From Anna Soubry MP
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Dear Lord Boswell,

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THE EUROPEAN COMMISSION'S PROPOSAL FOR A REVISED DIRECTIVE ON TOBACCO PRODUCTS

I am writing about the proposed European Tobacco Products Directive, following the evidence I gave before the House of Lords EU Sub-Committee F on 13 March 2013 and your subsequent letter of 24 April 2013. I am now in a position to provide more detailed answers to the questions that the Committee has asked.

Protecting tobacco control from vested interests

The Committee was keen to know more about how the Government is implementing its treaty obligations as a Party to the World Health Organization's Framework Convention on Tobacco Control (FCTC), particularly with respect to Article 5.3 of the treaty. This Article of the FCTC requires Parties to protect public health policies with respect to tobacco control from the commercial and other vested interests of the tobacco industry in accordance with national law.

To assist Parties to the FCTC to meet their Article 5.3 obligations, non-binding guidelines have been developed and agreed through consensus of Parties. The guidelines draw on the best available evidence and the practical experience of the Parties in addressing the strategies used by the tobacco industry to interfere public health policies with respect to tobacco control. More information on FCTC guidelines can be found at Annex A.

The guidelines recommend that Parties limit interactions with tobacco companies to those strictly necessary to enable effective regulation of the tobacco industry and tobacco products and to ensure that any such interactions that are necessary are conducted transparently.

The tobacco industry is welcome to provide its views in writing to the Department at any time and we welcome all responses to public consultations on tobacco control. However, the Department of Health limits its face-to-face interactions with tobacco manufacturers, and very few meetings are held. Any discussions with tobacco companies are generally limited to practical matters such as discussions about the implementation of legislation.

Recently, Departmental officials met with each of the major tobacco companies operating in the United Kingdom to gain more information about the potential costs to business of standardised packaging of tobacco products, so we could elaborate any further impact assessments necessary if this policy was to be taken forward. These meetings were needed as tobacco companies were reluctant to provide information that they regard as commercially sensitive through the written consultation process. Minutes of these meetings were taken (which do not contain any commercially sensitive information), and copies can be provided if you would like to see them.

Contact by other parts of government with tobacco companies is necessary and is not precluded by the FCTC. For example, HMRC meets with tobacco manufacturers to share information on the illicit tobacco trade to facilitate enforcement activity.

The Government's tobacco control strategy *Healthy Lives, Healthy People: A Tobacco Control Plan for England* (published in March 2011) includes a chapter on protecting tobacco control from vested interests. The Plan includes a commitment to ask all organisations engaging with the Department on tobacco control to declare any links with, or funding received from, the tobacco industry.

In addition, the Department encourages local authorities to follow the Government's lead and also take the action necessary to protect their tobacco control strategies from the vested interests of the tobacco industry.

The Department of Health is actively considering what more can be done to fulfil its treaty obligations, to ensure the utmost transparency in all dealings with the tobacco industry. My officials already receive many

Freedom of Information (FOI) requests relating to tobacco control and, when appropriate, the responses are published on the Department's website.

Subsidiarity

The Committee was interested in whether the Government had any concerns about subsidiarity with respect to the Commission's proposal.

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I share the Committee's conclusion that the proposed Directive respects the principle of subsidiarity bearing in mind the objectives of this proposal, and share its analysis of the Reasoned Opinions issued by other national parliaments. In addition, with reference to the principle of subsidiarity, I aim to negotiate a final text which would allow Member States adequate freedom to maintain or take forward certain domestic public health policies, aiming for a higher level of health protection, where the evidence supports this and it is justified in accordance with the Treaty on the Functioning of the European Union.

For example, the proposal for a revised EU directive sets out some rules on packaging of tobacco but does not require fully standardised packaging. The UK has run a consultation in relation to the introduction of standardised packaging for tobacco products in the UK. A decision is yet to be reached on this and as such, the Government seeks to preserve the option of taking domestic action to improve tobacco control in the future. In another example, while picture warnings are currently required on all smoked tobacco in the UK, the proposed Directive envisages an exemption for certain types of tobacco (such as cigars on which we require picture warnings). I will therefore, be seeking amendments to the proposed Directive to address this.

International trade law and other international agreements

I consider that the compatibility of this proposal for a directive with fundamental rights, international trade law and other international agreements, must be approached in the context of the proposal's legitimate objectives and effects. The requirements in this proposal would reduce some of the space available for the display of trade marks and restrict the opportunities for manufacturers to use certain features, words and pack designs.

