A response to the Department of Health request for Philip Morris Limited (PML) views on the EU Tobacco Products Directive

Further to the meeting on 30th January 2013, the Department of Health (DH) asked PML to provide our views on the current European Commission's proposal for a new Tobacco Products Directive, COM(2012) 788 final (TPD). We appreciate the opportunity to give our comments on certain aspects of the Commission's proposal.

It is a matter of principle for our Company to seek and support comprehensive, science-based regulation for all tobacco products. We do believe, however, that the proposal adopted by the EU Commission is misguided for numerous reasons and should be rejected.

The Commission's proposal is not acceptable in terms of its contents because it will lead to considerable market distortion with drastic effects on competition, employment and tax revenues, while not even coming near to achieving the envisaged objectives of public health policy. We highlight below our concerns in relation to the proposed ban on menthol cigarettes (one of several proposed prohibitive measures), the pack standardisation measures, and how the proposal prevents the access of smokers to reduced risk products.

Moreover, the EU lacks the competence to legislate as the proposed measures are not covered by the internal market competence laid down in Article 114 (1) of the Treaty on the Functioning of the European Union (TFEU). Finally, we also illustrate the severe deficiencies of the Commission's Impact Assessment and urge the UK Government to conduct its own impact assessment specifically for the impact the proposed new TPD will have on the UK.

1. The ban on menthol cigarettes will eliminate 8.5% of the UK cigarette market, which will give an additional boost to illicit trade and hurt the UK economy

The Commission's proposal calls for a ban on menthol cigarettes, which over 5 million smokers in the EU prefer (4.6% EU-wide market share). In the UK, menthol cigarettes represent 8.5% of total legal sales (3.4 bio cigarettes). This amount is nearly the same as all cigarette sales combined in Yorkshire and Humberside. Menthol cigarettes generate significant tax revenues: 4.4 billion EUR in the EU and 945 million pounds (1.1 bio EUR) in the UK alone.

The Commission's desire to simply ban this important segment is not supported by scientific evidence and ignores the severe negative consequences that will flow from such a prohibitionist approach.

a. Boost to illicit trade

If menthol cigarettes are banned, menthol smokers will have only one source to buy their preferred cigarettes: the already thriving illicit trade. As the Court of Justice's Advocate General has already recognised "*…it is entirely reasonable to assume that an illegal market will be established in cigarettes that are banned within the European Union but which can be obtained outside it*".[1] Similarly, in the recent debate in the U.S. on regulation of menthol

[1] Case C-491/01 British American Tobacco (Investments) and Imperial Tobacco. Opinion of Advocate General Geelhoed, delivered on 10 September 2002, paragraph 158.

cigarettes, law enforcement specialists warned that "*[p]rohibition of a previously legal product – specifically menthol cigarettes – [is] going to drive up criminal smuggling across this nation's already under-policed borders*."[2]

The substitution with illicit products will deprive the UK of tax revenue and hurt legitimate businesses, including many small retailers. We strongly urge the UK Government to assess the impact that prohibiting 8.5% of the entire market will have on illicit trade, jobs and tax revenues. Our own estimates indicate, for instance, that even in a conservative scenario where only about 30% of current menthol smokers move to the illicit trade (instead of switching to non-menthol cigarettes), 4,500 jobs would be lost, in particular in the retail sector, where small retailers will be particularly hard hit. This will also result in an additional loss of tax revenue in the amount of 260 million EUR. Obviously, the actual impact can be even much higher than in this rather conservative scenario.

However, the Commission failed to analyse or discuss these potential effects. In its Impact Assessment, the Commission limits its analysis to a footnote reading "*It is important to underline that the preferred policy options do not – in the assessment of the Commission – lead to increased illicit trade*."[3] Such a blanket assertion is obviously not sufficient for a solid impact assessment. Nobody asks the Commission to assume as a certainty that illicit trade will increase. But given its fundamental influence on central elements of the Impact Assessment and the severe economic consequences, the Commission should have at least considered it as one of several possible scenarios.

The risk of smokers substituting with illicit cigarettes is particularly high in countries where illicit trade is already widespread, as is the case in the UK. Despite law enforcement's considerable progress, nearly 11 billion units of illicit tobacco products are still consumed in the UK each year, equal to more than 9% of the total UK cigarette market[4] and 38% of the hand-rolling tobacco market. In total, illegal tobacco sales already cost the UK Treasury up to 2.9 billion pounds per year.[5]

Menthol cigarettes, too, are already available in UK black market channels, in proportions that roughly mirror the legal market demand for those products.[6] This phenomenon shows that the illicit market will be ready to satisfy an increasing demand for menthol cigarettes when these will no longer be available on the legal market.

b. Lack of Evidence

The Commission provides no evidence that menthol cigarettes turn non-smokers into smokers and prevent smokers from trying to quit or that banning menthol cigarettes will

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[2] Ted Deeds, Chief Operating Officer of Law Enforcement Alliance Of America, Law Enforcement Alliance Of America Sounds Alarm About Illicit Tobacco Trade, The Street, 27 May 2010.

