in terms of the amendments they make to the Tobacco and Related Products Regulations 2016.
- Electronic Cigarettes etc (Fees) Regulations 2016
- Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017

7.3 The EU tobacco control legislation referenced in paragraphs 2.5 to 2.7 of this explanatory memorandum sets the policy and legal framework for tobacco control and e-cigarettes in relation to reporting requirements, product presentation and advertising. Domestic legislation covers restrictions such as controls on age of sale for tobacco and related products, display bans, and smoke free premises.

7.4 Smoking causes 78,000 deaths a year in England and accounts for 16% of all deaths in England annually. This instrument is intended to implement the WA, in particular the Protocol, through amending the 2019 instrument to ensure that UK tobacco control

legislation continues to apply effectively after the end of the IP. The changes made by this instrument do what is necessary to implement the WA.

Protocol on Ireland/Northern Ireland

7.5 The Protocol on Ireland/Northern Ireland in the WA provides arrangements that ensure a practical solution to avoiding a hard border on the island of Ireland, while ensuring that the UK, including NI, could leave the EU as a whole. The Protocol also provides that the arrangements contained in the Protocol are to be subject to democratic consent in NI in relation to their operation and continuation.

7.6 The TPD is listed in Annex 2 of the Protocol meaning EU law will continue to be directly applicable in NI whilst the rest of the UK will set its own regulatory regime following the end of the IP. Article 5(4) states Union law listed in Annex 2 shall also apply in NI.

Unfettered access

7.7 Providing unfettered access for NI goods entering and being placed on the GB market is a key Government commitment. This has been set out in the 'New Decade, New Approach' deal to restore power-sharing in NI and in the May Command Paper on the UK's approach to implementing the Protocol.

7.8 This instrument will enable unfettered access from 1st January 2021 as the legislative requirements to place goods on the NI and GB markets are the same. Unfettered acess will not apply to Qualifying Northern Ireland Goods tobacco products which are required to carry EU picture warnings. This is as a result of international copyright obligations since the Commission holds the copyright in the EU picture warnings which are licensed for Member State use. Any tobacco products placed on the GB market have to feature the pictures set out in Schedule A1 of the TRPR as amended by the 2019 instrument, in order to lawfully be placed on the GB market.

Public interest

7.9 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.

Notification system

7.10 After the end of the TP, tobacco and e-cigarette products being sold in NI will be required to be notified to the EU Common Entry Gate system in line with the EU TPD. This instrument removes the requirement for NI to use a UK domestic notification system to notify tobacco and e-cigarette products.

Fees

7.11 As mentioned in paragraph 7.10 there will be two separate notification requirements for NI and GB. Due to this, amendments are being made to the Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017 and Electronic Cigarettes etc. (Fees) Regulations 2016 so that only one fee will be payable if a producer is placing the same product on both the GB and NI market.

Picture warnings

7.12 After the end of the TP, tobacco products sold in NI will be required to feature the EU picture warnings as set out in the TPD 2014/40/EU, whereas tobacco products sold in GB will need to feature the pictures set out in Schedule A1 of the 2019 instrument. The transitional provision in the 2019 instrument will be amended to take into account the terms of the WA for products carrying the EU picture library placed on the market in GB before 1st January 2021 to allow them to circulate until they reach the end user.

8. European Union (Withdrawal) Act 2018/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 being made under section 8C of that Act to implement the Protocol on Ireland/Northern Ireland in the Withdrawal Agreement.

8.2 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 instrument does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 Formal consent on this instrument was not required from Wales and Scotland. There has been ongoing engagement on the changes included in this instrument with counterparts in Scotland and Wales.

10.2 NI have given consent to the inclusion in this instrument of one provision that relates to a matter within devolved competence: provision of e-cigarette sponsorship to cross border events. This instrument amends the 2019 instrument to retain a prohibition for NI on provision of e-cigarette sponsorship to cross border events as this is a requirement of the TPD.

10.3 A public consultation was not carried out on this instrument as the changes to be made are technical in nature and determined by the terms of the Withdrawal Agreement and the Protocol. Guidance was published on 19th August 2020 on gov.uk to inform the industry of the changes to labelling tobacco products after the end of the IP.

11. Guidance

11.1 Guidance was published on 19th August 2020 to support changes made to the 2019 instrument and outlines the areas still relevant for the GB market. The picture warning guidance for GB will be recirculated and guidance on the notification system process for tobacco and e-cigarette products to be placed on the market in GB and NI will be issued later in Autumn. The main audience for this guidance will be businesses involved in the production and supply of tobacco products and e-cigarettes including businesses involved in the NI market.

12. Impact

12.1 There is some impact on business. 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 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 separate picture warning requirements for GB and NI for all tobacco packaging produced from the end of the IP onwards.

12.5 Manufacturers of tobacco products and e-cigarettes will need to submit notification information to the EU Common Entry Gate system for products sold in NI and to a domestic system for products sold in GB. Information requirements for GB and NI will remain very similar on both systems reducing burden on suppliers. This potential cost to business is difficult to estimate: However, the Regulatory Triage Assessment (RTA) estimates that annual costs are estimated at £128,500 for each of the ten years after the end of the IP.

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 the paragraphs above in relation to the notification system and fees.

13.3 The basis for the final decision on what action to take to assist small businesses is the Department's own economic analysis.

14. Monitoring & review

14.1 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

14.2 The majority of the amendments in this SI apply to the Tobacco and Related Products Regulations 2016 which include a review provision. This review provision 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.

15. Contact

15.1 Matthew Birkenshaw at the Department of Health and Social Care can be contacted with any queries regarding this instrument. Email: Healthybehaviours@dhsc.gov.uk

15.2 Mark Davies, Director at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Minister of State for Health Edward Argar 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 2018 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	Sub-paragraphs (3) and (7)	Ministers of the Crown	Set out the 'good reasons' for creating a

offences	of paragraph 28, Schedule 7	exercising clauses 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence.	criminal offence, and the penalty attached.
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 s. 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 1972.	Statement explaining the good reasons for modifying the instrument made under s.2(2) ECA 1972, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under s. 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) ECA1972.	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 Minister of State for Health Edward Argar MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Tobacco and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020 does no more than is appropriate

1.2 This is the case because they do more than implement the Withdrawal Agreement, in particular the Ireland / Northern Ireland Protocol in legislation for tobacco and related products and amend the fees structure as set out in section 7 of the explanatory memorandum.

2. Good reasons

2.1 The Minister of State for Health Edward Argar 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 The provisions in this instrument are necessary in order to ensure the UK meets its obligations under the Withdrawal Agreement, in particular the Ireland / Northern Ireland Protocol and to ensure tobacco control policy functions effectively after the end of the IP. The instrument amends provisions in The Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 in order to do this.

3. Equalities

3.1 The Minister of State for Health Edward Argar MP has made the following statement(s):

"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 Minister of State for Health Edward Argar 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, Minister of State for Health Edward Argar MP 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 section 2 of the main body of this explanatory memorandum.