Tobacco manufacturers understandably seek to protect such opportunities and direct the Committee's attention to international law relating to intellectual property. However, the manufacturers' submissions overlook the legitimate objective of the proposal which is to improve the functioning of the internal market and thereby achieve a high level of health protection. The obligations set out in the international agreements identified by the Committee are qualified in respect of measures that protect human health. For example, the Committee notes the World Trade Organisation ("WTO") Agreement on Technical Barriers to Trade. Article 2.2 of that instrument provides, among other things, that technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective and that the protection of human health is such a legitimate objective.

The Committee also refers to the European Convention on Human Rights ("ECHR") to which the UK is a party and to which the EU is expected to accede. Article 1 of Protocol 1 to the ECHR which concerns property, entitles States to enforce such laws as it deems necessary to control the use of property in accordance with the general interest, which includes the protection of public health. Analogous observations can be made in relation to the other treaties identified by the Committee, in addition to other arguments specific to each instrument. The Committee has already noted Case 491/01 in which the Court considered the compatibility of the current Tobacco Products Directive 2001/37 ("the 2001 Directive") with international law among other things.

The proposed Directive would assist the UK to meet some of its obligations under the World Health Organization's Framework Convention on Tobacco Control ("FCTC"). The European Union is also a Party to the FCTC.

The FCTC provisions concerning reporting, packaging, labelling and advertising are particularly relevant to this proposal. Contrary to the tobacco manufacturers' submissions, the health warning requirements required under the 2001 Directive are not sufficient to ensure compliance with the FCTC. For example the FCTC and its Guidelines indicate larger warning labels than required under the 2001 Directive and recommend the removal of TNCO[1] data which are required under the 2001 Directive. Certain elements of the FCTC are beyond the scope of the Commission's proposal, for example the regulation of tobacco vending machines. Conversely, elements of the proposal go further than the FCTC in respect
of illicit trade in tobacco products. Late last year, the text for a Protocol to eliminate illicit trade in tobacco products ("the FCTC Protocol") was agreed and is now open for signature. The proposals on tracking and tracing, and cross border sales in the proposed Directive look to go further than FCTC Protocol requirements.

Tracking and Tracing

The Committee asked whether it was the Government's opinion that one common EU approach to tracking and tracing tobacco products was better than 27 different Member State approaches.

The proposed Directive prescribes an EU system for tracking and tracing tobacco products, which goes further than the simpler approach set out in the FCTC Protocol. The Government recognises that there may be some advantages to an EU wide system but we must consider all the risks and costs of such an approach

[1] Tar, Nicotine and Carbon Monoxide

to ensure that we introduce arrangements that are effective and proportionate to the compliance burdens and economic impacts on business. If there is a strong case for an EU-wide tracking and tracing system, we will argue that such provisions are best introduced through the EU customs regime, where illicit tobacco has been addressed until now. This is an issue we are exploring with other Member States and the Commission during Council negotiations.

Delegated and implementing powers

The Committee noted that the proposal envisages a large number of implementing and delegated powers and seeks the Government's view on this aspect of the proposal.

I have scrutinised the use of implementing and delegated powers throughout this proposal on a case-by-case basis as well as horizontally.
In all cases, I will seek in negotiations to ensure that these powers are appropriately defined and effectively constrained. For example, while I accept that it may be useful to adapt the maximum tar, nicotine and carbon monoxide (TNCO) yields taking into account scientific development in the future, I consider that the delegated power at 3(2) ought to be further circumscribed to permit revision only in a downwards direction. Similarly, as details such as the font and format of the text and contents of the picture library are matters which are already harmonised, I consider that the delegated powers at 8(4)(b), 9(3)(b) and (c) could be redrafted as implementing powers consistent with the technical nature of this matter and advantages of such procedures.

In some cases, I believe the delegations to be justified, for example: the exercise of the implementing powers in article 5(3) that will enhance information sharing. I agree that the exemptions for certain types of tobacco product should be withdrawn if those products become more popular, particularly with young people, and support the aim of the delegated powers to enable a swift flexible response to such circumstances. The power at 9(3)(a) to update health warning messages is consistent with evidence that such messages must be regularly updated to ensure their continued effectiveness over time. As to the particular concern raised by the Committee regarding Member State discretion to regulate health warnings, I would observe that the format and content of health warning labels was previously regulated under the 2001 Directive which also provided for a comitology procedure to adapt the text.

Where the delegation is not clearly proportionate we will push for these powers to be removed. For example, the Government's preference is for the proposals for a tracking and tracing system to be removed from this Directive and taken up elsewhere. However, if they remain, I consider that the detailed terms and conditions of contracts between manufacturers and IT suppliers is a matter which might be left to the discretion of the Member State. Within the wider discussions on tracking and tracing, I will explore with the Commission whether the delegated power at Article 14(9)(a) is necessary.

