HOUSE OF LORDS

EUROPEAN UNION COMMITTEE

HOME AFFAIRS, HEALTH AND EDUCATION SUB-COMMITTEE

Tobacco Products Directive
Written Submissions

Contents

HOUSE OF LORDS

Action on Smoking and Health – Written submission

I am writing to you in response to some of the questions raised in the two sessions that you have held on the EU Tobacco Products Directive (TPD). Although I was unable to appear before your committee on Wednesday March 6 as I was abroad, I have followed the committee's hearings on the TPD with great interest. I would be grateful if you could have this letter circulated to the EU sub-committee F members.

1. What is the evidence for the impact of standardised packaging on the illicit trade in tobacco?

The idea that standardised packaging could lead to an increase in illicit trade may at first sight appear plausible, but a closer examination of the issue shows that there is no reason why it should be the case. With respect to concerns raised by retired police officers the committee should be aware that tackling illicit tobacco is the primary responsibility of HMRC not the police. In some parts of the country, for example in Greater Manchester, police have worked on the illicit trade in partnership with HMRC and regional offices of tobacco control. The Assistant Chief Constable of Greater Manchester Police, Terry Sweeney, presented on this issue to an Inquiry held by the APPG on smoking and health into the illicit trade in tobacco (for which ASH provides the Secretariat). He made clear that he did not believe that standardised packaging of tobacco products would lead to an increase in the illicit trade. This is covered in some detail in the report of the Inquiry which I enclose with this letter. For simplicity I include the relevant section of the report which gives a clear response to assertions that standardised packaging would be a *'counterfeiters' charter':*

"75. *The evidence for these claims is in fact poor, and there are three key reasons why the introduction of standardised packaging is not likely to make a significant difference to the volume of illicit trade.*

76. First, as Mr Luk Joossens pointed out in his evidence to our Inquiry, the production costs of illicit cigarettes (including packaging) are very low.{65] In Paraguay costs can be as low as 5 US cents a pack. A Jin Ling pack in Kaliningrad or a Chinese counterfeit pack may cost about 20 cents a pack to produce. Philip Morris International acknowledges that production costs are low and estimates the cost for a Chinese counterfeit pack at about 15 pence.

77. Secondly, counterfeiters are also able to produce quality and apparently genuine packaging at low prices in a short time. The quality of counterfeit cigarette packs has substantially improved from the 1990s, making it difficult to distinguish counterfeit from genuine cigarette packs. In 2004, HM Customs and Excise reported that the outside pack was the least likely indicator of the carton being counterfeit.[66] Even the tax stamps with more sophisticated security features used in other parts of the EU are easy to counterfeit.

78. Thirdly, the existing security systems used on packs would continue to be used on standardised packaging. These include:

- *a covert mark on each licit pack, which can be read by enforcement authorities using a simple scanner to determine whether or not a pack is counterfeit*
- *other security marks that vary between manufacturers, for example the configuration of marks on filter paper*

- *numerical codes printed on each pack, which will be developed and standardise through the introduction of the tracking and tracing system mandated under Article 8 of the Illicit Trade Protocol (discussed in paragraphs 141 to 155 of this report) [67]*

79. In oral evidence to our Inquiry, police, trading standards and OLAF representatives agreed that by maintaining security markings already in place and with new identifiers included to meet the terms of the Illicit Trade Protocol, the introduction of standardised packaging, would be likely to have little or no significant impact on the level of illicit trade."

Electronic copies of the report, containing the references included above can be found at http://www.ash.org.uk/APPGillicit2013.

In addition the TPD proposal requires an EU tracking and tracing system at packet level throughout the supply chain (excluding retail). The current Directive gives the Commission powers to adopt technical measures related to traceability and identification and this power is brought into effect in the current directive. This new measure will strengthen Member States powers to control the illicit trade and enable consumers to verify the authenticity of tobacco products. However, the proposal would be strengthened considerably by requiring links between identifiers of packs and outside packaging; invisible as well as visible security features; and data storage of tracking and tracing independent of the tobacco companies.

2. What is the evidence for the impact of slim cigarettes?

Research into the impact of pack design on young women, including the impact of brand descriptors such as "slims", as well as skinny packs and pink colours finds that such packs are both misleading and significantly more appealing to young women.[1] [2] In particular, such packs can reinforce the belief that smoking helps to control appetite and prevent weight gain as well as being less harmful. This is a growing problem which the TPD needs to address as global sales of slim cigarettes, which are explicitly targeted at women, are expected to grow from 4% to 13% market share between 2011 and 2016.[3]

3. What is the evidence for the impact of pictorial warnings?

A systematic review of the evidence shows that health warnings on tobacco packs are effective in discouraging young people from taking up smoking and motivating smokers to think about quitting. Picture warnings and warnings of 75% and above are significantly more effective than text-only warnings of 50% or below and are particularly effective with young people.[4] In Belgium the number of calls to the quitline increased by more than two thirds in the year that pictorial warnings containing the number to call were included on all packs.[5]

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[1] Hammond D, Daniel S, White CM: The effect of cigarette branding and plain packaging on female youth in the United Kingdom, Journal of Adolescent Health, 2012 (in press).

[2] Hammond D, Doxey J, DanielS, Bansal-Travers M. Impact of female-oriented cigarette packaging in the United States. Nicotine & Tobacco Research 2011 April 12; doi: 10.1093/ntr/ntr04

[3] Passport, New product development in cigarettes: innovate or fail - keeping price in power, Euromonitor International, 2012.

[4] Health warning Health Warning Messages on Tobacco Products: A Review (Hammond 2011, Tobacco Control) Sambrook Research International. A Review of the Science Base to Support the Development of Health Warnings for Tobacco Packages. Newport: Sambrook Research International; 2009. (Report prepared for the European Commission). http://www.tobaccolabels.ca/heaiUresources/2011hwmreviewhammondpdf accessed 3 March 2013

[5] Foundation against cancer, Press release, Brussels, 3 February 2012. http://www.cancer.be/sites/defau1Ufiles/cp-tabacstop-fev2012.pdf

Countries which have introduced large pictorial warnings have done so as part of a comprehensive tobacco control strategy and the impact of packaging changes is not immediate so it can sometimes be difficult to prove a causal link between health warnings and smoking initiation. However, in Canada there is good evidence that the introduction of pictorial warnings in 2001 was effective in increasing quit attempts and reducing smoking rates.[6] Smoking rates amongst 15 to 19 year olds fell from 25% to 22% in the year picture warnings were introduced and have continued to fall such that by 2011 only 12% of this age group were current smokers.[7]

4. Should nicotine containing products be contained within the scope of the protocol?

The current proposal requires that products above a certain nicotine concentration are authorised as medicines while below that level they come under the TPD. ASH does not support this approach and to the contrary recommends that all non-tobacco nicotine containing products require medicines authorisation. This is because:

- Medicines regulation could ensure that good quality products remain available to smokers, while preventing them being sold or promoted to children and young people who are non-smokers and enable prohibition of sweet-like flavourings such as bubble gum, chocolate and vanilla attractive to children. This would also ensure that the EU is in line with the UK where the MHRA is currently working on a regulatory framework for such products and is due to publish this in May 2013.
- The cutoff point in the Directive is difficult to measure as the level of nicotine taken in by users depends on how the product is used, not the nicotine content. This makes for bad regulation as determining whether the product comes above or below the cutoff point is difficult and expensive and very similar products will be regulated in very different ways.
- Products regulated under the TPD will require a 30% front and back warning stating "This product contains nicotine and can damage your health". This warning is misleading and could put smokers off using nicotine replacement therapy (NRT). NRT has a medicines license in the EU to help smokers quitbecause the nicotine it contains is effective in helping smokers quit without causing harm. E-cigarettes have not been authorised as medicines at the current time, but there is no evidence that they can damage users' health. Medicines authorisation for all nicotine containing products will remove the need for this warning.

For more detailed background information on nicotine containing products see the ASH briefing at http://www.ash.org.uk/files/documents/ASH_715.pdf.

25 March 2013

[6] Azagva, S, Sharaf, M. The Effect of Graphic Cigarette Warning Labels on Smoking Behaviour: Evidence from the Canadian Experience. Nicotine & Tobacco Research, 2012.

[7] Health Canada. Canadian Tobacco Use Monitoring Survey (CTUMS) 2011. http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/staUctums-esutc2011-eng.php Accessed 3 March 2013.

Clive Bates – Written submission

Introduction - tobacco harm reduction.
The WHO anticipates one billion premature deaths from tobacco on current trends would arise this century. Tobacco use is widespread and growing around the world – there are 1.1 billion smokers in the world today, and if current trends continue, that number is expected to increase to 1.6 billion by the year 2025. Even in UK where there has been years of determined public health campaigning and regulation, around one in five adults smoke – and the decline that was evident from the 1950s onwards has slowed recently. We need to embrace the concept of tobacco harm reduction, recognise the reality of continuing widespread nicotine use and design strategies to mitigate the damage. The harm reduction approach address the health risks of those who cannot or do not wish to give up using nicotine. Nicotine itself is addictive, but has only minor direct health impacts – perhaps similar to caffeine. The illnesses associated with smoking are caused by inhalation of smoke - hot gases and burning particles of tar. Smokeless tobacco and e-cigarettes can provide a satisfying 'hit' of nicotine, without the toxic burden of the smoke. The challenge to the directive is how well it encourages and enables this strategy.

A flawed directive for both the single market and for health.
As a single market measure with the underlying objective of a high level of health protection the proposal is very poorly designed. It is important to recognise that the products regulated by the directive have very pronounced differences in risk to the user. Smokeless tobacco like Swedish snus is at least 90% less dangerous than smoking (probably 95-99%) and e-cigarettes will be around 99% less dangerous. A good single market directive would promote competition between high and low risk products that reflected the advantages of the low risk products. In fact the directive does the opposite. Here are six serious flaws in the proposals:

1. Banning oral tobacco ('snus') (Article 15). It bans the safest form of tobacco (oral tobacco or snus), thereby applying the most excessive and discriminatory regulatory intervention to the least dangerous product. In contrast, cigarettes and more dangerous forms of smokeless tobacco are not banned and are barely regulated. Snus use in Sweden has created by far the lowest rates of smoking and smoking related diseases in Europe - and it has done this through consumer choice and market behaviour, of exactly the type that should be encourage in the EU internal market. There is no scientific, ethical or legal case for banning oral tobacco [see: *Death by regulation: the EU ban on low risk oral tobacco*]
Through this measure the directive provides *de facto* anti-competitive support to the cigarette market - it is bad for the single market and bad for health.

2. Banning characterising flavours (Article 6). It bans characterising flavours in smokeless tobacco products as well as cigarettes, even though characterising flavours matter much more in smokeless products than smoking products. Given less than 5% of cigarettes use characterising flavours and around 70% of smokeless tobacco products use them, this will impact severely on the much safer category and skew the nicotine market in favour of smoking and against smokeless tobacco products. By disproportionately reducing the attractiveness of smokeless tobacco products compared to cigarettes, this measure also provides anti-competitive support to the cigarette market.

3. Regulating nicotine containing products as medicines (Article 18). It imposes disproportionate regulatory burdens on e-cigarettes by wrongly classifying them as medicines, even though they are not remotely like medicines. The medicines regulatory regime set out in Directive 2001/83/EC will impose great compliance burdens, heavy costs and numerous barriers to innovation [see: *Medicines regulation for e-cigarettes – when caution can kill*]. The growth of e-cigarettes has astonishing potential to erode the market for cigarettes and to meet the demand for nicotine with products that are likely to be two order of magnitude (99%) less dangerous. Yet it is likely that the directive would wipe out or drive out many of the innovative firms currently supplying these products through long supply chains. By imposing burdens on e-cigarettes that do not apply to cigarettes, this measure also provides anti-competitive support to the cigarette market. It is also likely to be unlawful - four courts in the EU have struck down decisions by national medicines agencies to regulate e-cigarettes as medicines. The ECJ has tightly constrained creeping scope of medicines definition to protect competition and the internal market.

4. Misleading information (Article 11). The proposed descriptors for smokeless tobacco products convey nothing of the relative risks between smoking and smokeless products - the latter being at least 90% less hazardous than smoking. Yet this is the most interesting and relevant information to the consumers and would contribute to competition between tobacco products that led to improved health outcomes. This measure fails to provide information that supports informed choice in the competition between smoking and smokeless products, and so provides implicit protection from competition to the cigarette category.

5. Missed opportunity to establish coherent regulation (Article 3, 4, 5, 6, 15, 17,18, 19). Expert advice from the WHO's scientific regulatory advisory committee, the London based Royal College of Physicians, and experts wrote directly to the Commission [letter] has been ignored. The opportunity to establish a coherent regulatory framework for all nicotine products has been missed and a chaotic bundle of *ad hoc* measures is proposed instead. The recommended option to regulate concentrations of key toxins is superior in both health and single market terms than the approach of completely banning the products with the lowest toxicity and doing nothing to the products with the highest toxicity. These *ad hoc* arrangements favour the most damaging products.

6. Missed opportunity to regulate smoke toxicity (Art 3 & 4). The directive still relies on ISO measurements of tar, nicotine and carbon monoxide "yields" to characterise cigarette smoke. Thankfully these machine-measured numbers will no longer be placed on the pack. They do not reflect that smokers moderate their puffing (duration, depth, frequency) to get the dose of nicotine they want. Machines simply do not do this. Generations of smokers have been mislead by these measurements into believing that low tar cigarettes are less dangerous than full flavour, even though this is just not true. However, the opportunity to reduce the burden of particular toxins per unit of nicotine has again been missed. In the 12 years since the last directive, it appears no progress has been made on this potentially important agenda.

75% warnings and plain packaging. Though this is seen by many as the centre piece of the directive, I do not wish to enter the argument about this measure: many others will make the case. However, the evidence on the points 1-6 above is compelling, the risks serious and opportunities for improvement are considerable. I think they deserve the attention of the EU scrutiny committee.

What to do.
There are several changes to the proposal that would create a significant improvement:

1. Smokeless tobacco. Lift the ban on snus and replace it with system for regulating toxicity of all smokeless tobacco products - that is both the right outcome for health and for the internal market. If that cannot be achieved politically, then allow each member state to decide whether to lift the ban, and approximate toxicity standards where member state have allowed the products. This 'second best' pragmatic approach has been recommended by a a small group of experts. [source]

2. Characterising flavours. Only ban characterising flavours in smoking products. If there are flavours of particular concern in smokeless products then create a schedule to the directive with specific flavours that are to be banned or permitted.

3. E-cigarettes. Regulate e-cigarettes as consumer products, not medicines. There are plenty of existing legal tools in consumer protection legislation (the General Product Safety Directive etc) available to ensure that e-cigarettes are acceptably safe, work as intended and are properly described. It would be better to withdraw e-cigarettes (NCPs) from the directive altogether rather than proceed with the proposal in Article 18, and give the Commission a mandate to design and consult on options that are better suited to the product and proportionate to the risk.

4. Warnings. Devise a new helpful warning for smokeless tobacco products: *This product contains nicotine and may be addictive but presents substantially lower risks to health than cigarettes* - and make this proportionate to the risk (ie smaller)

5. Coherent regulation. Give the Commission a mandate to develop toxicity standards as recommended by most experts that have considered this issue properly.

6. Smoke toxicity. Give the Commission a mandate to develop investigate options for sound regulation of smoke toxicity and ask for a report back with proposals.

Some documents. Finally, as well as some supporting links included above, I have attached two documents that go into these issue in greater depth.

1. An assessment of the scientific reasoning and related legal vulnerabilities in the Commission's case to regulate oral tobacco - *A critique of the scientific reasoning supporting the proposed measures relating to oral tobacco*.

2. A discussion of whether e-cigarettes are medicines and the legal vulnerabilities arising from assuming they are when they are not: *Are e-cigarettes medicines?*

26 March 2013

Annex 1

A critique of the scientific reasoning supporting the proposed measures relating to oral tobacco

Clive Bates[8] and Lars Ramström[9]

18 March 2013

Introduction

Disclosure: both authors have worked in the field of tobacco control over many years and have consistently argued for harm reduction strategies based on promotion of low risk alternatives to cigarettes, including oral tobacco ('snus'). Both authors have no competing interests and are interested only in securing the best public health outcome from European measures to regulate tobacco and nicotine products.

The proposed revision of the Tobacco Products Directive. On 19 December 2012, the European Commission published its proposal for a revision to the 2001 Tobacco Products Directive[10]. The proposal was published as a package including an explanatory memorandum with draft directive[11] and impact assessment[12]. The impact assessment sets out the Commission's options analysis and rationale for the proposed measures. In the impact assessment, the Commission provides its rationale for the ban on oral tobacco ('snus') and other restrictions on smokeless tobacco. For oral tobacco, the proposed directive has the following effect: defines oral tobacco as tobacco that is consumed orally but not inhaled or chewed; maintains a ban on oral tobacco outside Sweden but does not ban other smoked or smokeless tobacco; bans 'characterising flavours' in all smokeless tobacco; controls the use of additives; and sets standards for labelling and warning consumers. This document provides an evidence-based critique of the scientific reasoning used in the impact assessment to justify the Commission's preferred policy and legislative options for oral tobacco.

Executive summary

The purpose of the proposed directive is to improve the functioning of the internal market in tobacco and nicotine products, whilst securing a high level of health protection. While some measures in the proposal are likely to support this purpose, the proposed regulatory framework for smokeless tobacco products would be sharply counterproductive. We show that the scientific reasoning in the impact assessment has pervasive errors of fact and interpretation, selective use of evidence, important omissions, and poor conceptual framing. Legislation based on flawed scientific foundations will harm the health of Europeans, impede the development of the internal market and open the directive to legal challenge.

Summary of the critique of the impact assessment

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[9] Executive Director, Institute for Tobacco Studies, Stockholm, Sweden
[10] 2001/37/EC
[11] COM(2012) 788 final
[12] SWD(2012) 452 final

The case for the Commission's preferred options rests on several arguments set out in the Impact Assessment:

- Harmful and addictive nature of oral tobacco use
- Inconclusive effectiveness on whether oral tobacco is effective in smoking cessation
- Risks of initiation, through creation of a 'gateway' into smoking or tobacco use
- Risks of 'dual use', through which oral tobacco will maintain smoking where users might otherwise quit tobacco use completely
- The use of characterising flavours to make the product more attractive
- Application of the precautionary principle to justify a ban where there is uncertainty about the science

The analysis that forms the body of this document shows the Commission's scientific reasoning to be fundamentally flawed. The Commission's case has failed to articulate the most important characteristics of oral tobacco, which are summarised here and developed through the detailed critique later in this analysis.

- **Health risks of snus are low**. The impact assessment seeks to establish that oral tobacco is associated with various diseases, but mostly without quantifying risk or harm. No-one argues that snus is perfectly safe, but *how unsafe* is important. What should matter to a regulator or legislator is the following: (1) that the *excess risk* of prolonged snus use compared to being a non-tobacco user is small and comparable with other lifestyle risks; (2) that the *relative risk* compared to smoking, for which it is a viable alternative, is very low, and thus presents opportunities for harm reduction and health benefits – and these are strongly evident in Sweden.

- **Relative risk compared to smoking is very low**. The relative risk of use of oral tobacco in the form of Swedish snus is *at least* 90% less than cigarette smoking and at the low end of the spectrum of risk arising from smokeless tobacco products. It is the least hazardous form of tobacco available, yet most severely regulated.

- **Health *benefits* from harm reduction are significant**. Oral tobacco can substitute for cigarette use and provide a substantial health benefit for those who switch. The *health benefit* arising from 'harm reduction' is unambiguously clear in Sweden, which has by far the lowest rates of smoking and smoking related disease in Europe. It takes particularly perverse reasoning to argue that the product that has created Europe's best tobacco-related *health outcomes* should be deliberately denied elsewhere. This has happened largely through the action of consumers and a competitive market for a much safer alternative to cigarettes, yet the ban on snus has the supposed purpose of improving the functioning of the internal market.

- **No significant gateway effects have been found**. Weight of evidence suggests that where oral tobacco is in widespread use it does not cause initiation, create new smokers or show any significant gateway effects. Its effect is to reduce smoking and to act as an exit not entrance.

- **Oral tobacco is an effective aid to smoking cessation**. That oral tobacco has been widely used as a smoking cessation aid and has been more effective than NRT.

- **Oral tobacco marginalises rather than encourages smoking**. A tiny fraction of users in Sweden use both snus and cigarettes. By reducing the visibility of smoking at home and in public, smokeless tobacco supports 'denormalisation' of smoking, not continued smoking.

- **Making snus relatively less attractive than cigarettes is dangerous.** Characterising flavours are integral to the viability of oral tobacco as a product category and as an alternative to smoking, but only a marginal part of the cigarette market. Making snus relatively less attractive by banning characterising flavours may cause users to return to smoking or never switch to snus from smoking – and so cause more harm.

- **Proper application of the precautionary principle would mean lifting the ban.** The Commission's own guidelines on the precautionary principle have not been followed, and this principle cannot be used to justify the ban on the grounds that snus is harmful and addictive. Application of the precautionary principle also requires assessment of the *unintended costs and risks of the ban itself* – and, on the available evidence, the estimated impact of denying smokers safer alternatives would be substantial.

