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24 April 2013

Dear Anna,

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 related products (Document 18068/12)

Thank you for your Explanatory Memorandum (EM) of 21 January 2013 on the above proposal, and for appearing before the Home Affairs, Health and Education Sub-Committee of the Select Committee on the European Union on 13 March 2013 to give oral evidence. This letter summarises the Committee's deliberations on the Commission's proposal and also sets out its position on its merits. It also requests the Government's response on a number of points.

The Sub-Committee decided that this proposal was of sufficient significance to justify a process of 'enhanced scrutiny' and it has endeavoured to conduct its scrutiny of this proposal in a fully transparent manner. We received a considerable amount of written evidence and we are grateful to all those who agreed to make their submissions publicly available on the parliament website.[1] Before your oral evidence session on 13 March, we also took oral evidence from the Tobacco Manufacturers' Association (TMA) and Cancer Research UK (CRUK) on 6 March.

On balance, we support the aim of the proposed revisions to the Tobacco Products Directive, particularly its focus on the protection of young people. However, we would like to make the following points about specific provisions:

Subsidiarity

The TMA, Imperial Tobacco and Japan Tobacco International (JTI) considered that Article 168 of the EU Treaty expressly prohibits the EU adopting harmonising measures in the public health area regarding tobacco and that the proposal therefore constitutes a failure to respect the principle of subsidiarity.[2] On the other hand, CRUK and the Government

[1] See the Annex to this letter for a list of those who submitted evidence. The submissions are available here: http://www.parliament.uk/business/committees/committees-a-z/lords-select/eu-home-affairs-sub-committee-f-/scrutiny-work1/parliament-2010/tobacco-enhanced-scrutiny/

[2] Q 7 (Jaine Chisholm Caunt)

pointed to the internal market legal base of the Commission's proposal, Article 114 of the Treaty on the Functioning of the European Union (TFEU), and considered that this gave the EU competence to act because internal market legislation is a shared competence.[3] We noted that the Court of Justice of the European Union upheld the use of an internal market legal basis and its compliance with the principle of subsidiarity with respect to Directive 2001/37 (which this proposal would replace) following a challenge brought by British American Tobacco and other tobacco manufacturers regarding its validity (Case C-491/01). We also note that a number of national parliaments issued Reasoned Opinions, before the deadline of 4 March 2013, expressing subsidiarity concerns about the present proposal but that the requisite threshold was not reached to require the Commission to undertake a review of the proposal. We further note that many of the Reasoned Opinions focussed on the proposal's provisions for the Commission itself to be empowered to adopt delegated and implementing acts, which, in our view, is more a matter of proportionality than of subsidiarity. **We reached the view that the proposal has a sound legal basis and does not fail to respect the principle of subsidiarity. We therefore chose not to recommend to issue a Reasoned Opinion.**

Delegated and implementing legislation *(Article 22 of the proposal)*
The proposal would allow the Commission to adopt delegated and implementing acts under Articles 290 and 291 TFEU, and give the Commission greater competence over areas which would previously have been regulated at national level, such as withdrawing exemptions for certain products, changing the format and content of health warnings, and other issues. Your EM states that the Government a considering carefully whether each of the delegated and implementing powers is proportionate; and also whether they could result in implementation problems. We welcome this cautious approach to such delegated powers. We would be grateful if you could let us know whether you are now satisfied that the proposed use of delegated and implementing acts is proportionate or whether you intend to press for changes in the negotiations, which would give the Member States greater control over any further delegation of powers and could also allow Member States more flexibility to implement the proposal in ways which best suit national circumstances. **We note the concerns expressed by a number of other national parliaments across the EU regarding the Commission's proposed use of delegated and implementing legislation within the proposal and consider that these raise important considerations which merit further scrutiny. We would like to know the Government's view on this aspect of the Commission's proposal.**

Consistency with international law *(Paragraphs 7, 26 and 45 of the recital to the proposal)*
The TMA, Imperial Tobacco and JTI argued that the health warning requirements in the current Tobacco Products Directive are sufficient to ensure compliance with the requisite provisions of the World Health Organisation's Framework Convention on Tobacco Control (FCTC).[4] They considered that the proposal's strengthening of these requirements went too far and that by doing so it infringes a number of fundamental legal rights to property, expression and trade, which are protected under international law, such as the World Trade Organisation's Agreement on Technical Barriers to Trade and the European Convention on Human Rights, among others.[5] However, the Government and CRUK considered that the

[3] Q 27 (Anna Soubry MP)
[4] The FCTC entered into force in 2005 and has been ratified by all Member States. The FCTC contains provisions on the use of pictorial and textual warnings about the health risks associated with smoking tobacco.
[5] TMA and JTI also cited the EU Treaties, the EU Charter of Fundamental Rights, the Paris Convention for the Protection of Intellectual Property, and bilateral investment treaties between certain Member States and third countries.

proposal would assist Member States in complying with their obligations in this respect under the FCTC.[6] **We would be grateful for clarification of the Government's position on the proposal's compatibility with the international treaty obligations of Member States and of the EU.**

Non-tobacco nicotine containing products (NCPs), including e-cigarettes *(Article 18 of the proposal)*

CRUK submitted evidence stating that tobacco companies are increasingly taking ownership of the e-cigarette market through mergers and acquisitions of smokeless tobacco companies.[7] Given that the Government[8] and Action on Smoking and Health (ASH) described how e-cigarettes were now, in their view, being marketed with bubble-gum flavours, which may make them attractive to young people and could act as a "gateway" to smoking real tobacco products, we agree with the Commission's proposal that some regulation of NCPs across the EU is necessary in order to protect public health.

