

EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL

10815/22 C(2022) 4367 final

COMMISSION DELEGATED DIRECTIVE (EU) .../... of 29.6.2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products

Department of Health and Social Care: 25 July 2022

SUBJECT MATTER

Heated tobacco is a tobacco stick that is inserted into a device that heats the tobacco to temperatures less than conventional cigarettes to release an aerosol. In the UK, heated tobacco is regulated as a novel tobacco product and is subject to certain requirements under current tobacco legislation, this includes a ban on advertising and sale to over 18's only. Product standards are contained in the Tobacco and Related Products Regulations (TRPR) 2016, which implemented the EU's Tobacco Products Directive (TPD) (2014/40/EU). However, unlike cigarettes, they currently do not have to have graphic picture warnings and can contain flavours such as menthol.

The European Commission has produced a Commission Delegated Directive amending Directive 2014/40/EU (Tobacco Products Directive) of the European Parliament and of the Council. This Directive will withdraw certain exemptions in respect of heated tobacco products and proposes to regulate these products on a similar footing as cigarettes and hand rolling tobacco.

This has been triggered due to the increase in use of these products across EU member states outlined in a report by the [Commission](#). As defined in the EU's TPD, a 'substantial change of circumstances' is defined as an increase of the sales volumes by product category by at least 10 % in at least five Member States. This proposal would extend the prohibition of tobacco products with a characterising flavour (currently applies to cigarettes and hand rolling tobacco) to heated tobacco. The proposal also includes a requirement for heated tobacco to have a graphic picture warning on packaging along with the written health text warning (at present they only have to include the latter).

The UK government agreed in the Northern Ireland Protocol, that the EU legislation listed in Annex 2, which includes the EU's Tobacco Products Directive, would continue to apply to the UK in respect of Northern Ireland. If the proposed amendment to the TPD is adopted, this would mean that the UK is obliged to implement the amendment in relation to Northern Ireland. The UK government will have to amend TRPR as it applies to heated tobacco placed on the Northern Ireland market. We await the outcome of The Council and the European Parliament on whether the decision will be adopted over the coming months.

It should also be noted that the Government introduced the Northern Ireland Protocol Bill on 13 June 2022, which includes proposals for a dual regulatory regime in Northern Ireland. The government is currently engaging with stakeholders on the operation of the dual regulatory regime and will provide further information in due course, alongside the Bill passage.

SCRUTINY HISTORY

The Government has undertaken post implementation reviews (PIRs) into two pieces of important tobacco control legislation to see if they have achieved their public health objectives. These are:

- [The Tobacco and Related Products Regulations 2016 \(TRPR\)](#)
- [The Standardised Packaging of Tobacco Products Regulations 2015 \(SPoT\)](#)

The Reviews were published in two reports on 25 March 2022. On balance, considering the range of evidence received and reviewed, it is the Department of Health and Social care view that both regulations have met their original objectives, and that these objectives could not be better achieved through alternative regulatory measures.

The response to questions on novel tobacco, such as heated tobacco, in the consultation received a mixed response. However, it was decided that on balance the evidence reviewed provided a strong argument for retention of the regulations in their current form. But we did commit to keep this under review.

When the UK was a Member State, Directive 2014/40 was subject to scrutiny as EU document 18068/12.

MINISTERIAL RESPONSIBILITY

The Secretary of State for the Department of Health and Social Care.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

Northern Ireland Executive tobacco policy leads have been made aware and asked to be kept updated on progress. The UK government would make any legislative changes on behalf of Northern Ireland. Tobacco control policy leads in the Welsh and Scottish governments have been informed about this. However, these changes do not apply to Great Britain (GB) and the devolved administrations for GB have therefore not been consulted more formally in the preparation of this EM.

LEGAL AND PROCEDURAL ISSUES

i. Legal Base

This Delegated Directive responds to the Commission's obligations under Article 7(12) and Article 11(6) of Directive 2014/40/EU to extend the prohibition of the

placing on the market of tobacco products with a characterising flavour or containing flavourings in any of their components or having certain technical features (which already exists for cigarettes and roll-your-own tobacco) to heated tobacco products and to remove the Member States' possibility to grant exemptions for these products from the labelling requirements laid down in Article 9(2) and Article 10 of Directive 2014/40/EU.

ii. Voting Procedure

In Council a Qualified Majority Voting (QMV) is needed for an objection, and in EP an absolute majority is needed for an objection.

iii. Timetable for adoption and implementation

European Parliament (EP) and Council have until the end of October 2022 to raise an objection to the proposed delegated directive. If there are no objections, the Delegated Directive comes into force 20 days after publication. It gives Member States 8 months to transpose the directive into national law, and a further 3 months before the provisions apply.

POLICY IMPLICATIONS

Although there is currently a limited evidence base on the health harms presented by heated tobacco products, it is clear that they do pose harm to users. The Government does not recommend use of these products and encourages users to quit. The Government continues to monitor developing evidence on these products.

The next vaping in England report commissioned by the Department of Health and Social Care will include a chapter on heated tobacco on its use by adults and youth, effectiveness for smoking cessation and health harms. There are no current plans to change the current regulatory framework in Great Britain, but we will keep this under review.

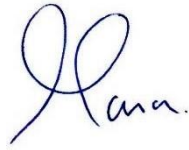
CONSULTATION

There are no plans to consult on these changes beyond the consultation issued by the EU. Heated tobacco products are produced by large tobacco companies, which provide their products to the UK and EU markets. The tobacco industry will be monitoring this Directive proposed change and what it may entail for its markets.

FINANCIAL IMPLICATIONS

Heated tobacco use remains low in England, at around 0.5% of the adult population using them and we do not collect specific data on the Northern Ireland market. There will be costs to manufacturers placing these products on the UK market as they will have to modify their products for the NI market and the proposed changes are unlikely to impact on small and medium size UK business. Northern Ireland businesses selling these products may be affected as well as consumer choice, but

impact is likely to be minimal given their use is so low and there are alternative products on the Northern Ireland market such as vaping.

A handwritten signature in black ink, appearing to read 'Maria'.

**MARIA CAULFIELD MP
MINISTER OF STATE FOR HEALTH**