Legal importance of sound scientific foundations for the proposed directive

The quality of scientific reasoning in these documents is important. This is not just because European citizens naturally hope and expect that laws are based on sound science, but because law-makers are constrained by various principles written into the governing treaties of the European Union[13], which may be violated if the underlying scientific case is flawed. These principles include: proper legal base; proportionality; subsidiarity; non-discrimination; free movement of goods facilitated by the approximation of laws, with the aim of a high level of health protection; and obligations to consult and to give reasons for measures. The draft directive does, at face value, conflict with several of these principles where it concerns oral tobacco:

- impedes free movement of goods and competition between tobacco products by banning sales of oral tobacco outside Sweden;
- restricts competition by regulating product characteristics, for example by banning characterising flavours, and adversely affects the competitive balance between smoking and smokeless tobacco;
- imposes the most severe restriction, a ban, on the least risky products, so appears disproportionate;
- treats similar products with discriminatory differences in regulation - some forms of smokeless tobacco are allowed and lightly regulated but others are banned, depending on whether the product is sucked or chewed once in the mouth.

It is conceivable that these apparent breaches of basic principle may be acceptable, *but only if there is robust science-based health protection justification*. This critique shows the scientific justification is wholly inadequate and the justification for the ban on snus used in the 2003-4

[13] Primarily the Treaty on the European Union and Treaty on the Functioning of the European Union

case before the European Court of Justice[14] would not be sustainable now, given the available evidence and quality of scientific reasoning in the impact assessment.

What should be done?

Mainstream scientific opinion does not support the European Commission's case. The report of the SCENIHR committee (2008) for the Commission provides no basis for a ban and substantial evidence to justify replacing a ban with regulation of ingredients. The WHO Study Group on Tobacco Regulation (WHO TobReg 2009), Royal College of Physicians (2007), European Monitoring Centre for Drugs and Drug Addiction (2010) all argue for ingredients regulation for common standards for product toxicity for all smokeless tobacco. Fifteen eminent scientists and experts wrote to Commissioner Dalli in May 2011 to argue this case (Axell T. *et al*, 2011). These views have not been faithfully represented in the impact assessment, but they support the regulatory option rejected by the Commission (option 1). There are many options for setting a regulatory standard for smokeless tobacco which would both protect health and improve functioning of the internal market. The obvious, proportional and non-discriminatory way to establish a single market in smokeless tobacco products is to regulate the toxicity of the products. This is exactly the proposal of the WHO Study Group on Tobacco Regulation (WHO TobReg 2009)

3. Report on setting regulatory limits for carcinogens in smokeless tobacco
3.9 Recommendations

- All products that deliver nicotine for human consumption should be regulated
- Smokeless tobacco products should be regulated by controlling the contents of the products
- The metric for measuring toxicants in smokeless tobacco should be the amount per gram of dry weight of tobacco
- Initially, upper limits should be set for two nitrosamines N-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and one polycyclic aromatic hydrocarbon, benzo[a]pyrene
- The combined concentration of NNN plus NNK in smokeless tobacco should be limited to 2 μg/g dry weight of tobacco
- The concentration of benzo[a]pyrene in smokeless tobacco should be limited to 5 ng/g dry weight of tobacco.
- Regulation of the distribution and sale of smokeless tobacco products should include a requirement for affixation of the date by which the product must be sold or returned to the manufacturer and a requirement for refrigeration of the product before sale in order to limit the increase in the concentration of nitrosamines that occurs over time of storage.

Other regulatory standards could be set for nitrites, heavy elements (cadmium, lead, arsenic, nickel, chromium) and pesticide residues – these are included in the voluntary Gothiatek standard, in use in Sweden (Rutqvist L et al 2011).

[14] Case C-210-03 Judgment of the Court (Grand Chamber) of 14 December 2004. The Queen, on the application of: Swedish Match AB and Swedish Match UK Ltd v Secretary of State for Health

Conclusion
There has been ample opportunity for the Commission to develop policy and legislation based on sound science, and thereby to produce good legislation that is beneficial to the health of European Union citizens will not be struck down when tested in the courts. This critique suggests that science has been misused to justify a predetermined policy, rather than the policy developed on the basis of sound science

The impact assessment as it relates to oral tobacco: an evidence based critique

The substantive part of this document takes statements made in the impact assessment (IA) and provides comment based on best available scientific understanding. The critique covers the evidence related to the following:

1. Health risk and harm
2. Cessation, initiation and dual use – changes in tobacco use status
3. Ban on characterising flavours and consequences of make oral tobacco relatively less attractive
4. Application of the precautionary principle

1. Critique of evidence on health risks and harm
The presence of toxins and addictive agents in oral tobacco is only a concern to the extent that it causes health risks.

1.1. Poor and unquantified framing of risk

IA Statement **(p.64) "In terms of health, all STP tobacco products contain nicotine and are addictive. They also contain carcinogenic substances, including tobacco specific N-nitrosamines (TSNA) and polycyclic aromatic hydrocarbons (PAH). The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded, in its opinion on 6 February 2008, that STP in all its forms can cause cancer (with the pancreas as a main target organ) and are addictive.[258] The International Agency for Research on Cancer (IARC) has also classified smokeless tobacco as "carcinogenic to humans".[259] A study on smokeless tobacco and cancer from 2008 concludes that the cancer risk of smokeless tobacco users is probably lower than that of smokers but higher than that of non-tobacco users.[260] Studies show that STP are less hazardous to health than FMC[257] and even option 1 would prevent STP with increased toxicity or addictiveness to enter the market."**

Comment: It is true that both TSNA and BaP (a human carcinogen included in the group of PAH) are present in snus, but it is important to distinguish between *cancer hazards* and *cancer risks*. *Cancer hazards* are agents that are capable to cause cancer under certain circumstances. *Cancer risks* are estimates of the carcinogenic effects expected from exposures to cancer hazards. This means that a cancer hazard can pose very low cancer risks at current exposure levels. In fact, a recent risk evaluation has indicated that the current levels of TSNA in Swedish snus are two orders of magnitude too low to be a risk factor for cancer (Nilsson, 2011).

PAH in snus products originate from air pollution and are present in trace amounts. *The levels are actually lower than those found in many foodstuffs.*

1.2. Overlooking the potential to reduce risks from the most toxic smokeless tobaccos through regulation

***IA Statement* (p.64): "There are many forms of smokeless tobacco products, which differ considerably in their composition and toxic potential. Some chewing tobacco products, in particular some products used by the South Asian community in the UK, according to a recent study, contain a wide range of toxic substances, such as tobacco-specific nitrosamines (TNSA) chromium, nickel and lead.[261] During the last two decades, the level of tobacco-specific nitrosamines (TNSA), the major group of carcinogens in smokeless tobacco, has been considerably lowered in some STP, including Swedish oral tobacco (snus).[262] This means that the adverse health effects of snus might differ from other non-combustible tobacco products. However, it does not mean that snus or any other oral tobacco product is safe or harmless. Products with lower levels of carcinogenic tobacco-specific nitrosamines (TNSA) have also been on the market for too short time for any convincing support in favour of the presence or absence of a lower cancer risk. The WHO Study Group on Tobacco Product Regulation concludes in its report from 2009 that existing evidence has not established that lowering TSNA or PAH levels in smokeless tobacco will lower cancer risks.[263]"**

Comment: It is now generally recognised that there is *a risk continuum* among tobacco products. This continuum is referred to by WHO in the report "The scientific basis of tobacco product regulation (2008)" where it is stated that "cigarette smoke is the most hazardous form of nicotine intake, and medicinal nicotine the least hazardous. Among smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes, while the risks associated with some products used in Africa and India approach those of smoking."

Snus is not safe and harmless. The important issue from a public health aspect is the *relative risk* of snus use compared to cigarette smoking and compared to other common lifestyle or consumption-related risks. The SCENIHR Report contains a section (3.8) on smokeless tobacco, public health, and the harm reduction argument, which was not addressed in the abstract or executive summary. One conclusion from this section is: "*Overall therefore, in relation to the risks of the above major smoking-related diseases, and with the exception of use in pregnancy, STP are clearly less hazardous, and in relation to respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking*." A study using a modified Delphi approach to *estimate the relative hazard of snus concluded that the product was likely to be approximately 90% less harmful than smoking* (Levy et al. 2004). Snus use is hence associated with substantially lower health risks than cigarette smoking.

The Impact Assessment Report chooses not to cite the complete passage from the WHO Report (2009), which reads "While existing evidence has not established that lowering TSNA or PAH levels in smokeless tobacco products will lower cancer risks*, it is difficult to justify allowing high levels of known carcinogenic constituents in a product that is known to cause cancer, when lower levels are readily achievable with existing technology. As they do for other consumer products, regulators should lower the concentrations of carcinogens present in smokeless tobacco by limiting the concentrations that can be present in products that are marketed."* The WHO TobReg group hence calls for *"product regulation having the aim to reduce toxicity."* This is not

attempted in either the current or proposed Tobacco Products Directive. In contrast the largest Swedish manufacturer of snus has voluntarily adopted the limits proposed by WHO for TSNA and BaP in their products.

1.3. Selective use of evidence exaggerates the risk of pancreatic cancer

***IA Statement* (p. 64-65): "The link between STPs and pancreatic cancer has been discussed by the research community in recent years. Based on a number of case-control and cohort studies, the two authoritative international research groups SCENIHR and IARC have concluded that there is sufficient evidence that STPs cause pancreatic cancer in humans.[264] A recent case-control study suggests, however, that there is no significant association between pancreatic cancer and smokeless tobacco.[265] The discrepant results of this study with other case-control studies have been questioned by a number of researchers calling for a cautious interpretation in view of existing strong cohort data supporting an association between STP and risk of pancreatic cancer.[266]"**

Comment: The Impact Assessment Report is *selective* in the use of scientific data. The outcome from the two Nordic cohort studies is actually inconsistent and neither study adjusts for alcohol use and history of diabetes, which are known risk factors and may confound the results (Boffetta et al. 2005, Luo et al. 2007). This is pointed out by the authors of the recent case-control study mentioned above, who noted that *"the apparent inconsistency between their findings and those from Nordic cohorts may be due to the absence of adjustment of estimates in the Nordic studies for most of the covariates allowed for in their analyses"* (Bertuccio et al. 2011). *Two meta- analyses* (i.e. a statistical combining of data or risk estimates from separate but similar epidemiological studies, leading to a single quantitative summary, a risk number for the pooled results) reported an increased risk of pancreatic cancer for snus users or subgroups of snus users, while a third meta-analysis did not find an association between snus use and cancer of the pancreas (Sponsiello-Wang et al. 2008, Lee et al. 2009a, 2009b. 2011). Of particular interest is the fact that the incidence of pancreatic cancer is low among Swedish men compared to that among men in other member states, despite the fact that 20% of Swedish men are snus users.

1.4. Selective use of evidence exaggerates the risk of oral cancer

***IA Statement* (p.65): "Risk of oral cancer have been found for various smokeless tobacco products, including some of the chewing tobacco products (e.g. areca nut and betel quid) used by ethnic minorities in the UK.[267] There are also suggestions that nasal tobacco increases the risk of certain cancers, e.g. oral cancers.[268] The risk for oral cancer is less clear as regards Swedish oral tobacco (snus).[269]"**

Comment: A summary of the evidence strongly suggests that use of Swedish snus does not increase the risk of oral cancer, a conclusion now strengthened by results from *three meta-analyses* (Boffetta et al. 2008, Weitkunat et al. 2007, Lee and Hamling 2009a). *Also, compared to men in other European countries the incidence of oral cancer is low among Swedish men.*

1.5. Selective use of evidence to exaggerate the risk of oesophageal cancer and omission of the most important data on lung cancer

***IA Statement* (p.65): "SCENIHR concluded in 2008 that published studies support a causal role of STP in the etiology of oesophageal cancer.[270] According to IARC, there is now sufficient evidence that there is a causal association between smokeless tobacco and oesophageal cancer.[271]"**

Comment: The evidence that the use of Swedish snus causes oesophageal cancer is *contradictory*. Three out of four studies found no effect, while the fourth did observe an elevated risk for one specific type of oesophageal cancer (Lewin et al. 1998, Lagergren et al. 2000, Boffetta et al. 2005 and Zendehdel et al. 2008). *Two meta-analyses have been performed; one reported an increased risk, while the second concluded that there was no real indication of an effect for snus in Scandinavia* (Boffetta et al. 2008 and Lee et al. 2009a, 2009b).

It should also be recognised that snus use is not associated with lung cancer, which is by far the largest cause of tobacco-related cancer mortality. Consistent with this is the fact that the incidence of lung cancer among Swedish men is the lowest among men in the EU-member states. There is no significant discussion of the most important cancer associated with tobacco use in the assessment to support oral tobacco policy.

1.6. Selective use of evidence to exaggerate the risk of heart disease

***IA Statement* (p.65): "In addition, there is evidence for an increased risk of fatal myocardial infarction among STP users.[272] Hansson concluded in a study from February 2012 that current snus users had a higher probability of dying from acute myocardial infarction (AMI) as compared to non-users, and that this increase may be explained in confounding factors, although a small increased risk of sudden death from AMI among snus users cannot be ruled out.[273]"**

Comment: The conclusion from Hansson's study (2012) is that "*there is no or a very low increased risk of fatal myocardial infarction among snus users".* For clarity, it should be pointed out that the incidence in myocardial infarction in total is not increased among snus users.

1.7 Significant omission of the diseases <u>not</u> caused by oral tobacco

Though it is probably the most important feature of oral tobacco, the IA does not adequately distinguish between the diseases risks of smokeless tobacco and smoking.

***IA statement* (p.22): <u>The role of tobacco in the society</u>. Tobacco is a legal product on the EU's internal market, but is no ordinary commodity in the sense that it is the largest avoidable health threat in the EU, responsible for almost 700,000 deaths in the EU each year (see Annex 5). Moreover, millions of people in the EU suffer from one or more of the six main disease categories associated with smoking: 1) Bronchitis and other lower respiratory infections, 2) Chronic obstructive pulmonary diseases, 3) Stroke, heart attacks, arterial obstructions (especially in the legs) and other cardiovascular diseases, 4) Asthma, 5) Lung cancers and 6) Other cancers, such as pancreas, oesophagus, and stomach. Studies show that around 50% of smokers die prematurely and if they do so they die on average 14 years earlier. In addition, smokers have more life years that are characterised by serious disease.**

Comment: Though the paragraph is headed 'the role of tobacco in society' the discussion relates to the disease impact of *smoking*. Oral tobacco does not cause (1), (2), (4) & (5) in the statement above. To the extent it causes (3) and (6), the risks are significantly lower than for smoking (see discussion above in 1.3-1.6 above). In the case of (6) the absolute risks are low in comparison to the major cancer risk – lung cancer. All of these conclusions are supported in depth by the advice of SCENIHR (2008). However, the IA attempts to make as much of the residual health impacts as possible, and simply ignores the significant reductions in risk - even though these explain why Sweden has the lowest rates of smoking-related disease in Europe. Though a figure of 14 years of lost life is given for smoking, no figure is given for oral tobacco users. In Gartner et al (2007) a central estimate of around 6 months (0.48 years) was made.

1.8. Risks to pregnant women are acknowledged but do not contribute to the case for a ban

***IA Statement* (p.65): "Some data also indicate that STP use is associated with several pregnancy complications, including pre-term birth, intrauterine growth restriction, placenta abruption and still birth.[274]"**

Comment: Pregnant women are advised to avoid many forms of consumption – including smoking, alcohol and unpasteurised dairy products. Snus and other nicotine-containing products should not be used by pregnant women, and NRT is a better option for those unable or unwilling to quit nicotine during pregnancy.

1.9. Unquantified risk statements are of less regulatory significance than risk relative to smoking

***IA Statement* (p.66): "In conclusion, despite differences in composition and carcinogenic potential, there is scientific evidence that all STPs are addictive and harmful to health. As shown above, some of the epidemiological data are questioned by studies (partly sponsored by the industry) inconsistent but this does not put into question the overall conclusion. In any event it justifies the application of the precautionary principle, i.e. it justifies not allowing market entry of products, which are addictive and harmful.[275]"**

Comment: The relevant conclusion is that snus, although addictive and not completely safe, is considerably less harmful than cigarette smoking (90% or more) and not particularly harmful in absolute terms compared to other lifestyle risks. Use of unquantified statements about harm does not provide a credible basis for regulation. Relative evaluations – compared to other lifestyle/consumption risks and, especially, relative to smoking are much more relevant. This poor framing of risk has the consequence that a much less harmful product is banned and at least ten times more hazardous cigarettes remain the only option for those EU citizens who have chosen to use tobacco. The precautionary principle in this case has been misapplied and most likely resulted in an increase in harm (see discussion on the precautionary principle below).

2. Critique of evidence on cessation, initiation and dual use

2.1 Understatement of the role of snus as a smoking cessation aid and positive experience in countries where snus is used

***IA Statement* (p.66-67): "In terms of substitution, some studies suggest that oral tobacco (snus) can play a role in smoking cessation[276] or that oral tobacco users are more likely to quit smoking than users of medicinal smoking cessation products.[277] Most of the studies are based on observational data, which makes it difficult to draw reliable conclusions as to the relative effectiveness of smokeless tobacco in smoking cessation.[278] On the other hand, a randomised controlled trial showed that use of STP in cessation did not have any long-terms efficacy.[279]**

Swedish Match recently sponsored two clinical trials comparing the effectiveness between oral tobacco (snus) and placebo products in smoking cessation in Serbia and the US.[280] The studies suggest that smokers using Swedish snus were 2-3 times more likely to quit smoking than those using placebo-products. However, the studies took place over a relatively short time (24 and 28 weeks) and it is impossible to say whether the relatively few people quitting smoking in these studies would have done so also without oral tobacco or also, or even more, with the assistance of NRT.[281] In this context it should also be considered that 2/3-3/4 of smokers quit un-aided.[282]"

Comment: It is concluded in section (3.7.2.3) of the SCENIHR Report that "*Observational data from Sweden indicate that snus has been used more often than pharmaceutical nicotine products by some men as an aid to stop smoking. The data are consistent in demonstrating that these male snus users are more likely to quit smoking than non-users. In these uncontrolled, retrospective studies, results on par with those achieved with nicotine replacement products and above, are quoted. A side effect, however, is that 60% or more smoking abstainers become chronic snus users*".

Since then additional studies from Sweden have corroborated these findings (e.g. Rutqvist, 2012). Moreover, several studies from Norway are consistent with the findings from Sweden that snus has, for many years, been the most widely used method for smoking cessation among men. The effects are better for snus than for NRT (Lund et al. 2010, Scheffel et al. 2012). The fact that most snus-users in Sweden and Norway are former smokers, shows that snus has long-term effects as an informal quit smoking aid (e.g. Ramström et al. 2006, Gilljam et al. 2003, Stenbeck et al. 2009, Lund et al. 2010, 2012). It should also be emphasized that most smoking cessation occurs outside of clinical settings so results from observational studies may even be more relevant than clinical studies.

The Impact Assessment Report uses the article by Barrett et al (2011)[277] to cast doubt about the acceptability of snus as cessation aid in a snus-naïve society, but it neglects to give references to other scientific reports, where snus is accepted and preferred over nicotine gum (e.g. Caldwell et al. (2009)).

It is true that the study by Tönnesen et al. (2008) showed no long-term efficacy, but neither did *counselling*, which is one of the few options offered to smokers in Europe. It should also be noted that *NRTs have very low long-term efficacy (ca 7%, when combined with counselling)* (Hughes et al. 2003).

It is also true that the randomized clinical studies on snus took place over a relatively short time, but other objections raised against these studies are irrelevant. Use of placebo-controls in clinical studies simply adjusts for such random effects.

A rough calculation shows that there are as many as 100-130 million smokers in the EU, who cannot quit on their own. Since smoking is a complex addictive behaviour, smokers react differently and would ideally need a wide range of aids to select from. For Swedish (and Norwegian) men, snus has been a viable and successful option for many years. It is obvious, however, that the smokers in the rest of the EU are left with very few efficient aids.

2.2 Understatement of the contribution of snus to low smoking prevalence in Sweden and Norway

***IA Statement* (p.67): "Sweden's low smoking prevalence in combination with the availability of oral tobacco (snus) is sometimes referred to as an indication of snus as an effective cessation method and there are some data indicating that snus has been used by Swedish smokers as an alternative to smoking.[283] On the other hand, SCENIHR concluded in 2008 that the overall smoking prevalence in Norway, as well as in young Norwegians, had decreased at the same rates in men and women during the last decade, whereas a marked increase in oral tobacco (snus) use during this time period has only occurred in young men.[284] In California, both the prevalence of smoking and smokeless tobacco use have decreased concurrently.[285] Some countries which have invested heavily in preventive measures have also managed to reduce smoking rates without the availability of STP.[286] These data imply that the association between patterns of STP tobacco use and smoking cessation differs between populations and is likely to be affected by cultural, societal and other factors. In this context, SCENIHR has concluded that it is not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco from countries where oral tobacco is available to EU-countries where oral tobacco is not currently available.[287] This is highly relevant, as the sale of the product cannot be limited to people who wish to stop smoking, unless the product is a medicinal product available only on prescription."**

Comment: It is true that there are cultural differences among nations but also that *consumers' knowledge about the differing health effects among tobacco products is almost non-existing* (Wikmans et al. 2010, Lund et al. 2011, Lund 2012, Borland et al. 2011a, 2011b). This will affect smokers' willingness to use STP products. Correct information should be a human right.

In the case of Sweden the prevalence of adult smoking is 13%, while the EU average is 28% and the closest member state is 23% (Eurobarometer 2012). In Norway, the adult smoking rate was 16% in 2012 , i.e. well under the EU average. Among young people (16-24 years of age) the smoking rate was only 7%, while snus was used by 19% in this age group.

