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EXPLANATORY MEMORANDUM ON EUROPEAN UNION LEGISLATION

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 the sale of tobacco and related products

Submitted by the Department of Health

21 January 2013

SUBJECT MATTER

1. The Commission's proposed revision to Directive 37/2001/EC (The Tobacco Products Directive), while having clear public health objectives, is based on the EU's competence to legislate to improve the internal market in tobacco products.
2. The 2001 Tobacco Products Directive sets down requirements in relation to the products themselves - their manufacture, presentation and sale - to align the laws, regulations and administrative provisions of the Member States. The Directive has remained largely unchanged for a decade and no longer reflects the nature of tobacco products and markets in the EU as well as it once did.
3. The European Commission adopted the proposal following an extensive consultation with stakeholders, including a public consultation which generated 85,000 responses, including one from the UK Government. During the proposal's preparation, a thorough impact assessment has been carried out by the Commission, evaluating economic, social and health effects of several policy options under consideration. Several external studies were commissioned by the Commission to inform its final proposal and impact assessment.

MINISTERIAL RESPONSIBILITY

4. The Secretary of State for Health has lead responsibility.

Interests of the Devolved Administrations

5. Ministers of the Northern Ireland Assembly, the Scottish Government and of the Welsh Government have an interest relating to their responsibilities and have been consulted in preparing this Explanatory Memorandum.

LEGAL AND PROCEDURAL ISSUES

Legal Basis

6. The stated legal base is Article 114 of the Treaty on the Functioning of the European Union ("TFEU").
7. Article 114 provides a basis for harmonising measures which have as their objective the establishment and functioning of the internal market, although the court has confirmed that health protection may be a decisive factor in the choices to be made. We are considering carefully whether each of the proposed measures falls within the established boundaries of Article 114.

Legislative procedure

8. Ordinary legislative procedure

Voting procedure

9. Qualified Majority Voting

Impact on United Kingdom law

10. The proposed Directive would require transposition into UK law by new regulations or amendments to existing regulations. The proposed Directive would replace Directive 2001/37/EC which is implemented in the UK by the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 (as amended in 2007) and the Tobacco for Oral Use (Safety) Regulations 1992.

Application to Gibraltar

11. The proposed directive would not apply to Gibraltar as the legal base is A114 TFEU and the provisions relate primarily to the free movement of goods.

Fundamental rights analysis

12. Elements of the proposed directive such as packaging and registration requirements may be argued to impact upon the rights of manufacturers, importers, distributors and retailers of tobacco products, including freedom of expression (Article 11 of the Charter of Fundamental Rights "the Charter"), freedom to conduct a business (Article 16 of the Charter) and the right to property (Article 17 of the Charter). However, these rights are not absolute and interference may be justified subject to the principle of proportionality, bearing in mind the general principles of EU law, recognised in the Charter, that union policies should ensure a high level of health protection and consumer protection.

APPLICATION TO THE EUROPEAN ECONOMIC AREA

13. The proposal will have relevance under the EEA Agreement.

SUBSIDIARITY

14. The stated legal base is Article 114 of the Treaty on the Functioning of the European Union ("TFEU"). This is an area of shared competence and the subsidiarity principle applies. We are considering carefully whether any elements of the proposal would raise subsidiarity issues.
15. The UK Government recently consulted on the standardised packaging of tobacco products and retains an open mind on this issue. The Government would wish to see a final text which leaves this option open for Member States.

POLICY IMPLICATIONS

16. The UK broadly welcomes the Commission's intention to improve public health and particularly to protect children's health as well as achieve the primary objective of improving the functioning of the internal market.

Legal form of a Directive

17. The proposed legal text takes the form of a Directive and would replace the existing Directive, 2001/37/EC.

Scope of the Directive

18. Extensions of the scope of the Directive to cover non-tobacco nicotine-containing products (e.g. electronic cigarettes) below a certain nicotine threshold and herbal products are proposed and discussed in more detail below.

19. The revision of the Tobacco Products Directive focuses on five policy areas. The Commission's key proposals in each of those areas are outlined below.

i. Smokeless tobacco and extension of product scope

Smokeless tobacco

20. The ban on placing tobacco for oral use (snus) on the market is maintained, as set out in Directive 2001/37/EC, except for Sweden which has an exemption in its Accession Treaty. The harmful effects of oral tobacco have been confirmed by the Commission's Scientific Committee on Emerging and Newly Identified Risks and other studies.

21. The Government welcomes the continued ban of snus and other oral tobacco products in the vast majority of EU Member States, including the UK. The Court of Justice of the European Union ruled in 2004 that the current ban was proportionate.

22. All smokeless tobacco products must carry health warnings on the main surfaces of the package and products with characterising flavours cannot be sold.

Novel tobacco products

23. Novel tobacco products are products containing tobacco which do not fall within any of the established tobacco product categories and which are placed on the market after entry into force of Directive 2001/37/EC. It is foreseen that these products will have to respect requirements of the Directive, including labelling and ingredients to ensure a level playing field for tobacco products. The proposal also foresees a notification obligation for novel tobacco products.