Articles 21 and 22 of the proposal provide for controls on the exercise of those powers, although I am exploring with the Commission whether there is an adequate justification for the indeterminate duration proposed at Article 22(2).

Commissioner Borg's comments on how cigarette packaging should look

During my evidence session, I mentioned that I had recently met Commissioner Borg at an informal Health Council meeting in Dublin and that he had made some comments regarding the packaging of tobacco products and the need for it to reflect the product itself. I undertook to give you an account of his remarks. Unfortunately, I am unable to provide further details on this specific discussion since these informal meetings are not minuted. I can, however, provide some account of Commissioner Borg's opinion on this matter from his speech when the proposed
Directive was published. In particular, I would draw your attention to the following part of the Commissioner's speech:

> *"Again I want to be very clear: a tobacco product should look like a tobacco product and not like a cosmetic or candy. My aim here is that people can take an informed decision when they look at a pack of cigarettes by getting the clear message that the product they buy harms their health."*

The full speech can be found on the Commission's website at:
http://europa.eu/rapid/press-release_SPEECH-12-968_en.htm

The potential impact on the illicit tobacco market
The Directive includes various measures which could impact positively on reducing the illicit trade in tobacco products, such as tracking and tracing and product authentication. Others could impact adversely on the illicit trade, such as requiring Member States to prohibit the placing on the EU market of certain types of tobacco products that would be available outside the EU.

It is worth reflecting that over the past decade, the UK Government, led by HMRC, has had great success in tackling illicit tobacco in the UK. The illicit trade is constantly changing as criminal gangs attempt to circumvent controls and avoid detection. In response, HMRC's anti fraud strategy has been continually refreshed to stay on top of new threats as they emerge. Since the first anti-fraud strategy was introduced in 2000 there has been a steady decline in the size of the illicit market. Latest HMRC estimates indicate the illicit cigarette market has more than halved - dropping from 21% to 9% in 2010/11. The hand-rolling tobacco illicit market has also reduced significantly, down from 61% to 38% over the same period.

Furthermore, the Government is not complacent and tackling illicit tobacco remains a priority. In 2011, HMRC published a renewed strategy to tackle the illicit tobacco trade titled *Tackling Tobacco Smuggling: Building on our success.* The strategy has been strengthened with around £25 million of re-investment funding to tackle tax fraud and avoidance.

The composition of the illicit market has also changed over the last few years and it is currently made up of three main product types: cheap white brands, counterfeit, and genuine products. The proposals may affect the risks associated with each of these product types differently, and may lead to the displacement of risk into other areas. The factors impacting on the illicit tobacco market are many and complex and we have drawn no firm conclusion at this time on how this proposed Directive will affect them.

The Government is not aware of any evidence that would enable the quantification of any potential adverse impact of the proposals on tobacco packaging or flavourings on the illicit market. The Commission's impact assessment does not include a revenue assessment and I will be engaging with the Commission on this point. This issue needs to be regarded in the wider context and I believe that, overall, the proposal in its entirety will help to further protect the public, especially young people, from the harms from tobacco.

Estimates of the impact of the proposal on the UK

You asked if the Department of Health had carried out any of its own work to estimate the potential impacts of the Commission's proposal on the UK, as described in our Explanatory Memorandum in January. The Department's Checklist for Analysis is almost complete and we will send it to the Committee once it is finalised.

Cooperation with Europol, Eurojust and OLAF

You asked for details of how the UK cooperates with Europol, Eurojust, and OLAF and for an assessment of effectiveness in this area.

HMRC has a network of overseas Fiscal Crime Liaison Officers (FCLOs) who work with law enforcement agencies and international organisations to tackle the illicit trade. In 2011, with additional investment from the Government's Spending Review, the FCLO network was expanded and coverage now extends to over 60 countries. While FCLOs primarily work on a bi-lateral basis their activity is complemented by various EU initiatives. HMRC has a permanently seconded an officer to Europol to exploit and engage with pan-European intelligence and analysis on tobacco fraud, and support projects driven by Europol.

In addition, HMRC fully engages with Eurojust on cases with a UK nexus and works closely with OLAF, collaborating at a strategic level by sharing information and analysing risks. On an operational level, HMRC has initiated and delivered joint operations with other Member States, funded by OLAF. All of this work is effective in sharing best practice, enhancing relationships with key overseas agencies and developing a common understanding of the tobacco smuggling threat which is vital given the international nature of the fraud.