2.3 Assertion without credible evidence that snus use will increase smoking, whereas evidence suggests it decreases smoking

***IA Statement* p.67-68): "Option 1 is also expected to result in uptake of STP use among individuals (including among young people) who would otherwise not have used tobacco. A survey undertaken by the Swedish National Institute of Public Health reveals that four out of ten oral tobacco (snus) users started using tobacco with oral tobacco.[288] In Norway, recruitment of oral tobacco (snus) users among young people, including recruitment of those with no previous experience**

of smoking, is increasing.[289] Results from cross-sectional studies from Norway show that over 40% of young people (16-20 years old) of daily snus users had no previous smoking experience.[290] Considering the current marketing strategies described under the problem identification (e.g. STP with distinctive tastes) and the obvious interest of the industry to recruit new users, a non-negligible uptake rate is expected under option 1. Smoke-free environment also play an important role in this respect.

Comment: It is concluded in the SCENIHR Report (Section 3.7.1.1.) that "*The Swedish data, with its prospective and long-term follow-up do not lend much support to the theory that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking*." This is also true for male youths, and it seems that early snus use prevents later uptake of cigarette smoking. Thus, studies from Sweden show that young people, who start with snus are less likely to take up smoking and the few snus-starters who take up smoking are more likely than average to quit eventually (Galanti et al. 2001, 2008)

Data from Norway shows that the prevalence of smoking is decreasing, whereas the prevalence of snus use is going up. This is valid both for young men and women. It cannot be excluded that some of the young snus users, who have characteristics similar to those of tobacco-free young people, would otherwise have stayed tobacco-free. Others have properties characteristic of smokers, which would indicate that they would have started smoking if snus was not available (Larsen et al. 2012). In addition, the fact that some 70% of the young snus users have used or are using cigarettes indicates that snus users are often recruited from smokers (Lund 2012).

2.4 Conjecture without evidence about new smokeless tobacco products with no acknowledgement of their role as an alternative to smoking and means to quit

***IA Statement* (p.68): "Although there is currently limited evidence regarding novel STP, which are yet to be marketed to consumers, there may also be a risk of uptake of these products among new users and smokers who would otherwise have quit smoking altogether. Despite the claim that these products are reduced risk products, they are addictive and harmful to health. As BAT states on their web site: "*Cigarette smoking is a cause of serious and fatal diseases and the only way to avoid the health risks associated with tobacco products is to not use them.* [291]"**

Comment: Even if the target is to achieve a tobacco free society, it is important that current users have viable means to stop smoking, reduce harm and eventually to quit. A ban on oral tobacco means that a sizable number of current smokers in the EU are left with very few efficient options and many will die prematurely from a smoking-related disease. With an EU average for smoking of 28% the target 0% is far off.

Snus is at least 90% less harmful (probably 95-98% less harmful) than cigarettes and novel STP are anticipated to have similar characteristics. It has been estimated that "*for net harm to occur 14-25 ex-smokers would have to start using snus to offset the health gain from every smoker who switched to snus rather than continuing to smoke. Likewise, 14-25 people who have never smoked would need to start using snus to offset the health gain from every new tobacco user who used snus rather than smoking* (Gartner et al. 2007)." It is obvious that allowing use of snus or similar products as an alternative tobacco product would not only be a health gain on an individual but also on a population level. The low incidence of lung cancer among Swedish

men is an obvious piece of evidence, but the significance of this highly relevant fact is not recognised in the assessment.

2.5. Overlooking more recent studies confirming snus does not function as a gateway

***IA Statement* (p.68): "There is also uncertainty as regards STPs' potential as a "gateway" to future smoking. Evidence from the US indicates that oral tobacco use may lead to subsequent FMC smoking, while some Swedish data do not support this hypothesis.[292] The SCENIHR opinion of February 2008 suggests caution in translating these data.[293]"**

Comment: The conclusion that it is more common among Swedish smokers to switch to snus use than for snus users to switch to smoking have been strengthened by new studies (Furberg et al. 2008, Stenbeck et al. 2009). Also, studies from Norway demonstrate that snus use is not a gateway to smoking (Lund et al. 2010).

2.6. Exaggerating the scale and consequences of 'dual use' and excluding significant evidence

***IA Statement* (p.68): "Moreover, there is a risk of "dual use". One study of snus as a cessation method found that 20% of unsuccessful quitters continued to use snus on a daily basis (dual use).[294] A recent Norwegian study has also found that around 30% of daily snus users were smoking at least occasionally.[295] Oral tobacco (snus) use in early adolescence has also been associated with increased risk of taking up occasional smoking in addition to snus in late adolescence.[296] There is also a risk that consumers taking up STP will become chronic users.[297]"**

Comment: New research from Sweden and Norway has shown that the increase snus use has not increased dual use of snus and cigarettes. It is also well established that the cigarette consumption is lower among dual users than among those who only smoke (i.e. reduction of harm). Data from Sweden shows that daily smokers, who start using snus, are more likely to quit daily smoking than non-snus users. Almost half of those who have switched from cigarettes to snus eventually quit snus. Only 1.7% of men and 0.2% of women pursue daily dual use. (Ramström et al.). This demonstrates that smokers' uptake of snus does not interfere with their incentives to quit smoking.

New results from Norway show that among dual users with daily intake of snus a majority reported that the purpose of their snus use was to quit smoking. It has been speculated that dual use represents a transition stage away from cigarettes (Lund et al. 2012).

It is true that snus use at the age of 16 was associated with an increased risk of taking up occasional smoking at the age of 19 among Norwegian boys. It is not mentioned in the Impact Assessment Report, however, that use of snus only at the age of 16 was not associated with increased odds of smoking only at the age of 19 (Grötvedt et al. 2012).

In their literature review on dual use, Frost-Pineda K et al. (2010) report: "*These data suggest that there are not any unique health risks associated with dual use of smokeless tobacco products and cigarettes, which are not anticipated or observed from cigarette smoking alone. Furthermore, studies show that dual users smoke fewer cigarettes than exclusive smokers, and studies of tobacco use patterns over time (tobacco use trajectory data) indicate that dual users are more likely than*

exclusive cigarette smokers to cease smoking". They conclude: "*Overall, the concern about dual use appears to be contradicted by the evidence in the literature that dual use of smokeless tobacco and cigarettes may result in reduction in smoking-related harm as smoking intensity is decreased and smoking cessation increases*"

2.7. Showing no evidence that snus undermines tobacco control policies and failing to acknowledge its role in denormalising smoking

***IA Statement* (p.68): "Finally, there is a risk under option 1 that lifting the ban on oral tobacco could have a negative impact on overall tobacco control policies. Norway has in its response to the public consultation on the TPD pointed to difficulties from a communication point of view of advocating non-use of oral tobacco (snus) among young people and at the same time advocating the use of the same product as a smoking cessation tool for another group.[298] The same is true for other types of STP, including novel non-combustible products. In addition, the introduction of oral tobacco could potentially weaken cessation policies, in particular as it would allow people to keep up their nicotine addiction in situations where smoking is not allowed (e.g. smoke-free environments) and subsequently resume smoking.**

Comment: The communication dilemma mentioned above is understandable but not insurmountable if health professionals and communicators are prepared to be clear and honest about the continuum of risk in tobacco products. It should be noted in this context that a number recent studies conducted in several countries have addressed consumers' knowledge about the health risks of snus and of smokeless tobacco products in general. The results show that *knowledge about the health effects is low and misconceptions are common among smokers in the countries studied. Even among health personnel knowledge is low* (Lund et al. 2011). This is an ethical problem, since it is a basic right to have good information to make informed choices about health effects of STP and cigarettes. It should also be understood that snus in Sweden contributes to the low visibility of smoking resulting from only 13% smoking prevalence (Eurobarometer 2012) and so supports 'denormalisation' of smoking in public places and in the home. This may explain why both smoking and snus prevalence is low among women. Whatever the effect on tobacco control policies the low prevalence of smoking found in Sweden and Norway is the intended outcome of tobacco control – which is, on this measure, much less successful where oral tobacco is not permitted in Europe, where average smoking prevalence (28%) is more than double that of Sweden (Eurobarometer 2012).

2.8 Concluding there is no clear evidence that snus assists smoking cessation or reduces smoking prevalence despite significance evidence to the contrary

***IA Statement* (p.69): "Summarising the findings on oral tobacco, it is not possible at this stage to draw the conclusions that oral tobacco is an effective smoking cessation aid in the long term. Any impacts therefore on smoking-related diseases remain uncertain under option 1. On the other hand, it is likely that new oral tobacco users would be recruited under option 1 who would otherwise not have used tobacco (entry gate) and current smokers who would otherwise have quit using tobacco altogether might switch to oral tobacco or use both products (dual use). This would lead to increased adverse health effects (see section 2.2.1).**

In this light, it appears difficult to reconcile lifting the ban with the precautionary principle.

Comment: Available data are consistent in showing that snus is and, for many years, has been an efficient long-term smoking cessation aid for smokers in Sweden and Norway. It cannot be excluded that some new oral tobacco users may be recruited. Studies both from Sweden and Norway show that young people who take up snus are less likely to begin smoking. Because snus use is associated significantly less harmful effects than smoking (at least 90%) there will be a net gain in health benefits both for the individual and on a population level.

A most recent review studied cancer and cardiovascular disease risk in current snus users who formerly smoked (switchers) with that of never snus users who continued to smoke (continuers) or of never smokers who quit smoking (quitters). Although there are some weaknesses in the study, the results were consistent in showing that *"switching from cigarettes to snus is associated with a clearly lower risk of cardiovascular disease and cancer than is continuing to smoke. The risk in switchers is no different from that in smokers who quit smoking. These findings are consistent with other evidence that adverse health effects of snus are at most minimal* (Lee 2013)*."*

It is evident therefore that not lifting the ban on snus will deprive many smokers of a less harmful alternative to cigarettes and is not consistent with the precautionary principle (see further discussion below).

3. Critique of evidence for ban on characterising flavours

The Commission proposal would ban characterising flavours in all tobacco products (Article 6.1), including oral tobacco.

3.1. Asserts that marketing strategies are aimed at recruiting young people without evidence

***IA Statement* (p.23) "As indicated in the market description (section 2.1.1), the main manufacturer of oral tobacco (snus) increased its portfolio from 22 to 180 brands between 2002 and 2008.[103] New market strategies target consumers outside the distinctive population groups who traditionally used these products, including young people. For example, there are STP available which are especially developed for modern taste or a younger generation. STP with characterising flavours (including chewing tobacco with tropical or bergamot flavours, nasal tobacco with peanut butter or cheese and bacon flavour and oral tobacco with elderflower and rhubarb taste) are put on the market and nasal tobacco has recently been promoted at youth parties throughout Germany".**

Comment. No evidence is provided to show that this brand diversification has increased tobacco initiation or smoking prevalence or is targeted at younger people or non-smokers – it is asserted. In fact, smoking prevalence in Sweden fell over this period from 18 to 13%, while snus use stayed approximately level at 11-12%[15]. It is important to recall that snus is used as a gateway exit from smoking and as an alternative to cigarettes. As a result, Sweden now has the lowest smoking prevalence, 13% in the EU by far (Eurobarometer 2012). This suggests that any marketing strategy is making snus relatively more attractive to smokers,

[15] Statistics from SCB (2002) and Swedish Public Health Institute (2008)

and so supporting switching, reducing smoking and causing a health benefit. The IA makes no credible assessment of the scale of the impact of banning characterising flavours in oral tobacco or what the likely health outcome could be, *even though it could be strongly detrimental*. These two themes – scale and health outcome – are discussed below.

3.2. Does not adequately estimate the impact of a ban on characterising flavours on the market for oral tobacco

Comment: scale of impact. Characterising flavours are a marginal segment of the cigarette market –

4.6% of sales in 2010 were menthol flavoured (Matrix 2012), and other flavours are not significant (<0.5% in any country), so less than 5% of the cigarette market would be included in a ban on characterising flavours. However, almost all oral tobacco in Sweden is sold with an artificial smoke aroma and around 70% with other flavours such as juniper or bergamot etc. Taking the definition literally, this could remove up to 70% of the snus products as currently formulated from the market. Commissioner Borg has suggested that the impact would be relatively small: "*prohibiting characterising flavours in snus would mean also only hitting 10% of the entire production of snus which relies on the characterising flavours themselves*" (statement at European Parliament ENVI committee public hearing, 25 February 2013). This appears to be based on a statement made by an investment firm about impact on Swedish Match's overall profitability following a ban on characterising flavours, and was published before the proposed directive was published. It is opaque and far from an adequate assessment of impact.

3.3. Does not recognise or assess the potential for additional harm if oral tobacco is made relatively less attractive than cigarettes

Comment: health outcome arising from market impact. If a snus product is withdrawn, the user is faced with several options: give up using snus altogether; switch to a different snus product; or switch to a different tobacco or nicotine product, including switching cigarettes. Potential snus users face similar pathways: if snus becomes less attractive, they may not switch to snus and continue to smoke; switch to a different snus product; or quit smoking and nicotine completely. The important point is that several of these switches make the health impact considerably worse. It may be impossible to know what the real-world switching behaviour would be in advance, but the 'downside' harm of increased smoking is far greater than the 'upside' benefit of a switch from snus to non-tobacco use. If smoking is 10-20 times more risky than snus use, then for 'risk/use equilibrium' (Kozlowsky LT et al. 2001) in which total population harm was unchanged, 10-20 users would need to quit tobacco completely for each user that switched back to smoking or remained a smoker rather than switching to snus. No attempt has been made in the impact assessment to comprehend or grapple with these issues. But given that Sweden has the lowest rate of smoking in the EU by far, there should be real concern about an ill-considered intervention in the regulation of the product that accounts in large part for this public health success.

4. Critique of application of the precautionary principle

The Impact Assessment relies on the 'precautionary principle' to make the case to retain the ban and in support of the rejection of option 1 in the options appraisal. This option, which does in fact have a solid basis in science, would replace the ban with stricter regulation of labelling and ingredients.

4.1 Misapplication of the precautionary principle and fails to apply the Commission's own guidelines

IA Statement (p75) "Lifting the ban on oral tobacco (option 1) would have adverse health effects. It could also attract new tobacco users who would otherwise not have taken up tobacco consumption. Moreover, it would have a negative health impact on smokers who would otherwise have quit smoking, but who continue to use both FMC/RYO and STP (dual use) and for smokers taking up STP use who would otherwise have quit using tobacco altogether. For individuals replacing FMC/RYO with STP completely, the health effects would be positive. Considering the uncertainty in relation to substitution, an overall negative outcome under option 1 cannot be excluded. Therefore, this option raises doubts in terms of coherence with the precautionary principle."

Comment: the precautionary principle does not justify this reasoning. The Commission's own guidance on the precautionary principle (CEC 2000) is much more sophisticated.

> *Where action is deemed necessary, measures based on the precautionary principle should be, inter alia: proportional to the chosen level of protection; non-discriminatory in their application; consistent with similar measures already taken; based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis); subject to review, in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.*

Application of these principles suggests at least two significant failings in the Commission's argument. First, the ban is disproportionate and discriminatory, given that other smokeless tobaccos are not banned and cigarettes, the most hazardous of all forms of tobacco, remain by far the dominant market leader – tobacco users are free to start smoking with cigarettes and switch from low risk snus to smoking. As the earlier sections of this critique have shown, there is no credible evidence supporting the various hypotheses raised to justify retaining the ban on a precautionary basis. These hypotheses include: that it may prevent quitting (in fact oral tobacco supports cessation and helps smokers reduce risk); that it may lead to smoking initiation (there is no evidence for this, and smoking prevalence is much lower in countries where oral tobacco is widely available); that 'dual use' may be a problem (it is insignificant and may reduce consumption of cigarettes or be part of a transition). In those situations where people use snus who would otherwise have quit completely, their risk is quite small (at least 90% less than smoking), so measures to protect against this outcome should be proportionate to the risk. The precautionary principle does not provide *carte blanche* to take excessive action based on any hypothesis, no matter how tenuous and poorly supported by evidence.

Second, the risks to health associated with <u>not</u> allowing oral tobacco on the market have not been considered and weighed into the decision-making, but the Commission's guidance require a symmetrical assessment of the costs of acting and not acting. The available evidence strongly suggests there have been *significant health benefits* from the use of oral tobacco in Sweden and Norway, at both individual level and population level. Properly applied, the precautionary principle would more realistically justify lifting the ban because of the high risk to health arising from extra smoking if smokers are denied low risk alternative nicotine products, combined with relatively low risks associated with any additional use of oral tobacco. The ban is a more reckless option from a health perspective, *and therefore it is the preferred option – the ban – that should be challenged on precautionary grounds*.

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Annex 2

Are e-cigarettes medicines?

A briefing by Clive Bates
Version 2
Updated 21 March 2013

This document discusses whether e-cigarettes should be classed as medicines or consumer products, focussing on legal and regulatory views of this issue.

Contents

Introduction - characteristics of e-cigarettes

If enacted, the proposed EU Tobacco Products Directive would mean that that the vast majority of e-cigarettes would be regulated as medicines. I have written at length about the danger of this:

- *Medicines Regulation for e-cigarettes: when caution can kill*
- *Reduce harm or protect the cigarette industry?*

But can e-cigarettes be lawfully classified as medicines? Should they? Some points to consider:

- **Positioning**. E-cigarettes are marketed as consumer products, not medicines. They are a modern technology for delivery of a legal widely used recreational drug, nicotine that has been historically sold as tobacco.
- **Comparator is cigarettes**. These products are sold as superior hi-tech alternatives to cigarettes, not as smoking cessation aids or as a form of NRT.
- **Consumer product characteristics**. E-cigarettes have important consumer product characteristics - such as dozens of (sometimes frivolous) flavours. These

increase the appeal relative to cigarettes but are not commonly found in medicines, and would likely be prevented by medicines regulation.

- **Claims**. They make no claims for quitting, and they satisfy rather than treat nicotine addiction. They are likely to have the effect of reducing disease, but they are not treatments for disease.
- **Type of risks**. Most of the risk associated with e-cigarettes relate to electrical and heating element safety and to the containment of e-liquids, rather than adverse physiological reactions or overdose by users.
- **Health risk.** Given what is already known of the product characteristics, the difference in risk between smoking tobacco cigarettes and e-cigarettes is likely to be at least two orders of magnitude. Given the relative risks, regulation of e-cigarettes should be proportionate and non-discriminatory, when compared to the regulation of cigarettes.
- **Normal concerns**. Safety and quality concerns are common to a vast number of consumer products and there is already adequate consumer protection legislation to cover these. These risks are better managed under the General Product Safety Directive and framework of consumer protection policy. The EU's RAPEX system captures reports of defective products and enables them to be removed from the market.
- **Consumer choice not regulatory decision**. Whether they are 'effective' alternatives to cigarettes is not a question for regulators, but a matter for consumer preference and there is no objective 'right answer' to this. As long as the products are acceptably safe, (ie far safer than cigarettes), work as designed and are described appropriately, they should not face further barriers to competing with cigarettes.

An expert view and user view

The expert. The late Professor Michael Russell, a pioneer in the understanding of nicotine and behaviour, captured the distinction more than twenty years ago. Writing in the British Journal of Addiction in 1991 he recognised the potential for a different type of nicotine delivery product:

> *It is argued here that it is not so much the efficacy of new nicotine delivery systems as temporary aids to cessation, but their potential as long-term alternatives to tobacco that makes the virtual elimination of tobacco a realistic future target. [...] A case is advanced for selected nicotine replacement products to be made as palatable and acceptable as possible and actively promoted on the open market to enable them to compete with tobacco products.*

The user. In response to a February 2013 article in the New Scientist *E-cigarettes may soon be sold as life-saving medicine*, a user 'Graham' left the following online comment, and it is typical of many of the testimonials of e-cigarette users.

> *I cannot offer a scientific analysis, just a personal one. I stopped by my local convenience store a few weeks ago, preparing for a night in front of the TV watching Euro football. As I purchased my 20 smokes with my beer, the cashier suggested I try an eCig. So I bought one. £4.99 for a metal tube that supposedly replicates 20 cigarettes. I got home, put on the footie, cracked a beer, and sucked on this metal tube thing for the*

> *first time ever. I haven't smoked a 'real' cigarette since. The pack of 20 real cigs remains in a drawer, next to the TV remote. It says on the pack - if you don't already smoke, don't try this product. But I did smoke, and now I can say I don't smoke cigarettes. If you recognise yourself in my story - please try them. They work.*

This gentleman does not regard himself as in treatment or taking a medicine - I hope that is obvious. It is important to listen carefully to what users say and how they use the products. The common thread is that they are using these as alternatives to cigarettes, not as medicines, exactly as envisaged by Michael Russell all those years ago.

Formal definition of medicine in EU law
This is the definition of a medical product in the medicines directive (2001/83/EC).

> ***Article 1. Definitions***
> *2. Medicinal product:*
>
> *(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*
>
> *(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.*

The UK medicines regulator, the Medicines and Healthcare Products Regulatory Authority believes this definition gives adequate legal cover to regulate e-cigarette as medicines (see this MHRA Q&A - question 2). But that doesn't mean they have to be regulated in this way.