CRUK and ASH argued that the proposal to include a warning on NCPs that "this product contains nicotine and can damage your health" could also add to the existing confusion between the risks associated with the tar in tobacco and nicotine.[9] In addition, ASH told us that it could also potentially dissuade smokers wishing to quit from using products which could help them to do so.[10]

CRUK stated that the Commission's desire to apply different regulatory regimes to NCPs based upon their nicotine content does not appear to be based on sound evidence.[11] Together with the British Heart Foundation and ASH, they argued that all NCPs should be regulated as medicinal products, bringing them into line with other nicotine-replacement therapies. However, Dr David Upton and Clive Bates, former Director of ASH, considered that placing NCPs under medicinal products regulations would stifle their production as the certification process is both resource and time intensive.[12] E-lites argued that there should be a framework of regulations to accommodate tobacco products, pharmaceutical nicotine-replacement therapies and "consumer products" such as e-cigarettes.[13]

We understand that the Medicines and Healthcare products Regulatory Authority and the National Institute of Clinical Excellence will publish the findings of their research into the physiological effects of nicotine and the safety of NCPs *vis a vis* tobacco products later this year. We encourage the Government to use this information in the negotiations on the draft Directive in order to develop a more scientifically robust proposal to regulate NCPs in the EU. **We believe that some regulation of NCPs is necessary but recommend that consideration should be given to doing so outside the scope of this draft Directive. The regulation of NCPs should be based on the results of scientific research into the physiological effects of nicotine while also considering the possible health benefits of the alternative that NCPs offer to smokers.**

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[6] Q 25 (Anna Soubry MP) and Q 8 (Dr Jean King)
[7] CRUK
[8] Q 31 (Anna Soubry MP)
[9] Q 15 (Dr Jean King), ASH
[10] ASH
[11] QQ 15-17 (Dr Jean King). NCPs would be regulated as medicinal products or as consumer products (featuring a health warning) depending on their levels of nicotine.
[12] Dr David Upton, Clive Bates
[13] E-lites said the Industry Standard of Excellence (ISE) developed by the UK Electronic Cigarette Industry Trade Association (ECITA) and existing consumer protection legislation provides the necessary regulatory framework in the UK.

Labelling and packaging *(Articles 7-13 of the proposal)*
The Commission's proposal would allow Member States to introduce full standardisation of tobacco packaging and labelling as long as it is compatible with the EU Treaties. We note that the Government's EM and your oral evidence[14] suggested that the Government is still reconciling the Commission's proposal with its own domestic plans for packaging and labelling, with respect to the results of the 2012 consultation on standardised packaging of tobacco products.

The TMA, JTI, and Imperial Tobacco argued that, if the Commission's proposal is implemented in its current form, tobacco companies would be left with insufficient space on their packaging to display, among other things, their logos and colour schemes, and that this would constitute a breach of their intellectual property rights. They also said that the banning of slim cigarettes and flavourings such as menthol in tobacco would inhibit creativity and innovation in the tobacco industry, as well as creating an illegal market to satisfy the demand for these products. Companies in the design and packaging sector also warned that tighter regulation on packaging and labelling would have a negative economic impact on their industry.[15] In contrast, CRUK, the British Heart Foundation and ASH welcomed the Commission's plans in this area. They considered that other countries' experiences suggested that increasing the size of health warnings on cigarette packaging will help to deter people from smoking, as well as making it more difficult for companies to market products such as slim cigarettes in a way that might make them more attractive to young people in particular.[16]

We agree with the Commission's proposal that information on tar, carbon monoxide and nicotine levels in cigarettes should be removed from tobacco packaging, and we note the Government's acceptance of this view.[17]

We received evidence primarily concerning the Commission's proposals, but the arguments made also applied to any form of standardised packaging. We would therefore be grateful to receive notification of the Government's final position on the Commission's proposal to regulate the packaging and labelling of tobacco products. **We would not wish to express a view on the merits of the Commission's proposal to prohibit certain tobacco products and to regulate the packaging and labelling of the majority of tobacco products without knowing the Government's own intentions in this area. We look forward to receiving further details about this in due course.**