UK consultation on standardised packaging of tobacco products

The Committee also requested information on the Government's decision on standardised packaging of tobacco products. You will have noted that there was no mention of standardised packaging in the Queen's speech on 8 May. The Government has not made a decision on this issue. We are closely watching what is happening around the world. We are going to take the time we need to consider fully all the points raised in consultation responses, all the evidence available and the relevant information.

I also note, as you will appreciate, the omission from the Queen's speech does not preclude Government from bringing the legislation forward in the future.

Nicotine-containing products and harm reduction

You expressed an interest in the scientific and market research coordinated by MHRA on nicotine containing products including e-cigarettes. I will write to you again once the MHRA is in a position to publish that research.

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Andrew Black, the Department's Tobacco Programme Manager who gave evidence with me on 13 March, mentioned in his evidence that there is public health guidance currently under development by the National Institute for Health and Clinical Excellence (NICE) on harm reduction in nicotine addiction. I understand that this guidance will be published in June 2013 and we will send this to the Committee in due course.

Other information

You brought two letters to my attention, which you had received from members of the public on the proposed Directive. My officials have written to these individuals and have provided copies to the Committee Clerk for the attention of members of the Committee.

Please contact me if there is any further information you would like.

Yours ever

ANNA SOUBRY

Annex A

The Framework Convention on Tobacco Control says:

> *In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.*

Furthermore, the non-binding Guidelines for implementation recommend that:

> "Parties should interact with the tobacco industry only when and to the extent strictly necessary to enable them to effectively regulate the tobacco industry and tobacco products.
>
> "Where interactions with the tobacco industry are necessary, Parties should ensure that such interactions are conducted transparently. Whenever possible, interactions should be conducted in public, for example through public hearings, public notice of interactions, disclosure of records of such interactions to the public."

The guidelines elaborate the application of the FCTC, saying:

> *"The purpose of these guidelines is to ensure that efforts to protect tobacco control from commercial and other vested interests of the tobacco industry are comprehensive and effective. Parties should implement measures in all branches of government that may have an interest in, or capacity to, affect public health policies with respect to tobacco control."*
>
> *"The guidelines are applicable to government officials, representatives and employees of any national, state, provincial, municipal, local or other public or semi/quasi-public institution or body within the jurisdiction of each Party, and to any person acting on their behalf. Any government branch (executive, legislative and judiciary) responsible for setting and implementing tobacco control policies and for protecting those policies against tobacco industry interests should be accountable."*

These terms are widely drawn to apply to anyone in the public sector who is responsible for the setting or implementation of tobacco control policies. With this in mind, officials in the Department's Tobacco Team are currently considering what further action might be taken to take to remind all Government departments (and Arm's Length Bodies) of their responsibilities under Article 5.3. One option would be to work with colleagues in the Cabinet Office to develop a strategic approach to ensure transparency in all Government dealings with the tobacco industry.

Annex B

Illicit tobacco

HMRC has the lead in Government on reducing illicit tobacco in the UK. Over the past decade, despite continued efforts by organised criminal groups and smaller scale smugglers to target illicit tobacco products on the UK, the Government, led by HMRC, has had great success in tackling the problem.

The latest analysis of large UK seizures of tobacco products indicates that the counterfeit share of *large seizures* of cigarettes is around 25%, reduced from around 50% ten years ago. For *large seizures* of hand-rolling tobacco (HRT) it is around 16%. Cheap illicit 'whites' (genuine products not intended for the UK market,) have presented a growing problem over the last five years, but genuine UK products, legitimately supplied to overseas markets and then smuggled into the UK, continue to present a significant risk to the UK Exchequer. HMRC estimates indicate that the UK illicit market share for both cigarettes and HRT have been on a downward trend since 2000.

The Government first published its comprehensive strategy for tackling tobacco smuggling in 2000. That strategy has been reviewed on three occasions, most recently in April 2011 when the joint strategy with the UK Border Agency (now Border Force) *Tackling Tobacco Smuggling: Building on our success* was published. This was underpinned by around £25 million additional funding as part of the £917 million additional investment in HMRC to tackle organised crime, tax evasion and avoidance through the Government's Spending Review. The objective is to achieve further sustainable downward pressure on the illicit market in cigarettes and hand-rolling tobacco through to 2015.

In addition, HMRC is working with the EU Commission and other Member States towards signing the WHO FCTC Protocol to eliminate illicit trade in tobacco products (the Protocol). The Protocol aims to eliminate all forms of illicit trade in tobacco products by requiring parties to the Protocol to take measures to control the supply chain of tobacco products effectively and to cooperate internationally on a wide range of matters. More information on this Protocol can be found on the WHO website at the following link;

http://www.who.int/fctc/protocol/illicit_trade/en/