Definition under part a. Some argue that part (a) in the definition above might apply - that e- cigarettes are used for quitting smoking and preventing disease, and therefore have an *implicit* therapeutic claim. They argue therefore that the tests of 'efficacy' are required to prove that these products work as smoking cessation aids. They may well be used in this way, but the manufacturers don't make that claim any more than *Tropicana* claims its orange juice wards off colds and flu. Just because something has beneficial health effects doesn't make it *de facto* or *de jure* a medicine. The real purpose of the first part of the definition of a medicine is to allow regulators is to test 'therapeutic claims'... ie. claims by the maker that it will help you quit smoking, reduce cancer risk, cure addiction or similar. But the vendors of these products do not make therapeutic claims, they simply argue that these are alternatives to cigarettes with largely self-evident superior characteristics. Note NRT products come under this definition because the makers seek an 'indication' that is a regulator-approved claim that the products have certain beneficial therapeutic effects.

Definition under part b. Some argue that part (b) in the definition might apply. This definition could cover things like pain killers or insulin, an agent that modifies physiological functions by exerting a pharmacological action. To the extent that e-cigarettes deliver a psychoactive drug effect this might apply - this argument is used by MHRA in its Q&A. But this idea isn't always applied - alcoholic drinks and caffeinated drinks like Red Bull could also fit this definition but come under food regulation, cigarettes deliver nicotine and come under tobacco regulation - in these cases an appropriate regulatory framework has been

defined. In reality, e-cigarettes are a cleaner delivery system for a legal recreational drug, rather than a medicine.

The following discussion outlines legal and regulatory scepticism about the classification of e- cigarettes as medicines.

UK regulatory committee challenges medicines classification

The special purpose Regulatory Policy Committee (RPC) provides independent scrutiny of regulatory proposals for the UK government. It dismissed the case for medical regulation in its opinion of June 2010 on the MHRA's consultation and impact assessment (IA):

> *The RPC is of the opinion that the IA and consultation letter do not provide sufficient evidence to suggest that there is a significant risk to public health from currently unlicensed NCPs which would justify the future regulation of these products. MHRA should have made clearer what evidence is available to suggest there are safety and public health concerns about these products and considered a wider range of policy options before consulting on the introduction of a mandatory licensing requirement for all NCPs. In addition, the data and assumptions used in the IA for estimating the costs and benefits of the new regulations do not appear to be robust.*

On 18 February 2013, a UK official confirmed that further regulatory scrutiny would be required (personal communication):

> *Ultimately any change to regulation in this area would (as with all regulatory changes affecting business) require collective Ministerial agreement and sign off by the Reducing Regulation Cabinet Sub-Committee. Prior to putting such proposals to the RRC - departments are required to send the associated Impact Assessment to the Regulatory Policy Committee.*

Legal interpretations in the European Union member states

There have been four cases where the courts have examined the interpretation of e-cigarettes as medicines under national laws which are implementations of the EU law in this area.

Here are some examples (my thanks to ECITA for their assistance)

1. Netherlands
United Tobacco Vapor Group Inc. versus the State of the Netherlands (the Ministry of Health, Welfare and Sport and the Ministry of Finance), in the Netherlands Court of the Hague, [2012], Case number 414117

The s-Gravenhage Court in the Netherlands concluded in its ruling of 13 March 2012 that:

> *"the state will be required to provide evidence that upon the use of an e-cigarette the pharmacological properties are, for that purpose, stronger than those observed when the original product (cut tobacco leaves) is used. The state has failed to supply any scientific evidence to prove its allegations"*

> *"The State has argued that it is not the State who has the burden to scientifically demonstrate that the e-cigarette produces pharmacological effects under the Medicines Directive. The judge considers this view untenable. It is the minister who has decided to classify e-cigarette products as medicinal brands. It is for the Minister to provide adequate justification. This case rests under Article 150 of the Code of Civil Procedure meaning the State has the burden of proof in law of the propositions which he wishes to see. On this basis, the court considers that the final decision of the Minister to classify the e-cigarette as medicinal brands is in violation of the law and the general principles of good governance, particularly the justification principle and the principle of legal certainty."*

Interpretation. This is interesting because it takes cigarettes as a reference point, and argues that the nicotine delivery would need to be somehow more potent than for cigarettes. Given that smokers and vapers generally control their own exposure to obtain their desired dose, this view suggests that a regulator would struggle to prove that e-cigarettes gave a nicotine exposure more than from cigarette smoking.

2. Cologne, Germany

The ruling of Administrative Court of Köln Case No. 7K3169/11: 20 March 2012 that

> *"the obligation to prove pharmacological properties lies with the defending party (i.e. the respective competent state authority), as it has alleged that we're dealing with a functional medicinal product [see clauses 111-113 jj of the ruling]. We need confirmation that the use of an e-cigarette would not just only wean smokers from their smoking habit, but also treat nicotine addiction [see clause 130 of the referred ruling]. There is no scientific evidence to show whether this specific product is suitable for the treatment of nicotine addiction. Above all, the Court has found that we're not speaking of nicotine addiction, as long as nicotine is obtained from electronic cigarette instead of a tobacco cigarette. The nicotine addiction will then prevail. Nicotine addiction is satisfied, not treated"* [see clause 132 of the ruling].

The Administrative Court of Köln ruled that:

> *"when observing the products that serve as the object of the dispute, we can't ignore the fact that the definition of a functional medicinal product usually covers authentic medicinal products and therefore, products that serve a therapeutic or prophylactic purpose. We have to distinguish products that have a different primary objective, for example, nourishment or getting a satisfaction" (see clause 171 of the ruling).*

Interpretation: this recognises that the purpose of an e-cigarette is not primarily as a therapeutic device to overcome addiction or quit smoking, but to provide 'satisfaction' in a different way to smoking.

3. Sachsen-Anhalt, Germany

The Supreme Court of Sachsen-Anhalt State of Germany stated in its ruling of 5 June 2012:

> *"We must not ignore the main function of a substance considered as a potential functional medicinal product. Regardless of pharmacological properties, a product is not considered as a functional medicinal product solely because it contains some substance – nicotine, in given case – that is accompanied by health risks when used, as a definition of*

> *a functional medicinal product includes fighting against diseases or undesirable physical conditions of reaching a medical diagnosis as a function of the medicinal product." /…/ "Pure physiological effect of nicotine is not sufficient to classify something as a functional medicinal product. Usually, only products that have either therapeutic or prophylactic purpose can be therefore functional medicinal product. The Medicinal Products Act does not cover products with different main objectives, for example, being used for nourishment or as substances for pleasure and gratification." /…/ "The Medicinal Products Act can only be applied if it's definitely known, as a product is manufactured, that it's future purpose will be, without exception, medicinal function in human body – even where combined effect with some other substance will be needed for that purposes. As for the object of dispute – a liquid that contains nicotine – this can't be assumed. Weaning from the use of tobacco cigarettes or alleviation of nicotine addiction do not take the front stage".*

In the final part of the ruling the Supreme Court of Sachsen-Anhalt State of Germany also explained:

> *"This would mean, above all, that the regulation applicable under the Medicinal Products Act can only be implemented if the suitability of a product as a medicinal product has been identified. Otherwise, the stricter rules, arising from the Medicinal Products Act, would be applicable also to other circumstances and this would prohibit the free movement of products in the European Union without the situation being sufficiently justified by health protection requirements".*

Interpretation: this makes an argument that the application of more restrictive medicines regulation inhibits free movement of goods in the EU without showing any health benefits. It asserts that the simple presence of psychoactive substance (nicotine) is insufficient to classify the product as a medicine.

4. Estonia

Tartu Administrative Court on behalf of the Republic of Estonia found in favour of the complainant, Zandera Ltd (an e-cigarette company) and against the respondent, the Estonia State Agency of Medicines, when the latter tried to classify e-cigarettes as medicines. In its ruling in Case 3-12-2345 on 7 March 2013, the court said:

> *The respondent [...] has not explained why the electronic cigarette is to be classified as a medicinal product, while the normal cigarettes which also contain nicotine and its consumption goal is the same, have never been defined as medicine products. It is not clear why the pharmacological effects of the manufactured liquid nicotine on the body are different from the effect of the nicotine in a normal cigarette or whether any pharmacological effect manifests itself in a normal cigarette. In the contested decisions, there is no answer to the claim raised by the complainant that there is no science based evidence and examples of why particularly E-Lites products or their properties negatively affect public health and influence human physiology more than do conventional cigarettes.*
>
> [...]
>
> *If the effects produced by E-Lites cigarettes are unique to medicinal products only, then the question arises as to why the normal cigarettes do not have the same effect unique to a*

> *medicinal product. In this case, the desired nicotine is received from an e-cigarette instead of a tobacco cigarette; nicotine addiction is satisfied, not cured.*
> [...]
> *Nicotine is received from an e-cigarette instead of a tobacco cigarette. Also, people who have given up smoking tobacco cigarettes in favor of e-cigarettes for health reasons do not use nicotine as a medicinal product, but as a drug which is less detrimental to the health instead of a more hazardous cigarette.*

Interpretation. The court does not find that the mere fact of a physiological effect is sufficient to regard something as a medicine. Throughout the judgement, the court compares e-cigarettes with cigarettes, not NRT or other pharmacological treatments for nicotine withdrawal.

Relevant European Court of Justice case law

1. Germany - the garlic case

The European Commission has also challenged member states when they have over-zealously classified non-medicinal products as medicines. In the 'garlic capsule' case of 2007 the European Commission challenged a member state classification of these products as a medicine by the regulators in the Federal Republic of Germany, on the grounds that they are not medicines and that the regulatory burdens of medicines regulation created disproportionate obstacles to trade in the EU internal market. For e-cigarettes, the case (C-319/05 – 15 November 2007) drew highly relevant conclusions in paragraphs 59-71 of the judgement. These are reproduced in full at the Appendix below, with commentary. Some critical extracts:

> *61 Contrary to the definition of medicinal product by presentation, whose broad interpretation is intended to protect consumers from products which do not have the effectiveness they are entitled to expect, the definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions. [...]*
> *64 In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease*. [emphasis added]
> *[...]*
> *71. … the definition of medicinal products in particular, cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.*

Interpretation: this judgement stresses the balance to be struck between the efficient operation of the internal market and the protection of public health through appropriate regulation. In pursuit of this aim, the ECJ has tightly circumscribed what can be lawfully classed as medicines. The judgement limits medicines to products that are '*genuinely designed*' to '*modify physiological functions*' strictly with the '*function of treating or preventing disease*'. That clearly rules out e-cigarettes, which are not designed to do this at all, but to supply an alternative source of recreational nicotine.

2. Germany - the fermented red rice case

In Case C140-07 (Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg), the ECJ lays down some important case law. This case was about classification of a novel food as a medicine. The ruling states

> *Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to determining whether that product falls within the definition of a medicinal product by function.*

Interpretation. This means that it is not just the pharmacological and physiological properties of nicotine that matter in defining a medicine by function (definition b above) it is also how it is traded and used by consumers.

Legal principle in the European Union

The principle of proportionality

Behind these judgements, is the idea that burdens should be proportionate to the objectives that measures are intended to achieve. The principle of proportionality is laid down in Article 5 of the Treaty on European Union.

> *Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.*

The criteria for applying it is set out in the Protocol (No 2) on the application of the principles of subsidiarity and proportionality annexed to the Treaty.

….Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved.

Interpretation: there is an obligation on the Commission to seek the least burdensome way of protecting health. This means it cannot just declare that the medicines regulatory framework embodied in directive 2001/83/EC can meet the health protection objectives. It has to show that the much less burdensome consumer protection framework *cannot* meet the health protection objectives. It has not shown this or attempted to show it, nor has it consulted on this option.

The principle of non-discrimination

The principle of non-discrimination or equal treatment is widely applied by the European Court of Justice. The following extract from an ECJ ruling is one concise expression of the idea: (Case 304/01 Sept 2004 para 31)

> *... the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.*

Interpretation. If e-cigarettes are alternatives to smoking cigarettes, rather than to NRT, then any excessive regulatory burdens that are placed on e-cigarettes and not on cigarettes would be discriminatory if not justified on health ground, which they cannot be. Conversely, restrictions placed on cigarettes but not on e-cigarettes, can be justified as non-discriminatory because of the pronounced difference in risk. The comparison with NRT is not valid, for the reasons described in the introduction above, but also because NRTs are licensed with a therapeutic claim (ie. they are medicines by virtue of part a of the definition of a medicine in EU law, whereas, e-cigarettes could only be justified under part b).

What is the right approach to take?

Regulation should go with the grain of reality. The proposed revision to the Tobacco Products Directive creates the opportunity to provide a genuine light touch regulatory framework for these products, working alongside standard consumer protection legislation that applies to all products. The overall change required to the proposal is that these products should be regulated as recreational consumer products with cigarettes as their main comparator, not as medicines for 'treatment' of smoking with NRT as the main comparator.

To do this, the TPD should be revised do six things differently with respect to NCPs:

1. Drop the requirement for mandatory medicine regulation, and allow this to become an opt-in for manufacturers who want to make a therapeutic claim or see commercial advantages in a medicines license;

2. Remove the arbitrary and poorly specified threshold in TPD Article 18.1 - it is not necessary to have a threshold, or alternatively set this at a level that captures only very high strength mixing liquids (>75 mg/ml nicotine density) at which poin they would be classed as poisons (in the UK);

3. Re-assert the basic framework of European consumer protection applies, and refer to or restate these. Member states all have legislation and institutional capacity to address this need.

4. As necessary, create a basis for a future light touch non-medicines regulatory regime, for example through a CE marking, Commission Decision or new regulation or directive specific to NCPs - the consumer protection tools exist outside medicines regulation;

5. Add a meaningful mandatory label proportionate to the risk and encouraging smokers to switch;

6. Design a proper transitional arrangement that will not destroy or drive away incumbents with no guarantee of adequate new entrants. The EU should not overburden small businesses with regulation where this is not necessary.

Or design a new regulatory approach. Alternatively, remove provisions relating to 'Nicotine Containing Products' (Article 18) of the Tobacco Products Directive and give the

European Commission a mandate to design a regulatory approach that is: proportionate and fit for purpose, aligned with the real-world characteristics of e-cigarettes, does not excessively burdensome relative to cigarettes and open to consultation so that those affected could have a proper opportunity to contribute to the design of a credible regulatory regime.

Clive Bates
Version 2
Updated 21 March 2013
London, UK

Appendix: The garlic case - extract from ECJ judgement paragraphs 59-71

This is from the judgement in case C-319/05 November 2007. My commentary is included between paragraphs.

> *59 The pharmacological properties of a product are the factor on the basis of which it must be ascertained, in the light of the potential capacities of the product, whether it may, for the purposes of the second subparagraph of Article 1(2) of Directive 2001/83, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings (HLH Warenvertrieb and Orthica, paragraph 52).*

59 highlights the relevance of the second part of the definition of a medicine - see above

> *60 Although, as the Advocate General observed in point 58[16] of her Opinion, that definition is broad enough to include products which, although they are capable of having an effect on bodily functions have in fact another purpose, that criterion must not lead to the classification as a medicinal product by function of substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (Upjohn, paragraph 22).*

60 states that products that have an effect on the body but do not significantly affect the metabolism and affect the way the body function - the 'significantly' is arguable for e-cigarettes, certainly by reference to other recreational drugs. You would certainly consider a drug like morphine as having a significant effect, but nicotine would be better compared with caffeine.

[16] Advocate General opinion (emphasis added) 58. As Advocate General Tesauro rightly stated in Delattre, (34) the wording 'restoring, correcting or modifying physiological functions' contained in the second subparagraph of Article 1(2) of Directive 2001/83 is formulated in broad terms in order to extend to those products which, although without doubt inherently able to affect physiological functions, have an essentially nutritional purpose. I have already argued elsewhere that such an interpretation ultimately promotes neither the protection of health nor the free movement of goods. (35) Nor can that be the intention of the Community legislature. Concurring with the proposals made by Advocate Generals Geelhoed (36) and Tesauro, (37) I therefore take the view that the concept of a medicinal product by function must be interpreted restrictively. (38) Accordingly, the definition should cover only products with scientifically identifiable pharmacological properties. It should not be sufficient for the product merely to have physiological and nutritional effects. Rather, I consider that it must either be intended to prevent or treat disease, have relevant health risks or secondary effects which are detrimental to health, or have an excessive effect on physical functions." (39)

> *61 Contrary to the definition of medicinal product by presentation, whose broad interpretation is intended to protect consumers from products which do not have the effectiveness they are entitled to expect, the definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions.*
>
> *62 Such an interpretation is in accordance with the aims of Directive 2001/83 which, as is clear from the second to the fifth recitals in the preamble, seeks to reconcile the aim of protection of public health with the principle of free movement of goods.*

61 states that there must be a purpose ('genuinely designed') to the modification of physiological functions and 62 notes that the importance of trade-offs between public health and free movement of goods]

> *63 Furthermore, although only the provisions of Community law specific to medicinal products apply to a product which satisfies the conditions for classification a medicinal product, even if it comes within the scope of other, less stringent Community rules (see, to that effect, Delattre, paragraph 22, Monteil and Samanni, paragraph 17, Ter Voort, paragraph 19, and HLH Warenvertrieb and Orthica, paragraph 43), it must be stated, as is shown by a reading of Article 1(2) of Directive 2001/83 in conjunction with Article 2 of Directive 2002/46, that the physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements.*

63 shows that not all products with physiological effect have to be classed as medicines

> *64 In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease*. [emphasis added]

64 is critical as it completes the reasoning that to be a medicines a product that has physiological effect must be designed to treat or prevent disease

> *65 That statement is even more relevant in the case of products which, in addition to being food supplements, are recognised as having beneficial effects on health. As the Advocate General observed, in point 60 of her Opinion, there are many products generally recognised as foodstuffs which may also serve therapeutic purposes. That fact is not sufficient however to confer on them the status of medicinal product within the meaning of Directive 2001/83.*

65 shows that simply being beneficial to health is not sufficient reason to class as a medicine

> *66 In this case, the Federal Republic of Germany does not dispute that the physiological effects that it relies on, essentially with respect to the prevention of arteriosclerosis, may also be obtained by ingesting 7.4 g of garlic as a foodstuff. It is significant in that regard that the fact that the studies on which the Federal Republic of Germany bases its arguments relate both to the potential effects of ingesting garlic preparations in the*

> *form of capsules, powders or solutions, and to the potential effects of consuming garlic in its natural state.*
>
> *67 It is also common ground that the disputed product does not have any additional effects as compared to those which derive from the consumption of garlic in its natural state and, as the Advocate General observed in point 62 of her Opinion, those effects should not be regarded as any greater than, or different from, those of other vegetable or animal products which are taken as part of the daily diet.*
>
> *68 In those circumstances, it must be held that the product concerned, whose effect on physiological functions is no more than the effects of a foodstuff consumed in a reasonable quantity may have on those functions, does not have a significant effect on the metabolism and cannot, therefore, be classified as a products capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.*

66-68 are relevant by virtue of comparison to the commonplace version of the product - in this case bulbs of garlic, in the case of e-cigarettes, the comparison would be drawn with cigarettes.

> *69 Finally, and contrary to the Federal Republic of Germany's submissions, the fact that ingesting the product concerned could give rise to risks to health is not an indication that it is pharmacologically effective. It is clear from the case-law that the risk to health, although it must be taken into consideration in the classification of a product as a medicinal product by function, is none the less an autonomous factor (HLH Warenvertrieb and Orthica, paragraph 53).*

69 clarifies that the risk of an adverse health impact is not in itself sufficient to justify medicines regulation.

> *70 The assessment of the potential risks related to the use of the product concerned must be undertaken in the context of Directive 2001/83 and in the light of the principles of Community law in general.*
>
> *71 As the Commission has observed, the Community provisions relating to medicinal products must ensure, in addition to the protection of human health, the free movement of goods, so that the interpretation of the provisions of Directive 2001/83 in general, and the definition of medicinal products in particular, cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.*

71 reiterates the importance of proportionate regulation and general idea of the free movement of goods. In other words, the restrictions placed on e-cigarettes must not be beyond those necessary to protect health. Given they are alternatives to cigarettes this is a low bar

British Heart Foundation – Written submission

I write to you [Lord Hannay of Chiswick] as a member of the Lords Home Affairs, Health and Education (EU Sub-Committee F) about the forthcoming meeting about the EU Tobacco Product Directive on 6th March.

As you are probably aware, smoking is a major risk factor for Coronary Heart Disease, and smokers are almost twice as likely to have a fatal heart attack as non-smokers. The BHF is therefore welcomes the EU Tobacco Product Directive, and its current proposal that packaging for both cigarettes and 'roll your own' tobacco must contain a combination of picture and text health warnings covering 75% of both the front and the back of the package. This is important because evidence suggests that large picture warnings on the front and back surfaces of tobacco packaging increase their effectiveness among young and adult smokers and non-smokers.

There are still around 200,000 children and young people in England that each year start smoking. Two thirds of adult smokers started smoking when they were underage indicating that young people who take up smoking continue to smoke in later life. Tobacco advertising is a major factor in encouraging young people starting to smoke.

There can be no justification for allowing tobacco manufacturers to continue to use packaging as an advertising and marketing tool to recruit the next generation of smokers. Tobacco is a unique product - half of its regular users will die prematurely of a smoking-related disease. This is why it is so important to ensure fewer people smoke in the future.

The Commission has also stated that Member States such as the UK remain free to introduce standardised packaging for tobacco products, which is vital to enable the UK Government to legislate for standardised packaging. Introducing standardised packaging in the UK would stop tobacco companies using packaging as a way to advertise the product, reduce both the attractiveness of tobacco to young people and the potential of packaging to mislead on issues of health - and ultimately, save lives.

Given the importance of this issue to the nation's public health, I encourage you to support the current proposals that will enable large picture health warnings to be placed on both sides of the pack. I attach a briefing note which provides further information.