Illicit trade in tobacco *(Article 14, 16, and 20 of the proposal)*
The Government, Imperial Tobacco and the TMA questioned the Commission's use of this proposal as a means of implementing the FCTC protocol on illicit trade.[18] They suggested that the issue of illicit tobacco could be best tackled through other means, for example, customs legislation. In particular, Imperial Tobacco stated that the requirements for tracking and tracing tobacco products are already covered under agreements between the EU Anti-

[14] QQ 28-30
[15] European Carton Makers Association (ECMA)
[16] CRUK, ASH, British Heart Foundation
[17] Q 34 (Andrew Black)
[18] The Protocol to Eliminate Illicit Trade in Tobacco Products, adopted by the Parties to the WHO FCTC in November 2012 in Seoul, was opened for signature in a ceremony at WHO Headquarters on 10 January 2013. Andrew Black, Department of Health, questioned whether the FCTC tracking and tracing requirements are best introduced in this proposal, and that the customs regime at the EU level might be a more appropriate means of achieving this.

Fraud Office (OLAF) and each of the tobacco companies, and argued that the Commission does not have the competence to legislate on this issue.[19]

Many witnesses felt that the illicit trade of tobacco products was inextricably linked to the regulation of tobacco packaging and labelling. The European Carton Makers Association (ECMA), the TMA and Peter Sheridan and Roy Ramm, former UK law enforcement officers, stated that intricate and constantly evolving tobacco packaging is the first line of defence against counterfeit tobacco, and that regulating it would create a "counterfeiters charter" as packaging and labelling with fewer divergent details would be easier for counterfeiters to copy.[20] However, we note the recent report by the All Party Parliamentary Group on Smoking and Health on the trade in illicit tobacco stated that law enforcement agencies do not rely on packaging appearance to test whether products are illicit. Instead they use a number of security features found on existing packaging, including coded numbers and covert anti-counterfeit marks, all of which would remain in place if the Commission's proposal is implemented.[21] ASH and the Government also told us that counterfeit tobacco is not necessarily attractive because the packaging is accurately copied but rather because it is cheaper to purchase than legitimately produced tobacco.[22]

We were unable to get a clear idea of the scale of the illicit tobacco trade in the UK. CRUK told us that illicit tobacco constituted 9 per cent of sales in the UK, while the TMA cited a figure of 21 per cent.[23] We would be grateful for clarification from the Government on this issue, including any robust statistics that may be available.

We believe that the trade in illicit tobacco is a major manifestation of internationally organised crime and that the Member States, alongside the EU, have an important role to play in tackling it. We note that the Commission is expected to publish an EU strategy to fight the illicit trade in cigarettes before the end of this year.[24] We are concerned that there may be insignificant cooperation at the EU level to tackle this problem effectively. We would like to know in detail how the UK currently cooperates with EU agencies such as Europol, Eurojust and OLAF in this area and what your assessment is of these agencies' effectiveness in this regard.[25] **We would be grateful for further information from the Government about the present scale of the illicit tobacco trade in the United Kingdom and their view on whether the Commission's proposal would contribute to the fight against this trade. We would therefore like to hear from you how effective the Government believes existing EU and United Kingdom efforts to be in this area.**

We look forward to receiving your response to the above points within the standard 10 days, at which point we may wish to comment further. We also look forward to receiving updates about the progress of the negotiations on the Commission's proposal in due course.

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[19] Imperial Tobacco

[20] Q 14 (Jaine Chisholm Caunt); Peter Sheridan and Roy Ramm; ECMA

[21] All Party Parliamentary Group on Smoking and Health (2013) *Inquiry into the illicit trade in tobacco products*, available at http://www.ash.org.uk/APPGillicit2013

[22] ASH, Q 37 (Anna Soubry MP)

[23] Q 20

[24] 2013 Commission Work Programme

[25] We express concerns about the possible lack of cooperation between these agencies regarding cigarette smuggling in our report on *The Fight Against Fraud on the EU's Finances* (12th Report of Session 2012-13, HL Paper 158), paragraph 93

I am copying this letter to William Cash MP, Chair of the House of Commons European Scrutiny Committee; Sarah Davies, Clerk to the Commons Committee; Les Saunders, Cabinet Office; and Arthur White, Departmental Scrutiny Co-ordinator.

Lord Boswell
Chairman of the European Union Committee

ANNEX

List of stakeholders who made submissions to the Committee regarding the proposed Tobacco Products Directive and which have been taken into account in the Committee's letter:

- Action on Smoking & Health (ASH)
- British Heart Foundation
- Cancer Research UK (CRUK)
- E-Lites
- European Carton Makers Association (ECMA)
- Imperial Tobacco
- Japan Tobacco International (JTI)
- David Melding AM, chair of the Constitutional and Legislative Affairs Committee, National Assembly for Wales
- Peter Sheridan OBE and Roy Ramm
- Smokefree ACTION
- Tobacco Manufacturers' Association (TMA)
- Dr David Upton
- Clive Bates, former Director, ASH