Nicotine-containing products

24. *Non-tobacco nicotine-containing products (NCPs)* currently fall outside the scope of Directive 2001/37/EC. Currently, Member States either regulate these products as medicines, apply provisions that are used for tobacco products or allow them to remain unregulated.

25. The proposal foresees that NCPs that either have a nicotine level exceeding 2mg, a nicotine concentration exceeding 4mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy.

26. The proposal would allow NCPs with nicotine levels below this threshold to be sold as consumer products, provided they feature an adapted health warning, details of which are set out in the proposal.

27. In the UK, to gain a better understanding and inform future policy decisions on NCPs, the Medicines and Healthcare products Regulatory Agency is currently co-ordinating a period of scientific and market research looking, in particular, at the levels of nicotine that have physiological effects. The Government will use the information to consider how public health can be protected and promoted.

28. In addition to looking further at legal issues in relation to NCPs' inclusion in the scope of the Directive, the Government has concerns about the Commission's approach to regulating NCPs as set out in its proposal in terms of gaining the maximum potential public health benefit from NCPs.

Herbal products

29. Herbal products for smoking currently fall outside the scope of Directive 2001/37/EC. Member States regulate these products in different ways.

30. The proposal foresees adapted health warnings for herbal smoking products, to inform consumers about the adverse health effects. No

promotional or misleading elements would be allowed on the packages.

31. The Government wishes to explore further the evidence about herbal products.

ii. Packaging and labelling

32. The proposal foresees that all cigarette and roll-your-own packages must contain a combined picture and text health warning increased in size from current requirements to cover 75% of the front and the back of the package and must carry no promotional deceptive or misleading elements. Pictorial warnings are optional rather than mandatory under the current Directive but the UK Government has legislated to make them a legal requirement here. The proposal exempts tobacco products other than cigarettes and roll-your-own from the larger health warnings.

33. Health warnings on smokeless tobacco products will have to be put on both sides of the package but their size will remain unchanged.

34. The current information on tar, nicotine and carbon monoxide, which is perceived as misleading and could be used as a relative risk tool by consumers, is replaced by an information message on the side of the pack that tobacco smoke contains more than 70 substances causing cancer.

35. Display of cessation information is added to the packages.

36. The proposal foresees that all unit packages of cigarettes shall have a cuboid shape and all unit packages of roll-your-own should take the form of a pouch. Only flip-top lids would be permitted for cigarette packs.

37. A unit pack of cigarettes would include a minimum of 20 cigarettes and a unit pack of roll-your-own would weigh at least 40g under the proposal.

38. The proposal is based on new evidence made available to the Commission showing that bigger and pictorial warnings are more effective. It also seeks to ensure that the appearance of the package

reflects the characteristics of the product within – one that has negative health consequences, is addictive and is not for sale to children.

39. The Government broadly welcomes the Commission's intention to reduce the appeal of tobacco products to children, but would need to carry out its own analysis to ascertain whether the proposal's suggested amendments to packaging and labelling requirements would have a beneficial impact in the UK, as well as consider further the Commission's proposed use of delegated acts in this area.
40. The UK Government recently consulted on the standardised packaging of tobacco products and retains an open mind on this issue.
41. The Government would wish to see a final text which leaves this option open for Member States.

iii. Ingredients and additives

42. The maximum yields of tar, nicotine and carbon monoxide as well as the measurement methods remain the same as in Directive 2001/37/EEC.
43. The proposal keeps in place the mandatory reporting system of ingredients but foresees a common electronic format for the reporting and manufacturers are required to provide supporting data (e.g. market research reports and sales data).
44. The proposal foresees that placing on the market of new or modified tobacco products must not take place before the submission of ingredients data.
45. The proposal foresees that tobacco products with characterising flavours, such as fruit flavours or chocolate are prohibited. Additives associated with energy and vitality or creating the impression that products have health benefits are prohibited. Tobacco products with increased toxicity or addictiveness shall not be placed on the market.
46. The proposal exempts products other than cigarettes, roll-you-own tobacco and smokeless tobacco products from some provisions such as the provision of products with characterising flavours.
47. The proposals on ingredients and emissions focus on products particularly attractive to young people which, the Commission argues, should help to reduce smoking initiation among young people.

48. The Government broadly welcomes the Commission's intention to reduce the appeal of tobacco products to children, but would need to carry out its own analysis to ascertain whether the proposal's suggested amendments to ingredients and additives requirements are proportionate and would have a beneficial impact in the UK.

iv. Cross-border distance sales

49. Cross-border distance sales of tobacco products fall outside the scope of Directive 2001/37/EC. The proposal includes a notification obligation for retailers of tobacco products intending to engage in cross-border distance sales. The proposal allows Member States to require the retailer to appoint a person to ensure compliance with the Directive.

50. Mandatory age verification is also foreseen.

51. The proposal is intended to address underage purchasing of tobacco products.

v. Traceability and security features

52. Directive 2001/37/EC grants a power to the Commission to adopt technical measures related to traceability and identification of tobacco products but this power has not been used. The proposal foresees a EU tracking and tracing system at packet level for tobacco products throughout the supply chain (excluding retail).