25 February 2013

Annex

Tobacco Products Directive: Briefing for UK MEPs

The British Heart Foundation (BHF) is the UK's heart charity. Our vision is a world where people do not die prematurely from heart disease, which is the UK's single biggest killer. We hope to achieve this through pioneering research, prevention activity and ensuring quality care and support for everyone living with heart disease.

Tobacco and heart disease

The BHF is actively involved in tobacco control issues because of the strong association between smoked tobacco and ill-health including coronary heart disease (CHD). Smoking is a major risk factor for CHD, and smokers are almost twice as likely to have a fatal heart attack as non-smokers. Every year in the UK, 100,000 smokers die as a result of smoking.[17]

There are still around 200,000 children and young people in England that each year start smoking. Two thirds of adult smokers started smoking when they were underage indicating that young people who take up smoking continue to smoke in later life. Tobacco advertising is a major factor in encouraging young people starting to smoke. People who begin smoking at a young age are more likely to suffer tobacco-related mortality and morbidity, and succumb to tobacco-related diseases earlier.[18]

EU Tobacco Products Directive

From 2005, cross-border sponsorship by tobacco brands has been banned across the European Union. A total ban on advertising and sponsorship is a core measure advocated within the Framework Convention on Tobacco Control (FCTC), the global treaty that aims to reduce tobacco consumption and smoking-related harm, to which the UK is a signatory. Tobacco packaging is now one of the last remaining means by which the tobacco industry can market its deadly products.

In December 2012, the European Commission put forward proposals to the European Parliament for an EU Tobacco Products Directive that would change requirements on how tobacco products can be manufactured, presented, and sold.

In the plans, the Commission has proposed that packaging for both cigarettes and 'roll your own' tobacco must contain a combination of picture and text health warnings covering 75% of both the front and the back of the package. The BHF welcomes this proposal as evidence suggests that large picture warnings on the front and back surfaces of tobacco packaging increase their effectiveness among young and adult smokers and non-smokers.[19][20]

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[17] Action on Smoking and Health. Smoking Statistics: Illness and Death. Published online 14/10/2011. Available at: http://www.ash.org.uk/files/documents/ASH_107.pdf

[18] Hammond D. Health warning messages on tobacco products: a review. *Tob Control* 2011; Sep;20(5):327-37. Epub 2011 May 23. Available at: htto:llwww,ncbi.nlm.nih.gov/pubmed/21606180

[19] Shanahan P, Elliott D. *Evaluation arthe Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008.*

[20] Hammond D. Health warning messages on tobacco products: a review. *Tob Control* 2011; Sep;20(5):327-37. Epub 2011 May 23. Available at: htto:llwww,ncbi.nlm.nih.gov/pubmed/21606180

The Commission has also stated that Member States such as the UK remain free to introduce standardised packaging for tobacco products. It is vital that the UK Government moves to legislate for standardised packaging at the earliest opportunity and that the Directive supports Member States in this aim. Introducing standardised packaging in the UK would stop tobacco companies using packaging as a way to advertise the product, reduce both the attractiveness of tobacco to young people and the potential of packaging to mislead on issues of health - and ultimately, save lives.

While the BHF welcomes the current provision we believe the Directive is missing an opportunity to introduce standardised packaging across all member states and encourage MEPs to go further by amending the Directive to apply standardised packaging EU-wide.

Packaging is a key way for the tobacco industry to express their brands. Internal tobacco industry documents confirm that they have invested heavily in package design to communicate to specific demographics, including young people.[21] [22] There can be no justification for allowing tobacco manufacturers to continue to use packaging as an advertising and marketing tool to recruit the next generation of smokers.

UK citizens should be free of the immense and entirely avoidable harm caused by an addictive product that, in any other consumer sphere, would surely be regarded as defective. Tobacco is a unique product - half of its regular users will die prematurely of a smoking-related disease. This is why it is so important to ensure fewer people smoke in the future - and why the tobacco industry should not be able to use its packaging to attract people to their products.

Contrary to industry claims, there is no evidence that standardised packaging would lead to an increase in illicit tobacco. Existing packaging is cheap to produce and easy to copy. That is why current packs – and standardised packs under any proposed new law - include covert markings which show whether the product is genuine, a unique number coding system which can be used to access information about manufacture and intended markets, and a UK duty paid notice.

Smokers' motivation in buying illicit cigarettes is down to price and availability. The illicit tobacco trade should be addressed via an integrated approach at national, regional and local level to crack down on smuggling, rather than through not introducing standardised packaging. Accordingly, we welcome plans included in the Directive for a tracking and tracing system and security features (e.g. holograms) to ensure that only products complying with the Directive are sold in the EU.

Given the importance of this issue to the nation's public health, we encourage MEPs to support the current proposals that will enable large picture health warnings to be placed on both sides of the pack as the Directive progresses through the European Parliament.

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[21] Wakefield M, Morley C, Horan J, Cummings K. The cigarette pack as image: new evidence from tobacco industry documents. *Tob Contro/2002;* Mar;11 Suppl1 :173-80. Available at: http://www.ncbi.nlm.nih.gov/pmclarticles/PMC1766062/

[22] Cummings KM, Morley CP, Horan JK, Steger C, Leavell NR. Marketing to America's youth: evidence from corporate documents. *Tob Control* 2002; Mar;11 Suppl1 :15-17.. Available at: http://www.ncbLnlm.nih.gov/pubmed/11893810

Concerns regarding nicotine-containing products

Whilst the BHF is largely very pleased with the Directive, we are extremely concerned about proposals in relation to the regulation of nicotine-containing products (NCPs) which propose the introduction of a split between high and low level nicotine products.

The key proposals are that products with a nicotine level exceeding 2 mg per unit, or with a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml will come under medicines regulation, any products with nicotine levels below those thresholds will carry the following health warning 'This product contains nicotine and can damage your health' (30% of the external area of the unit package and any outside packaging).

The **BHF** believes that the proposals will be confusing, expensive and difficult to enforce. Most problematically, we *believe* the proposals will also interfere with the Medicines and & Health Care Products Regulatory Authority's plans for regulation of all NCPs, which are expected to come into place in the UK in May.

Given the importance of this issue and the rapid growth in the use of NCPs, such as electronic cigarettes, we encourage MEPs to support an amendment of the NCP proposals so that all non-tobacco NCPs are covered under medicinal regulation.

Cancer Research UK – Written Submission

- **As tobacco causes more than a quarter (29%) of all deaths from cancer in Europe,** tobacco control is a key priority for the charity. We work in partnership with others to achieve the greatest impact in the global fight against cancer and we are partners in the European Smoke Free Partnership.

- **All tobacco products are harmful to health and there is no safe level of use.** Therefore all smoked and oral tobacco products should come under the Tobacco Products Directive (TPD), including any new products such as low emission cigarettes and novel forms of oral tobacco.

- Herbal cigarettes should be included within the TPD because they involve inhalation of smoke and the associated health hazards are poorly understood.

- Non-tobacco nicotine products should be regulated as pharmaceutical products. The manufacturers should be required to demonstrate consistent dose delivery and safety, but should not be allowed to make claims about aiding quitting unless their products have been subject to appropriate clinical trials. Regulation of non-tobacco nicotine products should not fall under the TPD.

- While snus (Swedish snuff tobacco) is less harmful than smoked tobacco, there are known health risks associated with its use particularly increased risk of cardiovascular disease and of pancreatic cancer.

- There is no legitimate reason to introduce a new tobacco product on to the market. We do not know whether this could create a new cohort of smokeless tobacco users who would not have smoked tobacco. Also as they remain addicted to the nicotine in tobacco, smokers who switch to oral tobacco could return to smoking with its attendant greater health risks.

- We do not advocate the banning of chewing tobacco used traditionally by South Asian communities, as this could drive it underground. Such products should be regulated in the same way as other tobacco products already on the market.

- We believe there is a need for improved consumer information and generic/plain packaging, including mandatory picture warnings; tar, nicotine and carbon monoxide (CO) levels replaced; further information on harmful substances inside pack; and health warnings on water pipes.

- There is strong evidence that **picture warnings** encourage smokers to think about quitting and are more salient than text warnings. We support the recommendation that there should be mandatory picture warnings on both the front and back of the pack covering at least 80% of the surface. As well as enhancing the health message this prevents the pack being used as a marketing tool.

- **Standardised packaging** can benefit health in three main ways: making health warnings more prominent; decreasing the promotional power of the pack; and preventing use of labels and creative devices that may deceive consumers. The Australian federal

government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow.

- Research shows that: on-pack warnings are an effective way to inform about the harms of smoking and encourage quitting; the tobacco industry acknowledges the pack as a marketing tool; and deceptive devices like light colours do deceive people into believing they are less harmful. There is a large body of evidence that: standardised packaging is less attractive than branded packs to both adults and children and makes them feel it would be easier to quit and less appealing to start; undermines brand values and boosts health warnings.

- Recent research, in which young adults were asked to use plain packs and were questioned about their feelings towards them, confirm these findings. Compared to branded packs, plain packs increased negative perceptions about the pack and about smoking and also increased avoidant behaviour.

- It is strongly recommended that the names of products should be in standard font/size/colour with no logo or other branding allowed, and that packaging should be brown/cardboard colour only as white/black/grey can be made to look attractive.

- The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis for Action on Smoking and Health concludes that this is incorrect and there are no legal impediments to the implementation of generic packaging in the EU.

- We support the prohibition of tobacco sales via the internet as this contradicts the principle in the Tobacco Advertising Directive (2001/0119) that sought to prevent cross-border promotion of tobacco products.

- **Removal of tobacco point of sale displays and vending machines is essential** if we are to protect children from tobacco marketing and access. The evidence has been detailed in submissions to the Governments of the UK. Point of sale displays are more noticed by children and increase their susceptibility to try smoking. Research from Ireland has shown that removing point of sale displays helps to denormalise smoking among children while not impacting on shop sales. Research also shows that children use vending machines more often than adults as a source of cigarettes in the UK and that they have a higher rate of failure in test purchasing.

February 2013

Annex
Other documents submitted

- New Cancer Research UK-funded report on smuggling, the tobacco industry, and plain [standard] packs, written by international expert on the illicit tobacco trade, Luk Joossens
- *Block, amend, delay*, Report on Tobacco industry's efforts to influence the European Union's Tobacco Products Directive (2001/37/EC), Smokefree Partnership
- The Tobacco Products Directive: Myth Busting, Cancer Research UK

E-Lites – Written submission

"… nicotine containing products that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 mg per ml may be placed on the market only if they have been authorised as medicinal products…"
Chapter V Article 18

The effect of the above (the Proposal) will be to require removal from the market of virtually all e-cigs pending their authorisation as medicinal products, despite being proven to be capable of being a satisfactory alternative to cigarettes.

1. Why would governments restrict their availability and make it harder to put e-cigs on the market than the harmful products they are designed to replace?

2. Removing existing e-cigs from the market would be detrimental to the overall aim of the European Union (EU) to promote the well-being of its people, it would do more harm than good and it would be counterproductive.

WHAT ARE E-CIGS?

- an electrical **consumer product proving popular with smokers as an alternative to cigarettes**
- battery powered, the smoker inhales a vapourised liquid solution containing nicotine to simulate the act of smoking
- **e-cigs are widely recognised as being safer than cigarettes**
- the benefits of e-cigs:
  - **no tobacco, smoke or tar ie no exposure to the 4,000 toxins and carcinogens found in tobacco smoke** (the e-cig's liquid solution has four ingredients: pharmaceutical grade nicotine, propylene glycol, food grade flavourings and water)
  - **no risk posed to non-smokers** from environmental tobacco smoke/'passive smoking'
  - **no smell, no litter, no fire risk**
- they are **widely recognised by leading public health experts and bodies as being able to reduce the harm caused by smoking**

" … if all the smokers in Britain stopped smoking cigarettes and started smoking e-cigs we would save 5 million deaths …. a massive potential public health prize … "
Professor John Britton, Leader of Tobacco Advisory Group Royal College of Physicians February 2013

" …. there is little real world evidence of harm from e-cigs to date, especially in comparison to smoking… consequently they represent a safer alternative to cigarettes …."
UK Action on Smoking & Health (ASH) January 2013

" … informing smokers about e-cigarettes and increasing access to these products is the best way we have to save millions of lives …."

Dr Gilbert Ross, Executive Director American Council on Science and Health (ACSH)

- e-cigs are marketed and sold only to adults who are smokers
- **described by UK Trading Standards as '... a code any industry would be proud to have ..', the Electronic Cigarette Industry Trade Association (ECITA)'s Industry Standard of Excellence (ISE) provides a regulatory framework for e-cigs**; ISE certification (with a bi-annual audit process) ensures compliance with (and in many cases surpasses) all relevant consumer protection legislation, rules and regulations relating to product/quality/ safety & marketing standards and is being used and reviewed for adoption and formal recognition in certain Member States
- e-cigs are **designed as an alternative to smoking cigarettes** - they don't contain tobacco and they deliver levels of nicotine directly comparable to cigarettes which, with the 'hand to mouth' behavioural component, provides an overall product **acceptable to smokers**
- **e-cigs are not nicotine replacement therapy (nrt)** products – those products are designed by pharmaceutical companies and are presented as aides to help smokers stop smoking cigarettes (which necessitates medicinal authorisation)

OUR POSITION RE THE PROPOSAL

- **we are not selling a tobacco product** (there's no tobacco in an e-cig)
- **we are not selling a medicinal product** (we don't present e-cigs as having health benefits and they are not functionally a medicine)
- **we are selling a consumer product** (a proven alternative to cigarettes)
- **e-cigs are an exciting, breakthrough and potentially 'transforming' product which are increasingly widely being recognised as making a very significant contribution to tobacco harm reduction (THR)**
- we want smokers to have access to an alternative and be able to make an informed choice between cigarettes and e-cigs; we also believe all smokers have the right to benefit from technological advances that provide an alternative to cigarettes which is widely recognised as being safer
- **regulation as a medicine is not necessary and will stifle THR progress across Member States**
  - existing consumer protection legislation and other regulations, proven by ISE to be capable of codification and adoption, provide the necessary regulatory framework#
  - removing already popular e-cig products from shelves would eradicate the contribution they are making to THR (sales of E-Lites in 2012 reduced consumption of cigarettes by 200million), it could drive millions of smokers back to cigarettes and provide impetus to an illicit trade in e-cigs
- we want freedom to compete against cigarette companies - **limitations on the wider availability of e-cigs will give cigarette companies an unfair competitive advantage and perversely 'protect' their existing markets**
- **in the best interests of public health across the EU we believe it is important:**
  - **e-cigs and nrt products are made as widely available as possible (ideally wherever cigarettes are sold and consumed)**

- **to have a framework of different regulations to accommodate 1.harmful cigarettes (as tobacco products), 2. pharmaceutical nrt products (as medicinal products) and 3. e-cigs (as consumer products)**

ABOUT US

- Since 2007 we have made significant investment in R&D, consumer research and new product development, to enable trading to start in 2009
- E-Lites G9 (9th generation) range is recognised as the world's most technologically advanced e-cig
- Based in Bromsgrove England, employing 128 people (58 employees in head office and 70 full and part-time sales & merchandising agents and franchisees) across the UK
- 300-500% yr on yr sales growth for the three years ending 03/2013
- +£20m forecast sales for 2012/13; one of the UK's fastest growing companies with **sales, into 26 European markets, replacing equivalent of +200million cigarettes in 2012**

25 February 2013

Annex 1

E-CIGS – THE REGULATORY FRAMEWORK

The UK Electronic Cigarette Industry Trade Association (ECITA) and it's increasingly highly regarded Industry Standard of Excellence (ISE) provides an important and widely recognised regulatory framework for e-cigs

"…a code any industry would be proud to have …." **UK Trading Standards, 2011**

ISE certification mandates a bi-annual audit and ensures compliance with (and in many cases imposes a higher regulatory burden than) all relevant consumer protection legislation, rules & regulations relating to product quality, product safety & marketing standards.

These include:

- General Product Safety Regulations 2005
- Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP) 2009
- Weights & Measures (Packaged Goods) Regulations 2006
- Plugs and Socket (Safety) Regulations 1994
- The Waste Electronic and Electrical Equipment Regulations 2006 (WEEE)
- The Batteries and Accumulators (Placing on the Market) Regulations 2008
- The Waste Batteries and Accumulators Regulations 2009
- Consumer Protection (Distance Selling) Regulations 2000
- Electronic Commerce (EC Directive) Regulations 2002
- Data Protection Act 1998
- Health and Safety at Work Act 1974
- Control of Misleading Advertising Regulations (1998)
- Business Protection from Misleading Marketing Regulations (2008)
- Enterprise Act (2002),
- Unfair Trading Regulations (2008)
- Advertising Standards Agency Code

ECITA's audit checks inter alia:

- CE Certification (required for electronic products and use of hazardous substances)
- e-liquid laboratory analysis at a UK accredited public analyst's laboratory
- the detailed analysis of nicotine, propylene glycol and glycerol
- CHIP/CLP and Reach Compliance
- child-proof testing
- product labelling to ensure not sold to minors under 18
- (unique to E-Lites) batch coding for every cartridge/tip and
- product liability insurance

ECITA has worked with UK Trading Standards and the National Measurement Office in the development of the ISE and is in discussions with the regulatory authorities in Hungary regarding formal recognition of the ISE.
The ISE has been formally adopted in States of Guernsey.

Annex 2

E-CIGS – WHAT THE PUBLIC HEALTH EXPERTS ARE SAYING

" … if all the smokers in Britain stopped smoking cigarettes and started smoking e-cigs we would save 5 million deaths …. a massive potential public health prize … "
Professor John Britton, Leader of Tobacco Advisory Group Royal College of Physicians

" …. there is little real world evidence of harm from e-cigs to date, especially in comparison to smoking… consequently they represent a safer alternative to cigarettes …."
UK Action on Smoking & Health (ASH)

" … informing smokers about e-cigarettes and increasing access to these products is the best way we have to save millions of lives …."
Dr Gilbert Ross, Executive Director American Council on Science and Health (ACSH)

".. [e-cigs are] very safe relative to cigarettes and also safe in absolute terms on all measurements we have applied.."

" .. e-cig vapour is not toxicant free, but is free of most smoke toxicants particularly of the leading carcinogen in cigarette smoke,1,3 butadiene, and the leading cardiovascular toxicant, hydrogen cyanide. Importantly, e-cigs directly substitute for the habit as well as the nicotine, without the smoke. As persistent smokers face a one in two risk of dying early (they are on death row so to speak) they need to get out jail card and substitutes can provide it. To deny them such relief is inhumane and unconscionable ..."
Dr Murray Laugesen, Founder and Managing Director Health New Zealand & Chair of End Smoking NZ

"..there is no question that any risks associated with e-cigs are dwarfed by those caused by smoking and second-hand smoke exposure. Thus, e-cigs are a viable alternative to cigarettes that drastically reduce health risks .."
Professor Michael Siegel, Community Health Sciences, Boston University School of Public Health

".. e-cigs are a rival consumer product to cigarettes. In a couple of respects ,[they've] got spectacularly better characteristics – in terms of the health impact, in terms of the nuisance and passive smoking effect on other people.."
Clive Bates, former Director ASH

"..the death and disability toll from cigarette smoking is far too high not to be doing all that we can. The rise of a consumer movement, as I understand almost entirely consisting of ex-smokers, supporting the use of e-cigs is the first social-level evidence that there might now be substitutes for cigarettes that will be readily taken up by smokers. These and other strategies should be actively considered .."
Professor Ron Borland, Distinguished Fellow in Cancer Prevention Cancer Council Victoria & Professorial Fellow School of Population Health & Dept Information Systems University of Melbourne

"..harm reduction strategies which allow smokers to substitute cigarettes with less hazardous sources of nicotine have the potential to prevent millions of avoidable deaths … new nicotine containing devices such as e-cigs have the potential to provide an even less hazardous, and more effective, substitute for tobacco smoke. It is important that nicotine products are regulated rationally, affording market freedom in inverse relation to their hazard, rather than the status quo, in which the most dangerous product is freely available but less hazardous alternatives are not.."
Professor John Britton, Leader of Tobacco Advisory Group Royal College of Physicians

"..if one believes that tobacco/nicotine is here to stay, and nicotine is not a big health problem by the way, how can one not want the least harmful forms to be used.."
Dr Karl Fägerström, Founding Member Society Research on Nicotine &Tobacco & Deputy Editor Nicotine & Tobacco Research Journal

".. around a billion people are addicted to nicotine in deadly cigarettes and many have no immediate plans to quit. Young people will also continue to try dangerous and addictive products. We believe it is preferable that, if people become addicted to cigarettes or decide to try tobacco, they can use a product that is markedly less harmful than cigarettes. […] …we should be prepared to accurately inform smokers about the relative risks of cigarettes … e-cigs and approved smoking-cessation medications. In light of all the available evidence, banning or exaggerated opposition to e-cigs in cigarette-rife environments is not sound public-health policy.."
Professor Jonathan Foulds, Professor of Public Health Sciences & Psychiatry, Penn State University, College of Medicine

".. cigarette smoking is a huge cause of death due almost entirely to the repeated inhalation of the products of combustion. There are products currently available that can substitute for cigarettes without inhalation of smoke .."
David Sweanor, Adjunct Professor (Law Faculty of Law) University of Ottawa & Special Lecturer, Division of Epidemiology and Public Health, University of Nottingham

"..THR is still the best kept secret in global public health and hundreds of millions of lives could be saved if THR strategies, science and products were to be adopted .."
Dr Delon Human, President & CEO Health Diplomats

European Carton Makers Association – Written submission

The European Carton Makers Association (ECMA) is the established forum for national carton associations throughout Europe. ECMA today represents approximately 500 carton producers which account, by volume, for 90 per cent of the total European market, providing innovative packaging solutions for a range of consumer sectors from pharmaceuticals and food and drink to tobacco. The total EU turnover for the sector as a whole is €9bn. Further information about ECMA and its members is available at www.ecma.org.

The European Commission's proposal for a revised Tobacco Products Directive (TPD) promotes standardised packaging, including restrictions on the shape and size of the pack as well as the space available for the packaging industry to add complex features to the pack surface.

If these proposals become EU law, it will be ECMA's members that will be required to implement its provisions. ECMA therefore has an important stake in this debate and, as experts on packaging, a valuable contribution to make to any objective assessment of the TPD proposals.

Please find below an outline of the industry's key concerns in relation to the Commission's proposal.

Response of the European Carton Makers Association to the proposed Tobacco Products Directive

- ECMA supports the Commission's objectives: protect consumer health and harmonise regulation in the Internal Market. However, the text, as proposed, falls short of this ambition. While the Commission has acknowledged the threat that illicit trade poses, i.e. by including mandatory security features on tobacco packs, it has not fully recognised that these features should be a complement to packaging complexity and not a substitute for it. This failure will undermine the public health objectives of the proposal by making it easier for unregulated counterfeit product to be manufactured and distributed in the EU.
- The complexity of tobacco packaging is the first and best line of defence against counterfeiting. It is the hi-tech printing, enhanced design features and the constant updating of the package design and also package shape, which pose substantial and expensive barriers to counterfeit.
- Tackling misleading packaging can be achieved while retaining packaging complexity. Measures designed to standardise packs and remove complexity will only benefit counterfeit producers and unnecessarily damage the EU packaging industry, which we believe is not the intended target of these measures. Such damage includes loss of jobs and lower tax revenue.

Specific views on the packaging elements of the Commission's proposal

The packaging industry is concerned that the existing proposal is simply plain packaging through the back door. It is overly restrictive in a way which is unnecessary to achieve its objectives and risks an increasing volume of low-cost and unregulated product on the market.

Package shape: Restrictions on shape for cigarette cartons and roll your own tobacco (cuboid shape, flip-top lid and, for roll-your-own tobacco the requirement for units to come in pouch form) will inhibit the packaging industry's ability to add complexity to a tobacco pack and remove another significant barrier to counterfeit.

Package design: The packaging industry is concerned that the proposal leaves insufficient space for carton manufacturers to add complexity.

Under the existing text, the actual proportion of the pack that will be dedicated to mandated features is in reality much larger than 75 per cent front and back and 50 per cent on the sides. The text requires the pack to display, in a way which does not encroach on the health warnings:

- A 1cm² security feature
- Price marks
- Tracking feature (probably through a bar code).

ECMA estimates that the current proposal leaves approximately 10% of the package surface for complexity to be added, which is not sufficient to combat counterfeiting.

In addition, ECMA believes that the powers for the European Commission to vary the proportion of health warnings through delegated acts (e.g. article 3(c)) would create significant uncertainty for the packaging industry and should be removed.

Security & tracking features: The best protection against counterfeiting is a complex and frequently changing design. The proposed inclusion of security and tracking features will not be effective in fighting illicit trade and counterfeit products if they are at the expense of packaging complexity.

Effective security features cannot be copied, and are supplied by one single source. However, for tobacco packaging, security features would need to be shared between various industry participants.

Tracking features (e.g. barcode) are a useful investigative tool once counterfeiting has been identified, but in themselves they offer no protection against counterfeit, particularly at the retail or consumer level.

February 2013

HOUSE OF LORDS

Imperial Tobacco – Written submission

Introduction

Imperial Tobacco is a FTSE 30 Company based in Bristol UK representing approximately 46% of the UK tobacco market. Imperial Tobacco submits these comments for consideration due to our serious concerns with regards to the Proposal for a Directive of the European Parliament and the Council on the approximation of the laws, regulation and administrative provisions of Member States concerning the manufacture, presentation and sale of tobacco and related products. COM(2012) 788 final ('the Proposal').

Why are the Commission's proposals so controversial?

Tobacco products are among the most highly taxed and strictly regulated consumer goods in the world. Extensive legislation governs, among other aspects, the sale, presentation and marketing of tobacco products. A ban already exists on advertising on radio, television, in the print media and on the Internet and on the sale of tobacco products to minors. In the UK cigarette packs have front text only health warnings and rear pictorial health warnings. Consumers are already aware of the risks associated with their smoking and there is no evidence that making these warnings bigger will achieve any additional public health objective.

Tobacco is a legal stimulant and a centuries-old cultural object. The beneficial effects of the Commission's planned regulatory proposals are highly questionable. The measures blatantly ignore any semblance of proportionality and merely serve to further demonise a legal consumer product.

1. Legal Basis: EU is not granted the competence to legislate many of these provisions

The Union is only empowered to legislate within the limits of the competences conferred upon it by the Member States in the Treaties. It should be noted that, under the Treaties, the Union does not have general competence to legislate on public health matters. Indeed, the Union may only legislate on such matters if it is acting on the basis of one of the competences conferred upon it in the Treaties. Here, the sole legal basis for the proposed TPD is the Union's internal market competence under Article 114(1) TFEU. Under Article 114(1) TFEU the Union may "*adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and the functioning of the internal market.*"

The Proposal further reduces product differentiation, product innovation, bans certain products altogether and invites Member States to adopt more stringent national provisions (such as plain packaging packaging) that will invariably result in a patchwork of inconsistent requirements through the 27 Member States. Thus, while claiming to improve the internal market by adopting harmonising measures, the proposed TPD clearly aims to achieve just

the opposite, which is to *impede* the functioning of the internal market by creating barriers to trade.

In summary, the Commission fails to respect the clearly defined limits of its power and fundamentally undermines the sovereignty of the Member States.

2. Delegated Acts: Undermining national sovereignty

The EUTPD proposal currently foresees that **the Commission can act based on delegated powers in 16 cases**. As we all know the devil is always in the detail of European legislation, and much of the detail of this legislative proposal will come though Delegated Acts. Whilst we understand the appeal of framework legislation with heavy delegation of powers back to the Commission, the EUTPD proposal clearly goes too far. In a general sense there is simply too much delegation of powers, to the extent that the Commission will ultimately replace the governments of the Member States in the decision-making procedure.

The European Commission is not entitled to be granted powers of delegation over 'essential' elements of the proposal as these are reserved for the legislators. If accepted in its current form the Commission will be granted broad powers, including the right to ban certain tobacco products either directly or indirectly by further reducing tar nicotine or carbon monoxide levels, potentially to zero (see Art. 3(2) in conjunction with Art. 2(19) of the Proposal). Furthermore the Commission will be empowered to change the content, position, format, and proportions of health warnings and further reduce the pack space available for manufacturer branding. These are all essential elements that national governments should regulate on – and National Parliaments need to safeguard the legislative prerogatives of their governments.

.**Details of proposed measures**

Scope of the Tobacco Products Directive

The European Commission also wants to extend, and thereby significantly expand, the scope of the Tobacco Products Directive to "related products". Nicotine products, such as electronic cigarettes for example, with a nicotine level exceeding 2 mg or a nicotine concentration exceeding 4 mg per ml may only be placed on the market if they are approved as medicinal products within the meaning of Directive 2001/83/EC. Nicotine products below this threshold could be sold as consumer goods, provided that they come with a warning covering 30 percent of the two largest surfaces of the packet.[23]

Nicotine products would therefore be regulated in two different ways – as a tobacco product and as a medicinal product. This may result in two very similar consumer products having to be labelled in a completely different way causing consumer confusion. .

A review of nicotine containing products is currently being undertaken in the UK by the MHRA and should be concluded prior to appropriate new regulations being proposed for this new product sector and not undermined and negated by the developments at an EU level. This proposal to include nicotine containing products by the Commission is not based

[23] 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. European Commission: COM(2012), 788 final 2012/0366 (COD). Brussels, 19 December 2012, p. 39

on sound science or credible evidence. Current discussion recommends that a distinction should be made on the basis of cessation claims. Products making cessation claims should only be placed on the market if they are authorised pursuant to Directive 2001/83/EC. Regulating all other products should await further scientific evidence.

The proposed scope also now includes herbal products for smoking and requires this sector to carry health warnings. The definition for "herbal products for smoking" should be aligned with the taxation Directive 2011/64/EU and include that they may or may not contain tobacco.

The addition for all products covered by the Directive of Tracking and Tracing up to and including retail outlets, would be subject to an unprecedented level of bureaucracy for all industry players including SME's. Extensive amounts of data would have to be collected, saved and processed to ensure product traceability along the entire supply chain. The tobacco industry is expected to cover the costs of the necessary infrastructure. The approval of new products would also be disproportionately impeded: these would have to go through a notification procedure six months before they are launched on the market. At this stage, information about ingredients, available studies about consumer preferences and a risk/benefit analysis of the product would have to be presented. Product innovations would be virtually impossible under these conditions in the future. Smaller and medium-sized companies would disappear from the market as they would not be in a position to afford the bureaucratic burden.

Pictorial health warnings (PHWs)

The Commission is considering stipulating the mandatory use of pictorial warnings, featuring graphic imagery, on all packets of cigarettes and fine-cut tobacco. Starting at the upper edge of the packet, these pictorial warnings would cover 75 percent of the surface on the front and back of the packet. A text warning would also be printed on the lateral sides of the packet (covering 50% of each surface). If we take into account the "UK Duty Paid" (impossible to accommodate in its present location in light of the Proposal) mark and other legally required elements and the bar code required by retailers, the manufacturers would be left with less than 15% of the packet surface for their own design.

According to the EU Commission, studies have shown that, compared to the required text warnings, pictorial warnings are a more effective measure when it comes to informing the public about the risks of smoking. However, there is no empirical evidence to support this claim. For example in Germany the Federal Minister Daniel Bahr (FDP) has called on the Commission to provide proof of the effectiveness of pictorial warnings before any political debate begins.[24]

Experience from other countries has shown that pictorial warnings have no effect on consumer behaviour. In the United Kingdom, two years after the introduction of pictorial warnings, the number of smokers who attempted to give up smoking declined significantly. In 2009, according to Eurobarometer, 14 percent fewer smokers wanted to give up smoking, compared to 2006. Similar observations were made in Belgium. The prevalence of smoking actually increased there after the introduction of pictorial warnings.[25] In a comparative study,

[24] *Der Tagesspiegel*, 13 January 2013, p.2

[25] In 2005, 28 percent of respondents claimed that they smoked. In 2009, 30 percent of respondents claimed that they smoked. Special Eurobarometer 239: Attitudes of Europeans towards tobacco. Conducted on behalf of the Health and

which looked at the USA and Canada, the Montreal Economic Institute (MEI) also found that the size of the (pictorial) warning did not have any identifiable effect on consumer behaviour.[26]

There has not been any credible research in the UK that demonstrates the proposals by the commission would have any beneficial effect in the UK over and above the provisions already in place. Independent unbiased research by research workers who have an open view so not previously involved in anti-tobacco or pro-tobacco initiatives is required before UK should agree further progress.

The Commission is mistaken in trying to justify the introduction of 75% graphic health warnings by referring to the Framework Convention on Tobacco Control. The warning requirements in the current Tobacco Products Directive 2001/37/EC are sufficient to meet the obligations under FCTC.

According to the EU Commission, the majority of citizens who responded to the public consultation expressed their clear opposition to tougher legislation and were largely in favour of maintaining the status quo.[27]

Standardisation

The Commission also proposes the further standardisation of the design, of packets used for cigarettes and fine-cut tobacco. Under this proposal, manufacturers would only be allowed to sell their products in cuboid-shaped packets (cigarettes) and pouches (fine cut tobacco/roll your own). These would have to have a "rectangular cut of a certain width and depth". Cigarette packets would also have to be resealable and have only a flip-top lid that is attached to the back of the packet. This would prevent differentiation of the brand portfolio through the shape of the packet and would rule out further future packet innovations. Many types of packaging that is currently readily available and of significant market size would be prohibited from the legitimate market, creating an immediate and appealing black market for criminal gangs. Small and medium-sized companies in particular would suffer greatly – without any public health benefits.

Furthermore, it is proposed **each packet must contain at least 20 cigarettes**: depriving many consumers of 10s which provides them an effective means of controlling or limiting their consumption. Many consumers who buy 10s and only smoke 10 per day report that if 10s are not available and therefore they have to buy a pack of 20 they will consume most if not all the 20 in a day.

Or for roll-your-own at least **40 grams of tobacco**: In the UK most sales (approx. 80%) of hand rolling tobacco are either 12.5g or 25g. Nearly the entire UK market of hand rolling tobacco in 50g pouches is illicit and therefore this proposal will just advantage the criminals and destroy legitimate business. A 40g pouch with UK duty rates would be unaffordable to most consumers. Even if affordable it could encourage consumers to smoke more as it has a limited shelf life at its optimum once opened, and lacks the limiting consumption factor provided by smaller packs.

Consumer Protection Directorate-General. January 2006, p. 68; Special Eurobarometer 332: Tobacco Conducted on behalf of the Health and Consumer Protection Directorate-General. May 2010, p. 9

[26] Plain packaging for cigarettes: at best, ineffective; at worst, harmful. Montreal Economic Institute, August 2011

[27] Report on the public consultation on the possible revision of the Tobacco Products Directive (2001/37/EC). European Commission, Health and Consumers Directorate-General, July 2011, p. 15

In future, cigarettes would have to be cylindrical in shape and not measure less than 7.5 mm in diameter and be made using white paper. Therefore '**Slim' cigarettes** would not be permitted; as these contain less tobacco the unintended consequence is that it will result in increasing the consumption of tobacco for these consumers. It should be noted that one of the studies quoted in the Commission's Impact assessment (Borland 2010) found that standard stick length and diameter (so not slim cigarettes) was perceived as the most attractive.

It is not at all clear how moving towards full standardisation is intended to benefit public health. Many products that are currently readily available, however, would be de facto banned and small and medium-sized companies would be hit particularly badly.

Excessive large warnings, further standardisation of packaging and products represent a massive infringement of the manufacturers' trademark and ownership rights. Such a measure also violates international legal principles such as the free movement of goods (e.g. TRIPS agreement).

Ban on ingredients

Tobacco ingredients include flavourings such as the kind that are used in food. These are added to some tobacco products to give the particular brand its own unmistakable taste or to replace certain ingredients lost as part of the manufacturing process. Without these ingredients, manufacturers would lose the opportunity to make a sensory distinction between their various products in accordance with consumer preferences. The Commission is considering a ban on certain ingredients. It contends that ingredients would increase the "addiction potential", the health risk and the "attractiveness" of tobacco products. This would mean a complete ban on traditional menthol cigarettes for example.

In the UK, **menthol cigarettes have a market share of approx. 6.7% representing over £800million per year in duty and VAT received by HM Treasury** and are consumed primarily by older smokers. Even a study conducted by the Commission could not find evidence that a significant number of young people start to smoke by consuming menthol cigarettes.[28] A major report published by the American Council on Science and Health, which the Commission quotes in its Impact Assessment report, comes to the following conclusion: "Overall the evidence summarized in this section does not suggest that mentholated cigarettes are associated with any independent reduction in age of starting to smoke."[29]

Nor was the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) able to find any evidence to support the claim that ingredients are addictive or that they augment addictive effects. Moreover, according to SCENIHR, there is no proof that ingredients make tobacco products "more attractive".[30] Their opinion concludes "*there is a lack of evidence regarding the specific impact of menthol on smoking behaviour*" and the

[28] European Commission: Special Eurobarometer 385: "Attitudes of Europeans towards Tobacco", Brussels, May 2012, p.70
[29] American Council on Science and Health: The Mentholation of Cigarettes: A Position Statement of the American Council on Science and Health. New York 2010, p. 19
[30] The Synthesis Report on the public consultation of the SCENIHR opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies. SCENIHR, 2005

findings in the report "*do not provide clear evidence that [any] specific additive affects the attractiveness of tobacco products intended for smoking*"[31].

Empirical evidence from other countries also confirms this finding. The prevalence of smoking in the United Kingdom or Ireland, where cigarettes are sold mainly without ingredients (Virginia cigarettes), is not lower than its prevalence in countries where cigarettes are sold mainly with additional ingredients or blended (American blend cigarettes). Similarly, the number of young smokers is not lower in countries in which cigarettes are sold primarily without ingredients.

It is clear that "addiction potential" and "attractiveness" are unsuitable criteria for dealing with ingredients and they lack any scientific basis. Tobacco products that do not have ingredients are not less harmful. Banning them, therefore, would not generate any positive health effects. All tobacco products would smell and taste the same. Consumers should not be misled by these types of discriminatory regulatory proposals. In addition, manufacturers would not have the opportunity to make a sensory distinction between their products.

According to the Commission, a significant majority of citizens who responded to the public consultation were opposed to the regulation of ingredients at EU level.[32]

The **banning of flavours in filters** eliminates a new technology, such as the insertion of a "capsule" containing for example mint flavour appreciated by smokers and introduced as a result of significant capital investment of factory machinery.

Track and Trace

This is covered under the OLAF (European Anti-Fraud Office) agreements between each of the main tobacco companies, The European Union represented by the European Commission and each Member State (a copy of the Imperial Tobacco Co-Operation Agreement dated 27 September 2010) and OLAF has responsibility to negotiate the WHO Framework Convention on Tobacco Control Illicit Trade Protocol which sets out internationally agreed track and trace requirements it should be left to OLAF to deal with this and this section must be removed from the Directive. DG SANCO is not granted the competences to legislate for this.

The expropriation of intellectual property rights sabotages the vitality of European industries.

The value of brands and trademarks is one of the key elements for EU competitiveness in a globalised market. Often, they are the most valuable asset of European companies. Owners of renowned brands can charge higher prices, pay higher wages and invest more in research and training. Accordingly, the protection of brands, trademarks and intellectual property (IP) rights in general is one of the cornerstones of EU trade policy.

Banning or seriously restricting tobacco trademarks (by, for example, banning logos and requiring oversized warning labels) would undermine the EU's push for IPR protection in international fora and trade agreements by setting the following precedent: The use of trademarks on any consumer products and their packaging in the EU can be prohibited or

[31] SCENIHR (2010). Addictiveness and Attractiveness of Tobacco Additives – Final Opinion. European Commission

[32] Report on the public consultation on the possible revision of the Tobacco Products Directive (2001/37/EC). European Commission, Health and Consumers Directorate-General, July 2011, p. 19

seriously encumbered if these products pose health risks even in the absence of any evidence linking the use of the trademark to the health concern. This sends an alarming signal to other IP owners and will undermine the EU's attempts to prevent other countries from introducing similar measures against other products that drive European competitiveness, such as food and alcohol [note the introduction of graphic health warnings on alcohol containers in Thailand].

CONCLUSION

Many of the provisions contained in this proposal DG SANCO is not granted by the competences under the Treaty (TFEU) and therefore this proposal requires major amendment before any further progress or discussion takes place particularly on standardisation, ingredients and nicotine containing products. In addition The track and trace proposal needs close review and amendment as it takes no account of existing signed EU agreements nor the AITP agreed as part of the WHO FCTC.

Imperial Tobacco would welcome the opportunity to discuss this in more detail with the Department of Health and other UK Government Departments involved as stakeholders.

21 February 2013

Japan Tobacco International (JTI) UK – Written submission

Please allow me to introduce myself, my name is Ben Townsend, and I am Head of Government Relations at Japan Tobacco International (JTI) UK. JTI is a leading tobacco manufacturer with a significant presence in the UK, employing almost 2,000 people. I am writing to you in your capacity as **Clerk of the EU Sub-Committee F (Home Affairs, Health and Education)**. As you may be aware, on 19th December 2012 the European Commission adopted its proposal to revise the TPD (the Proposal).

We understand the UK Parliament, through its respective scrutiny committees in the House of Commons and House of Lords, and the Parliamentary Assembly Council of Europe (PACE), will consider this Proposal over the coming months as part of the process of informing the UK's position. As part of this, the House of Lords EU Sub-Committee F (Home Affairs, Health and Education) is conducting a review of the Proposal.

Indeed, the European Scrutiny Committee of the House of Commons has already conducted a preliminary assessment of the Proposal noting that the timetable is "ambitious" and has requested further information from the Government on whether the legal base is "appropriate" or gives rise to concerns about subsidiarity. It is worth noting that both the Italian Senate and the Czech Republic Committee for the European Union have both already given negative opinions in relation to the Proposal and subsidiarity.

I am writing to set out JTI's position on the Proposal. JTI supports appropriate and proportionate regulation of tobacco products, but the Commission's Proposal is neither, in its construction or content. The measures set out in the Proposal are unlikely to be effective in practice, achieving neither Internal Market (the 27 Member States will be able to impose different regulations) nor public health objectives. Rather, the Proposal would have widespread negative effects, including an increase in the availability of smuggled and counterfeit tobacco products.

The extreme and disproportionate measures proposed include: the imposition of **outsized pictorial health warnings** covering 75% of the front and back surfaces position at the top edge of the pack and leaving inadequate space for branding; the **banning of entire categories of popular products** (menthol cigarettes and small diameter cigarettes); prescribing **minimum pack sizes** (40g for rolling tobacco and 20 cigarettes); prescribing extensive details of **pack design** (including shape, size, materials, opening mechanisms, and further prescribing descriptors); banning various ingredients, without any scientific basis; and expanding the ingredients regime to make it unworkable.