53. Visible security features shall be put on all tobacco products placed on the EU market in order to facilitate the identification of authentic products.

54. The proposal foresees that technical standards to ensure compatibility between the tracking and tracing systems used as well as for the contacts with third parties shall be adopted by delegated acts. Technical standards for security features shall also be adopted by the use of delegated acts.

55. The UK Government is surprised to see the WHO Framework Convention on Tobacco Control illicit trade protocol tracking and tracing requirements set out in the proposal, together with detailed requirements which may possibly go beyond those agreed in the protocol.

IMPACT ASSESSMENT

56. A broad description of the likely costs and benefits is set out. A more detailed analysis will follow in the form of the standard checklist for analysis on EU proposals.
57. The proposal's impacts will be wide ranging, affecting the manufacturers and retailers of tobacco products, as well as the UK Government, society and the wider economy. The impact on each affected area is outlined below:

Internal Market

58. The intention is to improve the functioning of the internal market by removing current disparities. This should help UK tobacco manufacturers in the long run insofar as harmonized regulations simplify cross border trade.

Factory Made Cigarette (FMC) and Roll Your Own Tobacco (RYO) manufacturers

59. The impacts on FMC and RYO manufacturers consists of the direct impact from complying with the revised directive and indirect impacts following an expected decrease in consumption.
60. The direct impacts include the cost of re-labelling and re-packaging, and familiarisation with changes to the directive. Whilst these may rise in the short term as, for example, machinery, packaging and printing are changed to comply with the directive, in the long run they may fall as regulations become more consistent across countries.
61. The indirect impact of the proposal is likely to lead to a loss of revenue for FMC and RYO manufacturers as stricter tobacco control leads to falls in smoking prevalence.

The Packaging and Labelling Industry

62. Initially companies that make packaging, or provide printing services to tobacco manufacturers should benefit as cigarette pack design is changed to comply with the new directive. However, in the long run there is likely to be an adverse impact as smoking prevalence falls and the demand for their services diminishes.

Wholesalers

63. Complying with tracking and tracing systems regulations should raise cost for wholesalers, and the indirect effect lowering smoking prevalence is likely to reduce revenues. This needs to be counterbalanced, however, with the increased revenues stemming from reduced illicit trade.

SMEs

64. The Directive is mainly targeted at FMC, RYO and smoke-free tobacco products. Pipe tobacco and cigars which are often manufactured by SMEs are not affected, in the first stage, in most policy areas. Retailers will also be largely unaffected except for the indirect impact of lower demand for cigarettes.

Employment

65. In terms of employment, it is estimated that jobs lost in tobacco will be off-set by jobs gained in other sectors, as money not spent on tobacco is spent on other goods and services. This will be a gradual process as any decrease in tobacco consumption is expected to happen slowly.

Government and Wider Society

66. The main impact on the Government, and society more generally, will be through health improvements from lower smoking prevalence. This includes reduced NHS expenditure on smoking-related diseases, but also wider societal impacts such as better general health and lower absenteeism. The benefit would need to offset, however, by likely falls in duty revenue.

FINANCIAL IMPLICATIONS

67. The proposals may result in a number of additional administrative costs for national authorities. For example, a limited additional burden may be expected when assessing nicotine containing products under the medicinal products framework, although these costs need to be weighed against the fees payable by those seeking to license their products as medicines.

68. Additional resources may also need to be found to fund cessation services if there is greater take up because of the contact information now provided on packs.

69. Some additional resources may also need to be allocated to monitoring the ingredients of tobacco products

70. If the Directive reduces smoking prevalence in the UK, the Exchequer may see revenues fall due to lower duty receipts.

IMPLEMENTING / DELEGATED ACTS

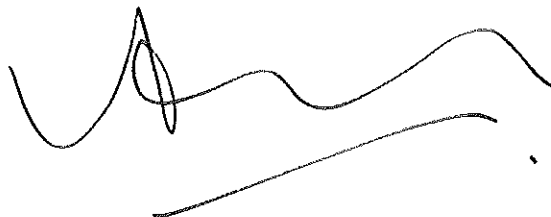
71. The proposal contains a number of powers for the Commission to adopt delegated and implementing acts under A290 and A291 TFEU, including, for example, powers to define the key elements of contracts with third parties to define data formats, and to withdraw exemptions for certain products. We are considering carefully whether each of the powers proposed overstretch the boundaries of A290 or A291 or could result in implementation problems for the UK.

CONSULTATION

72. Extensive consultation was conducted by the Commission before the proposal was adopted. There are no specific plans for a formal UK consultation.

TIMETABLE

74. Detailed negotiations will start on 21 January 2013 under the Irish Presidency which is keen to reach a Common Position on the revised Directive by the end of its Presidency. The European Parliament will consider the text in parallel to the Council. It is expected that the revised Directive will be adopted in 2014 and come into effect in 2015/2016.



ANNA SOUBRY
PARLIAMENTARY UNDER SECRETARY OF STATE FOR PUBLIC
HEALTH
DEPARTMENT OF HEALTH