It is the view of JTI that:

- The Proposal is **constitutionally flawed, creates tensions with international law and infringes fundamental rights** - notably to property, expression and trade - that are protected by UK law, the EU Charter, the ECHR and under international law (WTO and bilateral investment treaties).
- It will create **new opportunities for criminals and exacerbate the illicit trade**, with the banning of entire classes of currently legal products used by millions of adult consumers and innovative packaging designs that currently deter

counterfeiters (in the UK, HMRC estimates up to 16% of cigarettes and up to 44% of handrolling tobacco is smuggled, costing the Treasury almost £3bn a year in lost revenue).

- It **lacks a legal basis** in the EU Treaties and **disregards the principle of subsidiarity**. Further, the Commission confers on itself indefinite and almost unfettered delegated or implementing powers in 16 areas that effectively transfer public health policy regarding tobacco products (and indeed non-tobacco products) to the Commission at the expense of Member States, the Council and the European Parliament.
- The Proposal will cause **serious and unnecessary damage to free and fair competition**, limit consumer choice leading to down-trading, create barriers to entry and inhibit innovation.
- The Proposal is based upon the flawed and **unsubstantiated self-stated "assumption" that it will reduce smoking prevalence or consumption by 2%,** when the Commission has the burden to provide clear and reliable evidence to justify its measures.
- It **ignores contemporary scientific thinking on the smoking behaviour of adults and minors**, and will fail to achieve the goal of reducing smoking consumption and prevalence, particularly amongst minors.
- The **process itself has been deeply flawed**. In all, twelve measures excluded from the public consultation are now adopted in the Proposal, for example the characterising flavours ban, small diameter cigarettes ban and a range of restrictive pack design elements.

A variety of major international business and intellectual property associations have also voiced their concerns on the EU's approach to the TPD review, with the Proposal now attracting strong criticism for its damaging impact on intellectual property and illicit trade.

JTI does not object to all of the elements of the Proposal, and indeed positively welcomes certain aspects, for example, the introduction of a standardised and harmonised ingredients reporting process as based on EMTOC (Electronic Model Tobacco Control) and the 2007 EU Practical Guide would be a helpful development (if the ingredients regime is not expanded in such a way as to become unworkable). However, the key proposals suffer from very significant procedural, evidential, legal and constitutional flaws.

We have long advocated that alternative, more proportionate solutions are available to prevent underage smoking and support legitimate public health policy objectives. This package of measures should include: better enforcement to tackle the illicit trade (including more penalties and prosecutions); reinforcing retail access preventions measures such as 'No ID, No Sale' in the UK; greater resources and manpower to support the current regulatory regime; penalising proxy purchasing by adults; penalising the purchase or attempted purchase of tobacco products by minors; and targeted public information campaigns.

In summary, we ask UK Parliamentarians to urge the UK Government to consider carefully the implications of the draft Proposal and to request that the Commission re-considers its approach in light of the serious negative impacts which could result.

28 February 2013

An additional letter from Ben Townsend, JTI UK, dated 28 March 2013 is available here

Roy Ramm and Peter Sheridan – Written submission

We are contacting you in your capacity as the Chair of the House of Lords EU Sub Committee F, to provide you with a considered view on the potential implications of the proposed EU regulations on the international tobacco black market. It is a matter we feel very passionate about and we hope you will acknowledge our views as part your committee considerations.

We are two former senior officers that have collectively served for over 60 years in the police service tackling domestic and international organised crime.

Between us career positions have included - Assistant Chief Constable with the Police Service of Northern Ireland responsible for Crime Operations including cross-border smuggling; and Commander of Specialist Operations at New Scotland Yard leading the Organised Crimes branch, the Flying Squad and the Fraud Squad.

During our careers we have conducted numerous operations against organised crime in the UK, EU, US, Russia, Africa and Asia.

We hope you will find our experience relevant when considering our view about the potential impact that TPD might have on tobacco smuggling and the fight against organised crime.

Our two principle areas of concern in these proposals are:

- **Standardisation of tobacco packaging** (Articles 7, 8, 9, 13: Labelling and Packaging) may make tobacco packets easier to copy because there will be fewer distinguishing features to replicate. It will make it much harder for retailers, consumers and police on the streets to distinguish black market goods from the real thing, making meaningful intelligence operations much harder.
- **Prohibition** (Article 6: Regulation of Ingredients) of any consumable goods could create another market for criminal gangs to exploit. The EU regulations would ban a number of tobacco products currently sold by retailers, such as menthol and slim cigarettes that could cause further exploitation.

Below is some further information to help illustrate these concerns.

Organised Criminal Operations

Smuggled tobacco comes to the UK from the Far East, UAE, China, Russia and Eastern Europe predominantly. These sophisticated operations are run by highly organised criminal gangs and help to fund other criminal activity.

The Financial Action Task Force, an inter---governmental body composed of 34 member states (including UK, Germany, China, Russia and South Africa), has reported that tobacco smuggling "*is a low risk, high profit enterprise that entices traditional criminal traffickers to move into more lucrative and dangerous criminal enterprises such as money laundering, arms dealing and drug trafficking.*" (FATF, Illicit Tobacco Trade Report, June 2012)

These criminal gangs operate in a similar manner to legitimate businesses. They closely monitor all new regulations to see if they present opportunities to increase their profits. We firmly believe the proposed TPD regulations will provide significant opportunity for criminal elements to do just that.

Lucrative Market

High taxation on tobacco products has made the UK and Ireland very attractive to organised crime. According to HMRC's *Measuring Tax Gaps 2012* report, the black market is worth approximately £3 billion every year. For example, an average pack of twenty cigarettes costs approximately £7.50 of which around £5.50 is tax. A criminal can make the same counterfeit packet outside Europe for 25p and sell it for up to £4. Organised criminals can make approximately £1.2 million profit per 40ft container lorry coming into the UK. The margin of profit is worth the risk of arrest and imprisonment.

One of the justifications for the new regulations is to create a level playing field for the internal market. But there is already a dual market in operation here, a legal one and an illegal one. The more regulated one market becomes the more opportunities are created in the other. Until these criminal opportunities are fully understood and respective mitigation measures taken, the idea of a level playing field will be undermined.

Intelligence Led Operations

Pivotal to any operation against organised crime is good street level intelligence. Any standardisation of pack appearance may make it more difficult to spot and track smuggled tobacco because the lack of distinguishing features make it more difficult to identify.
Only law enforcement officers carrying specialist equipment can detect covert markings. This equipment is not available to retailers and consumers who rely instead on colour, embossing and shapes to authenticate a pack.

Dissident Groups

We know from previous operations that members of the dissident Irish Republican groups such as the CIRA and the RIRA use counterfeit and non-duty-paid tobacco to fund their continued activities - including funding terrorist organisatisons. This is corroborated in the 25th report of the Independent Monitoring Commission in 2010.

Groups such as the PKK, Islamic Jihad, Al-Qaeda, Hezbollah and Hamas are widely known to finance their terrorist operations through selling counterfeit or non-duty- paid tobacco. As recent events in Algeria demonstrate, the Al-Qaeda terrorist leader, Mokhtar Belmokhtar (aka Mr. Marlboro), has funded militant jihadist networks in the region through tobacco smuggling.

In our experience, many people are not aware of this fact and they view smuggled tobacco as a 'Robin Hood' crime.

The TPD proposals risk compounding this view because it will ban already popular tobacco products allowing criminals to fill the hole, giving the consumer what they want. We must do

more to help communities understand the damaging nature this organised crime can have and in doing so encourage more people to come forward with information.

Alternative Options

We believe that before additional tobacco control options are considered, a more thorough analysis should be carried out on the potential impact of those policies on the organised crime market. This analysis should include projections of how new regulations in the legal market present new opportunities in the illegal market. For example, how the banning menthol cigarettes could increase distribution of these products in the illegal market. Additionally, other non-regulatory options should be assessed that will have less unintended consequences on the illegal market, including better education.

We would also like to see member states spend less time on symbolic cessation driven regulations if the evidence base is scant and more time considering practical measures such as tougher sentencing for illegal tobacco crimes. This would help foster a more negative community response to this organised crime.

Paradoxically, if member states focused on combating the black market they could produce better overall improvements to public health. Smuggled counterfeit tobacco contains levels of cadmium and other highly toxic metals. These products are often targeted at those communities with low levels of disposable income. Therefore any increase in levels of counterfeit tobacco as a result of the TPD regulations could embed and not break cycles of ill-health and crime in these areas.

28 February 2013

Smokefree Action – Written submission

Standardised packaging of tobacco products

The Smokefree Action Coalition (SFAC) is writing to urge you to write to the Secretary of State for Health, the Rt Hon. Jeremy Hunt MP, to request that he ensures that legislation to put all tobacco products in plain standard packs is included in the forthcoming parliamentary session.

The enclosed advertisement in Total Politics demonstrates that putting tobacco products in standardised packs is a popular measure. Public opinion polls show that 63% of the public and over 190 health organisations in the Smokefree Action Coalition, including medical royal colleges, the BMA, the Trading Standards Institute, the Chartered Institute of Environmental Health, the Faculty of Public Health, and the Association of Directors of Public Health, support the introduction of standard packs[33].

Since the government's consultation on standardised packaging of tobacco products ended over six months ago 78,500 children will have started smoking in the UK. We are calling on the government to make a decision now since every day we wait another 430 children start smoking[34].

Legislation which ensures tobacco packaging is free from attractive and misleading designs will help to discourage children from starting to smoke[35]. Smoking is a childhood addiction, not an adult choice, with two thirds of smokers starting smoking before the age of 18[36] Half of all lifelong smokers will die from their addiction, amounting to over 100,000 people last year in the UK[37].

The tobacco industry is claiming that standardised packaging will increase the illegal tobacco trade and lead to loss of jobs in small retailers and packaging companies. These are arguments that the industry has used against all previous tobacco control measures but the evidence has not shown this to be the case[38].

Branded tobacco packaging is no obstacle to counterfeiters and standardised packs would carry the same covert markings currently used to distinguish legal from illicit tobacco products. Early research from Australia has shown that retailers have found it straightforward to introduce the measure since December 2012. Indeed, the time taken to serve customers has reduced since standard packs were introduced[39]. Tobacco sales will decline gradually but not overnight as the main impact will be on reducing uptake amongst young people and not on current smokers, so shops will have time to adapt.

25 February 2013

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[33] An online poll undertaken by YouGov for Cancer Research UK. Total sample size was 2064 adults. Fieldwork was undertaken between 16th - 19th November 2012 The figures have been weighted and are representative of all UK adults (aged 18+).

[34] Estimate based on figures taken by CRUK from Smoking, Drinking and Drug Use Among Young People in England (2001 to 2010).

[35] See evidence summarised in the Public Health Research Consortium report, Plain Tobacco Packaging: A Systematic Review, published on the launch of the consultation in 2012.

[36] See data from the General Lifestyle Survey, 2010.

[37] Data from national sources from England, Scotland, Wales and Northern Ireland.

[38] Smuggling, the tobacco industry, and plain packs. A report by Luk Joossens for Cancer Research UK, November 2012.

[39] See letter from Owen Carter, Edith Cowan University, Western Australia, published in the BMJ on 11th February 2013

Tobacco Manufacturers' Association – Written submission

Introduction:
The Tobacco Manufacturers' Association (TMA) is the trade association for tobacco companies that operate in the UK.

It has three member companies: British American Tobacco UK Ltd, Gallaher Ltd (a member of the Japan Tobacco International group) and Imperial Tobacco Ltd (http://www.the-tma.org.uk/).

The TMA also supports the Tobacco Retailers Alliance (TRA), a network of 26,000 independent shopkeepers who all sell tobacco as part of their product range http://www.tobaccoretailersalliance.org.uk/).

Legislative Context in the European Union (the EU):

The Proposal

The revision to the TPD (the Proposal) was adopted by the European Commission on 19th December 2012 to replace the TPD (2001/37/EC). The provisions in the Proposal move towards a standardisation of pack and product design, through use of 75% health warnings (legislation in the UK currently requires 30% text warning on the front of packs, and 40% picture warning on the back), the introduction of the requirement that packs are cuboid in shape, a ban on selling cigarettes in packs of less than 20 cigarettes or hand-rolling tobacco in pouches of less than 40g, and a ban on characterising flavourings such as menthol. It also proposes new regulations on internet sales, complex 'track and trace' requirements, and restrictions on the nicotine content of 'e-cigarettes', as well as proposing new regulations on herbal tobacco products and 'novel' tobacco products.

Legal framework

The Proposal is based on Article 114 of the Treaty on the Functioning of the EU (TFEU) which permits the EU to improve the functioning of the internal market. The internal market is an area of *shared competence* of the EU and its member states (MS) (Article 4 TFEU). In areas of shared competence, the principle of subsidiarity dictates that the EU should not act *unless* the Union adds value and produces benefits that could not be achieved at the MS level. Established in 1992 following the Maastricht Agreement, the principle of subsidiarity dictates that all decisions should be made "close to its citizens" and should "respect the history, culture and traditions of individual nations." Further, it confirms that the EU may "act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by Member States…but can…be better achieved at Union level" (Article 5 (3) TFEU). It is worth noting that there are also distinct MS consumer preferences for particular tobacco products – for example, a significant proportion of consumers in both the UK and Poland prefer menthol cigarettes; smokeless tobacco products (Snus) are more popular than traditional tobacco products in Sweden; and 'slim' cigarettes make up 30% of the market in Bulgaria.

The Proposal violates the principle of subsidiarity, as it attempts to introduce public health measures (which are primarily a national competence) under the guise of 'harmonisation'

under Article 114 when the provisions in the Proposal, in fact, encourage more diversification than harmonisation. For example, MS are free to go further than the Proposal's 'standardisation' requirement and introduce 'plain packaging' for tobacco products if they wish. In a speech to the European Parliament on 25 February 2013, Commissioner Borg has been candid about the fact that the Proposal is a health measure. He said that the Proposal "is a health issue" and the aim of the Proposal is that "when people look at tobacco product they realise that it will damage their health" and repeated that "the main aim is saving lives."

The EU has no competence to adopt harmonising measures – such as a directive – with the direct objective of protecting public health regarding tobacco. Article 6 of the TFEU limits the EU's competence in the area of public health to actions "to support, coordinate or supplement" MS. Article 168 (5) TFEU expressly states that the EU may adopt "measures which have as their direct objective the protection of human health regarding tobacco and the abuse of alcohol, *excluding any harmonisation* of the laws and regulations of the Member States."

The EU will achieve *an impermissible 'land-grab' of powers* for itself from MS if the Proposal is adopted in its current form. The UK government is currently consulting on the balance of competencies between UK government departments and the EU, and the Proposal provides a clear example of how MS powers may be compromised despite an agreed legal framework[40]. The Commission is seeking to acquire delegated or implementing powers in 16 areas that effectively transfer public health policy regarding tobacco products (and non-tobacco products) to the Commission, without proper oversight by MS:

- Setting future maximum yields of TNCO and introducing new measurement methods (Articles 3.2, 4.3)
- Setting future maximum yields for other (as yet unidentified) emissions and their measurement methods (Articles 3.2, 4.3)
- Determining whether a product has a "characterising flavour", adopting rules on the procedures for such determinations and, ultimately, prohibiting additives over maximum levels that are said to impart such flavours (Articles 3.2, 4.3)
- Prohibiting additives (or their maximum quantities) that increase in an appreciable manner at the stage of consumption, the toxic or addictive effect of a tobacco product (Articles 6.2, 6.9)
- Mandating the shape and size of tobacco product packages (Articles 13.3, 13.4)
- Mandating the contractual provisions between private companies and applicable technical standards regarding tracking and tracing obligations (Article 14.9)#
- Determining the thresholds at which nicotine-containing products are treated as medicines (Article 18.2)

The proposed provision for the EU to acquire delegating powers contravenes Article 290 of the TFEU which indicates that only "non-essential elements" can be delegated (when, in fact, the areas above are essential areas of tobacco control policy) and which clearly requires that "the objectives, content, scope and duration of the delegated powers shall be explicitly defined in the legislative acts."

[40] Member companies have submitted a detailed response to the Department of Health's call for evidence regarding balance of competences. The TMA would be happy to provide copies of the responses if that would be of assistance.

The Proposal undermines a number of fundamental rights and other protections that are guaranteed under the EU Charter of Fundamental Rights and the European Convention on Human Rights (ECHR). These rights include the right to property (including intellectual property), the right to freedom of expression (including commercial speech), the right to conduct business, and the rights of consumers to receive information, and to choose. In particular, the proposed provisions on packaging not only unjustifiably impair the use of existing trademarks and innovation in the area of patents but also breach international law. The Proposal *violates a number of important obligations of the EU under the relevant rules of the WTO* and, in particular, the Agreement on Technical Barriers to Trade (TBT Agreement) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). The Proposal also introduces 'track and trace' measures, despite the fact that such requirements are already covered by existing international treaty, the Protocol to Eliminate Illicit Trade in Tobacco Products.

Better Regulation?

Article 5.3 of the Framework Convention on Tobacco Control (FCTC)

It is necessary and right to engage all stakeholders in policy-making. Indeed the Department of Health has recently met with the TMA member companies to discuss a consultation-stage impact assessment. Further, Catherine Day, the current Secretary-General of the European Commission recently confirmed that Article 5.3 of the FCTC and the relevant guidelines had been wrongly used:

"*First and foremost, it is important to underline that the WHO Guidelines for the implementation of Article 5.3 of the FCTC are not binding. Parties are encouraged to follow them to the extent possible, in accordance with their national law. Those Guidelines contain no specific compulsory requirements on holding meetings or on the publicity of such meetings*."[41]

Given that the Commission accepts the correct interpretation of FCTC guidelines, it is concerning to say the least that the UK's Permanent Representatives in Brussels have declined to meet with the TMA and its member companies, incorrectly citing Article 5.3. This is especially disappointing given that virtually all other MS Permanent Representatives are meeting with the tobacco manufacturers in relation to the Proposal.

Indeed transparency and stakeholder participation are critical to ensuring that the resulting regulation is effective, proportionate and meaningful. It is profoundly undemocratic and injurious to the UK's position in Europe, that the views of citizens and legitimate businesses in the UK should be ignored.

The Impact Assessment (IA)

The TMA also has concerns regarding the IA accompanying the Proposal as the IA is inadequate and breaches Better Regulation principles. Not only does the wording of the IA not necessarily match up with the wording in the Proposal, there are three measures included in the proposal which were specifically excluded from the Consultation. In addition,

[41] See http://www.alter-eu.org/sites/default/files/documents/RE%20Alter-EU.pdf.

following the 2010 RAND report, a further 12 measures which did not feature in either the earlier analysis for the Commission (the RAND report) or the public consultation are now included in the Proposal.

The IA is based on a series of assumptions rather than evidence. The 'finger in the air' argument that a 2% reduction in smoking prevalence will be achieved is a case in point. Dangerously, however, assumptions are then used to justify a set of disparate proposals that allegedly will have an effect on smoking behaviour. In particular, the Proposal and the IA are both based on incorrect assumptions about smoking behaviour. The IA is premised on the idea that the Proposal will 'increase awareness' although there is no evidence that consumers lack awareness about risks of smoking. Further, evidence indicates that children who smoke, do so because of the influence of peer or family members who smoke, and because they have access to tobacco. Interventions such as the TPD or the Proposal that have a 'deficit model' of smoking behaviour, based on assumptions of smoker ignorance and vulnerability, inevitably will not work.

Tobacco is a controversial product, but it is a legal and already highly-regulated product. Tobacco Companies are not opposed to further regulation of their product, but any further regulation must be:

- Necessary
- Proportionate
- Evidence-based
- And in line with 'Better Regulation' principles.

The Proposal is not *necessary* – there is no evidence that adult or youth smoking prevalence is increasing. It is, in fact, in decline across Europe. This proposal is not *proportionate* – despite the fact that the Commission believes there is confusion caused by so-called 'misleading' terms, it does not consider merits of any labelling options that would be more targeted and proportionate.

It is also concerning that on the important issue of preventing youth smoking, measures that seek to *reduce children's access to cigarettes* (such as a ban on proxy purchasing) are ignored, in favour of speculation about 'misleading' colours and flavours, when there is no credible evidence that these play any part in youth initiation. Rather than any direct access-based solutions to tackle youth smoking (which would be outside of the EU's legal competence), the Proposal instead seeks to change consumer behaviour by disproportionate measures which not only will not work but also restrict the operation of legitimate businesses.
The proposals are not '*evidence-based',* and the predicted 2% reduction in smoking prevalence in the IA is no more than a 'finger in the air' best guess. For all these reasons and more, the proposal is *not in-line with 'Better Regulation'* principles; and certainly not in line with the Better Regulation Executive's "One in, Two Out" (OITO) approach to reducing unnecessary business red tape and regulation. It is also noticeable that the Proposal does not comply with the same high standards that the EU requires of its MS in terms of the evidence required to support trade barriers and the availability of less restrictive alternatives.

Proposals:

The proposal does not have a proper legal basis, is not based on credible evidence, and premised on incorrect assumptions about smoking behaviour. It is, therefore, perhaps not

surprising, that the proposals themselves *will not bring about the desired outcome.* In many cases, the Proposal will *have unintended negative consequences* instead.

Requirements relating to tobacco packaging

While there is no credible evidence that further standardisation of pack size, shape, opening and 75% health warnings will have an impact on adult smoking prevalence or youth initiation, it will affect over 70,000 UK jobs in the supply chain in retail, packaging and wholesale by 'homogenising' the tobacco market and infringing the value of many brands, patents and investments in new technology, stifling innovation which makes the product harder to counterfeit. Further, illicit traders will fill the gaps in the market created by the bans on various products, such as menthol and slim cigarettes, providing lucrative opportunities for criminal gangs and racketeers to further infiltrate into local communities. Studies by tobacco control groups such as 'Fresh' have shown that 14 and 15 years olds are twice as likely to purchase illicit tobacco than adults. Homogenising the tobacco market will only worsen illicit trade and increase the opportunities for those underage to buy tobacco.

These are just some of the reasons that led over *half a million people in the UK to oppose* the government's proposals to introduce standardised or 'plain' packaging in the recent UK consultation. This unprecedented level of responses represents views from thousands of members of the public as well as retailers, packaging companies, marketing and design firms, manufacturers, wholesalers, politicians, employers, employees, business groups, trade unions, the intellectual property community, international business, trade associations and the law enforcement community.

Banning whole categories of products

The proposal to ban flavoured cigarettes, including menthol, is an unjustifiable restriction on consumer choice and has no evidential basis. The scientific evidence does not support the contention that menthol increases smoking initiation, prevalence or harmfulness. Further, to reiterate the point made earlier, consumption of menthol cigarettes is strongly associated with cultural preference of MS consumers. MS consumers also demonstrate varying preferences in relation to slim cigarettes, which make up 30% of the market in Bulgaria but only 0.4% in the UK.

Similarly, proposals to ban crush-ball or capsule technologies in filters are both anti-innovation and anti-competitive, based on the spurious belief that these will increase smoking initiation through making tobacco more 'attractive'. Flavourings may improve the taste of a product for some existing smokers. The question of whether a flavour is 'attractive', however, is a highly subjective one. 'Attractiveness' per se cannot serve as a regulatory goal, objective or yardstick as it is inherently subjective and, therefore, arbitrary.

Proposing a ban of whole categories of products on the premise that they appeal more to women is not only based on a flawed understanding of tobacco consumption patterns across Europe, it also raises questions about the appropriateness of introducing legislative bans on a gender basis. No scientific criteria have been developed to assess the attractiveness of tobacco products, or their ingredients, let alone to regulate on that basis. The role of flavouring in smoking initiation is, in any case, not supported by worldwide consumption patterns of flavoured versus non-flavoured tobacco products.

Minimum pack/pouch sizes

One of the provisions in the Proposal is the requirement to sell cigarettes in packs of a minimum of 20, and hand-rolling tobacco in pouches of no less than 40g. Apart from the fact that this provision, at a stroke, destroys the businesses of UK companies who make other kinds of packaging for tobacco, such as tins and tubs, it in effect obligates the consumer to 'super-size' their tobacco consumption. Such suggestion is akin to mandating that sugary drinks must only be sold in 'supersize' volumes – it does not make sense. Many people in the UK purchase packs of 10 cigarettes as a way of managing or reducing their consumption, while nearly 80% of the hand-rolling tobacco market is sold in 12.5g or 25g quantities.

Mandating minimum pack/pouch sizes, if unchanged, could also lead to consumers sourcing other suppliers for their products, including those involved in the illegal trade, which will deny the UK Treasury of its much needed revenue. Retailers will be particularly hard hit by the provisions in the Proposal which in effect will see scores of legal products removed from their shelves, without there being any public health benefits. As these products will still be manufactured and sold legally *outside* the EU, and will provide a significant market opportunity for criminal gangs operating *inside* the EU, consumers may simply opt to buy their preferred product from 'other' sources. Further, it will damage the viability of UK retailers, unnecessarily damage UK jobs and businesses in the packaging industry, deprive the UK Treasury of further revenue – it currently loses up to *£8 million per day* to the illicit trade in tobacco – increase the profits and prevalence of criminal gangs, and increase access opportunities for young people to buy tobacco – illicit tobacco sellers do not ask for ID.

Novel tobacco products and other tobacco products

The Proposal also proposes new restrictions on novel tobacco products, e-cigarettes, herbal cigarettes, and maintains the existing bans on sale of 'snus' within the EU, outside of Sweden. As the trade association for tobacco manufacturers, this area is outside the remit of the TMA.

Trace and trace

The Proposal also provides for provisions regarding 'track and trace' which already form part of legal agreements between the TMA member companies and OLAF, as well as being part of the recently agreed WHO Protocol to Eliminate Illicit Trade in Tobacco Products. It is the view of the TMA that these track and trace provisions have no place within the Proposal.

Conclusion:

The Proposal does not have a proper legal basis and lacks a discernible evidence base. The provisions in the Proposal are broad and diverse and will affect a huge number of businesses in the UK and throughout the EU. CECCM, the tobacco industry European trade association, notes that there are more than 1.5 million jobs in the tobacco industry and its supply chain across Europe.

The Proposal is also based on flawed views about smoking behaviour and is therefore unlikely to achieve the behaviour change it seeks to achieve. There are, however, likely to be a number of serious unintended consequences, including impacts on businesses and

employment, an increase in illicit trade, a reduction in UK tax receipts, and increased opportunities for children to access illicit tobacco.

We urge the UK government to consider carefully the issues raised in this submission and submissions made by member companies to Department of Health's review of the balance of competences about harmonisation, subsidiarity, and the management of shared competences between Europe and MS. We also urge the government to carefully question whether the evidence base presented provides sufficient support for the measures included in the Proposal, and to reflect that effective regulation can only be developed through open and transparent dialogue with those being regulated, and that the views of consumers and manufacturers need to be genuinely taken on board throughout the negotiation process.

Jaine Chisholm Caunt
Secretary General, Tobacco Manufacturers' Association

March 2013

Tobacco Manufacturers' Association – Supplementary written submission

Further to my appearance before the Committee on 6 March 2013, on the inquiry on the European Commission's proposal to revise the EU Tobacco Products Directive *(the Proposal),* and Paul Dowling's subsequent email of March 13th, I would like to provide some additional information regarding matters raised at the hearing.

Obligations under the Framework Convention on Tobacco Control *(FCTC)* and infringements of fundamental rights

Lord Tomlinson and Lord Richard referred (Uncorrected transcript, pages 14-16) to a letter from Mr Ben Townsend of JTI UK concerning tensions with international law and infringements of fundamental rights.

First, I attach a letter that I have received from Mr Ben Townsend in which he sets out further details of the infringements of legal rights occasioned by the Proposal, in response to the questions raised by the Committee.

Secondly, regarding the reference to the FCTC, it is TMA's view that the EU is fully compliant with the obligations imposed by the FCTe. It is important to distinguish between the *obligations* imposed by the text of the FCTC and the *non-binding guidelines* (adopted subsequently by the Conference of the Parties - COP) which address issues above and beyond the FCTC itself. The existing EU obligations may not go as far as the Guidelines. However, given the fact that the Guidelines are not binding, the EU is already in full compliance with the FCTe's obligations.

As set out in TMA's submission to the Select Committee, Catherine Day, the current Secretary General of the European Commission recently confirmed this point: "*First and foremost, it is important to underline that the WHO Guidelines for the implementation of Article* 5.3 *of the FCTC are not binding. Parties are encouraged* to *follow them* to *the extent possible, in accordance with their national law. Those Guidelines contain no specific compulsory requirements on holding meetings or on the publicity of such meetings.*"[42] While this statement had been made specifically in relation to Article 5.3, the same principle applies to all FCTC guidelines.[43]

European Court of Justice ruling on the original Tobacco Products Directive

The Chairman asked for details as to whether the TMA contested the subsidiarity of the original TPD before the European Court of Justice (Uncorrected transcript, page 7). The TMA did not challenge the original TPD. However, the TMA's member companies sought a judicial review of the original TPD, and that case was ruled upon by the European Court of

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[42] See http://www.alter-eu.org/sites/default/files/documents/RE%20Alter-EU.pdf

[43] Similar confirmations have been made in a number of occasions in COP decisions. For examples, in relation to Article 12, it was stated that (emphasis added): "*Emphasizing that the aim oj these guidelines is* to *assist Parties* to *meet their obligations under Article* 12 *of the WHO FCTC and that they are not intended* to *increase Parties*' obligations under this article." (FCTC/COP/4/DIV/6: GL on Art 12)

Justice on 10 December 2002 (Case C-491/01, *British American Tobacco (Investments) Ltd* [2002] ECR 111453). I attach a copy of the judgment and the opinion of the Advocate General.

The ECJ assessed the original TPD against the principle of subsidiarity and the then applicable Treaty provisions on legal basis (which have subsequently changed) at paragraphs 177 to 185 of its judgment, and concluded that the TPD was not invalid by reason of an infringement of that principle.

The tobacco market, competition between manufacturers and existing legislation

It may assist the Committee if I provide additional details of the UK tobacco market, competition between manufacturers and existing tobacco control legislation in order to address certain points raised by the Committee in this regard (Uncorrected transcript, notably pages 25 and 28-30).

The UK tobacco market is a mature and declining market. The Department of Health reported, in its 2012 Consultation on Standardised Packaging of Tobacco Products, that the rate of smoking in the UK has fallen to around 21% (from around 28% in 1998). Also, HMRC's data shows that UK duty-paid cigarette volumes have fallen from 56.6 billion sticks in 2000 to 40.4 billion sticks in 2012.[44]

Manufacturers compete and innovate in order to increase their share (of the declining market). Packaging and pack labelling are fundamental to the operation of the market economy in legal tobacco products, consumer choice, innovation, product information and brand value. The Proposal would restrict manufacturers' ability to differentiate their products, firstly, by mandating pack shape, size and design and, secondly, by restricting branding and trademarks to less than 25% of the front and back of cigarette packs.

In this regard, the TMA does not accept the contention that the cigarette pack itself constitutes a form of promotional advertising. The advertising and promotion of tobacco products have been progressively banned since 1965. All television commercials for cigarettes were banned in the UK on 1st August 1965. Non-television advertising campaigns came under stricter guidelines in 1986, which notably prevented advertisements from showing a person smoking.

The 1989 Television Without Frontiers Directive (89/552) banned all forms of television advertising for cigarettes and other tobacco products. The UK Tobacco Advertising and Promotion Act 2002 then progressively banned, with criminal sanctions for non-compliance, general advertising in the UK such as on billboards and in cinemas, promotions, sponsorship of national and international sporting events, retail advertising and merchandising such as ash trays or parasols. The 2003 Tobacco Advertising Directive (2003/33) banned tobacco advertising on radio, printed publications, the internet and international sponsorship.

The TPD, adopted in 2001, regulated the labelling of tobacco products. It required, notably, that health warnings appear on 30% and 40% of the front and back of cigarette packets in the

[44] See "Summary Table - Quantities Released for Consumption (sheet 6)" published in HMRC's February 2013 Tobacco Bulletin

UK and banned descriptors, such as "light", "low tar" and "ultra light", that might suggest a product is less harmful than others. These elements of the TPD were implemented into UK law by the Tobacco Products (Manufacture, Presentation and Sale)(Safety) Regulations 2002 (2002 No. 3041). Picture warnings on packs were introduced in the UK under the Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007 (2007 No. 2473).

The tobacco control regime therefore separates out the regulation of (a) the advertising and promotion of tobacco products and (b) the labelling and design of the pack itself. Tobacco product packaging is not explicitly included within the definition of tobacco "advertising" in the legislation of any EU Member State. Similarly, tobacco advertising, promotion and sponsorship is dealt with in Article 13 of the FCTC, and Article 11 deals with packaging and labelling of tobacco products.

28 March 2013

Annex – Letter from Ben Townsend (JTI UK) to Jayne Chisholm Caunt (TMA), dated 28 March 2013

Further to your recent attendance at hearing held by the House of Lords' EU Sub-Committee to consider the European Commission's proposal to revise the EU Tobacco Products Directive *(the Proposal),* I understand that the Sub-Committee addressed questions to you arising from my letter of 20 February 2013 to the Clerk of the Sub-Committee, in particular, asking for more information about the ways in which Proposal infringes upon intellectual property rights, freedom of expression and trading rights.

I set out in this letter some additional information about the effects of the Proposal in respect of these fundamental legal rights, in case this is helpful for you.

Appropriate and Proportionate Regulation

I should note, at the outset, that JTI believes that appropriate and proportionate regulation is both necessary and right. Tobacco products carry risks to health. Minors should not smoke and should not be able to obtain tobacco products. Everyone should be appropriately informed about the health risks of smoking. These core principles are central to our Code of Conduct, Global Marketing Standard, operational policies and the way JTI does business.

Tobacco is a legal product, and manufacturers compete among themselves for their share of the legal tobacco market. JTI acts with openness and transparency about the products adult smokers choose to purchase. Adults who choose to smoke are entitled to be treated fairly, and have the right to choose the product they prefer.

Additional information in respect of fundamental legal rights affected by the Proposal

As set out in my letter of 20 February 2013, it is JTI's view that the extreme and disproportionate prohibitions and requirements in respect of pack design and outsized pictorial health warnings unjustifiably infringe fundamental legal rights to property, expression and trade. Relevant protections are contained in the following instruments:

- the EU Treaties, the Charter of Fundamental Rights, and the general principles of EU law, notably including Articles 11 (freedom of expression), 16 JTI UK (freedom to conduct a business) and 17 (right to property) of the Charter (and their equivalent protections in the European Convention on Human Rights) and the principles of legal certainty, equal treatment and proportionality;
- national constitutional protections, as enshrined in the Human Rights Act;
- international trade treaties and international intellectual property laws to which the UK and the EU are parties, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights *(TRIPS),* the Agreement on Technical Barriers to Trade *(TBT),* and the World Intellectual Property Organisation's Paris Convention for the Protection of Intellectual Property *(Paris Convention);* and
- bilateral investment treaties that have been entered into by certain EU Member States, notably with Switzerland (in which JTI has its international headquarters).

Under the Proposal, manufacturers would be deprived - contrary to fundamental rights and international law protections - of using various trademarks and design rights that they have in respect of pack design (e.g. 3D pack shape, pack front trademarks, etc) and a wide range of product descriptors. Indeed, the inability to use certain branding trademarks as registered. notably device marks, in the remaining space would deprive manufacturers of their use. Such deprivations are presumed to be disproportionate unless fully compensated, which is not provided for in the Proposal.

Even if certain intellectual property rights, such as some branding trademarks, are not deprived of use, they may only be used in a remaining space, being 25% (or less) of the front and back of cigarette packaging. The reduction in size and/or the necessary redesigns for use in that space may unjustifiably impair the very substance of those intellectual property rights, as well as the associated goodwill and value of the brands and get-up. Manufacturers would not have sufficient space for the normal use of their intellectual property rights. The Proposal restricts, without compensation or justification, manufacturers' normal use of their trademarks and other intellectual property rights, and amounts to an unjustified and disproportionate interference with manufacturers' property rights.

The European Court of Justice has considered the issue of the size of health warnings in Case C-491/01, *British American Tobacco (Investments) Ltd.* In terms of the decision in that case, the Proposal may not leave manufacturers "*sufficient space*" to affix their trademarks, such that "*normal usage is* no *longer possible*" and the very substance of the trade mark rights are impaired. In this regard, Advocate General Geelhoed noted as part of the justification for the existing TPD's health warnings of 30% and 40% of the front and back of the pack that this "*amounts to even less than 50%*". It is clear that the Proposal significantly exceed these thresholds and gives rise to deprivations and impairments of intellectual property.

Further information

JTI also recently made a submission to the Department of Health and Children for Ireland in response to its consultation in respect of the Proposal. This submission considers the Proposal in more detail, including the points raised by the Sub-Committee. I attach a copy of this submission for your information. We would, of course be happy for a copy to be provided to the Sub-Committee if this would be helpful in addressing the questions arising from my letter.

I would be happy to provide further information if it would assist.

Dr David Upton – Written submission

I have today watched with interest the committee meeting regarding the EU TPD.

I was disappointed to see that one aspect of the proposed directive was not discussed in the depth I would consider necessary. Rather, it failed to give due regard to what evidence does exist. This aspect could have the most significant public health impact on smoking cessation of the 21st century. I believe that both representatives that spoke do not have a full & adequate understanding of the key issues with regard to this aspect. In particular, Jean King's assertion that NCP's should be regulated as other NRT products – i.e. as medicinal products needs to be challenged.

I should, perhaps, first point out that I have no connection with the tobacco; electronic cigarette or pharmaceutical industries and that I do strongly support measures to prevent young people from beginning to start smoking. I also support changes to packaging to dissuade existing smokers. I have nothing other than a personal commitment to harm reduction.

The issue of how the EU TPD arrived at the levels of nicotine whereby medicinal authorisation would be required is, I suspect, based on assumptions regarding how much nicotine is in a single (normal) cigarette, or single low dose NRT gum, and makes the (incorrect) assumption that e-cigarettes are used in exactly the same manner.
Minister Borg has been asked by a number of people, to my knowledge, to present the evidence regarding how these levels were decided upon. He has not responded to calls for the evidence as far as I am aware.

There is very little rigorous scientific evidence in general, and none that I have seen which could be used to justify the chosen levels. I am happy to supply you with the references to academic studies on E-cigarettes (those which support my view & the two or so that do not) should this be helpful to you. I would also be happy to provide further help by email if you would find this useful and I may be able to suggest an expert witness on the subject, since I do not consider myself such – merely someone who has experience of the practical.

In my opinion, a 20 a day smoker moving from normal cigarettes to electronic cigarettes will need a nicotine liquid somewhere between 36mg/ml and 24mg/ml to start. Most heavy smokers seem to be able to 'manage' on between 18mg/ml and 24mg/ml for maintenance, although a starter might require 36mg/ml. E-cigarettes are used in a different way to combustible cigarettes – a combustible cig. Has a finite 'life' – say 5 minutes, whereas an e-cigarette is 'puffed' slower & longer & put down before a normal cig. would be finished. Roughly speaking, a new user of e-cigarettes will consume approx. 3.5 – 6ml of liquid per day & in reality this (roughly) equates with a pack of 20 combustible cigarettes in terms of overall nicotine provided. In this respect the proposed EU levels would effectively ban e-cigarettes by regulation (they state a max of 4mg/ml).

Should medicinal regulation be required, as suggested by Jean King, the manufacturers would be required to apply for marketing authorisation from the MHRA. This process would take around 2 years at cost per individual product (& there are hundreds) I would estimate at around £2M per product (based on pharma. Product MA's). Unfortunately, the majority of manufacturers are (as far as I know) one man or SME's without the funds to cover this. Only

the tobacco or Pharmaceutical industries have sufficient funds to deal with this & apart from putting these SME's out of business, there is an arguably more serious consequence:

Around 700,000 individuals in the UK currently using e-cigarettes would have no choice but to go back to tobacco.

Reputable dealers in the UK use EU sourced pharma. grade nicotine, propylene glycol and aqueous glycerine in their products and they are already regulated by a range of consumer regulations. (I can detail if you require)

I fully accept the need to provide the consumer with safe products but if trading standards are allowed to monitor vendors and ensure that (already regulated) pharma grade products are the only ones allowed, surely there should be no problem. Every vendor I have come across so far uses adequate labelling, CHIP bottles, won't sell to under 18's etc. It seems to me that the industry is already quite good at regulating itself & there are quite active internet fora (or example http://ukvapers.org) whereby rogue traders are likely to be quickly pointed out by consumers.

I am embarrassed to admit that I was a smoker myself until August 2012. I have been well aware of the danger of smoking since my teens in the 1960's/70's. I have tried both NHS and private quit methods many times over the last few years and nothing worked. I continued to smoke & my health was deteriorating.

I tried an e-cigarette during July of last year with the full expectation that it could possibly work. I made the assessment that with the amount of money that the NHS spends on smoking cessation, e-cigarettes would've been recommended by my own GP, had they been safe and efficacious.

Prior to purchasing, I used the limited resources of the internet to investigate academic journal articles on the subject. I am now convinced that we currently cannot say that e-cigarettes are safe (and we will almost certainly be unable to do so objectively for another 10 to 20 years). However, I strongly believe that the evidence of analyses that I have seen in peer reviewed documents indicates to me that e-cigarettes are somewhere between 95-99% safer that combustible cigarettes and that they may prove to be 100% safe – only time will tell.

The MHRA consultation exercise – which was NOT well publicised – produced many hundreds, albeit anecdotal, replies testifying to how e-cigs had been beneficial for people giving up cigarettes where no other method had worked.

My concern about the MHRA regulating is based on the fact that there seems to be very much a revolving door policy regarding staffing of the organisation from pharmaceutical organisations and clearly if medical regulation is introduced, the only likely winners will be the pharmaceutical companies. There does seem to be a game being played by the pharma. organisations at the moment in that they seem to be on the look-out for any claims that e-cigarettes can help people quit – if they find them they can argue that a medical claim has been made & therefore that e-cigs are medicinal & must be regulated ... by them in effect.

Thus, consumers are confused – friends tell them that e-cigs really work to quit fags but they go to a vendor and see disclaimers about e-cigs not being a medicinal product and to see their GP for cessation. This is a public health scandal caused by 'interested parties'.

I apologise for writing such a long letter to you & I'm sure that it must be tedious going through such correspondence. I do, however, feel that e-cigarettes could represent a means of drastically reducing smoking in the UK – were they to be given a 'level playing field' without the influence of the big pharmaceutical companies and without the influence of the tobacco companies.

7 March 2013