[3] Impact Assessment, p. 6, footnote 31.

[4] KPMG, Project Star Results 2011, p. 262, available at http://www.pmi.com/eng/tobacco_regulation/illicit_trade/documents/project%20star%202011%20results.pdf; HMRC, Measuring Tax Gaps 2012, 18 October 2012, p. 20, available at http://www.hmrc.gov.uk/statistics/tax-gaps/mtg-2012.pdf.

[5] HMRC and UK Border Agency, Tackling Tobacco Smuggling – building on our success, April 2011.

[6] PMI empty pack survey study conducted in 2012: menthol cigarettes represented 7% of the total collected sample of non-domestic products.

reduce smoking prevalence among youth or adults. In fact, the Commission relies on assumptions and is highly biased in how it has selected and presents the studies it claims support its proposal.

Citing a 2010 study by SCENIHR on additives,[7] the Commission claims that menthol facilitates deeper inhalation as well as smoking uptake among young people. This claim is demonstrably false and runs contrary to the scientific advice provided to the Commission by SCENIHR on tobacco additives. In fact, the Committee stated that "…*there is a* ***lack of evidence regarding the specific impact of menthol on smoking behaviour***..." and that "[T]*he potential for menthol … to influence smoking initiation and behaviour is discussed in the report but the* ***data are inconclusive***" (emphasis added).

In a March 7, 2012 meeting with industry stakeholders, DG SANCO specifically requested the industry to produce any data and studies it deemed relevant on the issue of menthol cigarettes (among other issues). One week later, DG SANCO received a wide range of data, including several key publications showing that banning menthol is not supported by science.[8] Yet, none of these data and studies are even mentioned in the Commission's analysis of the evidence, let alone considered or discussed.

There is also a conspicuous absence of EU-specific data on actual youth brand preferences, which would be a necessary starting point for any claim that a given type of product triggers youth smoking initiation. However, the limited available data (not considered by the Commission) all point to the same conclusion: underage and young smokers smoke the brands most prominent on the market. SCENIHR made this observation, in fact based on UK data: "*data from the UK … suggest*[s] *that brand preferences of children and adults can be quite similar.*" "[T]*he most popular brands with 11-16 year olds were: Mayfair (58%), Lambert & Butler (56%), Richmond (45%), Benson & Hedges (28%) and Sovereign (23%). Four of the brands were common to both adults and youth…*"[9]

Still, the Commission seeks to tie menthol to increases in youth smoking, even though no such evidence exists. For example, the Commission states that "[t]*he market share of menthol* [cigarettes] *has more than doubled in Germany in the past ten years, from 1.3 to 3%*". What the Commission fails to report, however, is that, in Germany, over the same period, youth smoking rates steadily decreased, reaching an all-time low in 2011.[10] Clearly, an increasing relative preference for menthol cigarettes in Germany has not prevented the steady decline in youth smoking prevalence.

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[7] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Addictiveness and Attractiveness of Tobacco Additives, 12 November 2010.

[8] See, for example, American Council on Science and Health, The Mentholation of Cigarettes, Spring 2010; Blot, W. J., et al., Lung cancer risk among smokers of menthol cigarettes. Journal of the National Cancer Institute (10) 810-6, 2011; Cubbin C, et al., The intersection of gender and race/ethnicity in smoking behaviors among menthol and non menthol smokers in the United States, Addiction 105:32 38, 2010.

[9] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Addictiveness and Attractiveness of Tobacco Additives, 12 November 2010.

[10] The percentage of smokers among young people aged between 12 and 17 years has dropped to 11.7% in 2011 from 27.5% in 2001. Smoking prevalence among young adults aged 18 to 25 has declined significantly during the same period, to 36.8% from 44.5%. Drug affinity among young in the Federal Republic of Germany, Federal Central Office for Health Education (BZgA), 2011.

The Commission could have made similar findings in the UK, where menthol consumption is higher than in Germany. The 2012 Smoking, Drinking and Drug Use survey shows that the prevalence of regular smoking among the 11-15 year old has decreased from 11% in 1982 to 5% in 2011.[11] Over the same period, the market share of menthol cigarettes almost doubled, from 4.6% in 2001 to 7.9% in 2011.[12] Thus, UK-specific data confirm that it is simply false to claim, as the Commission does, that menthol will be an obstacle to reducing smoking rates.

Cross-country comparisons likewise demonstrate that there is no correlation between the availability of menthol cigarettes and youth smoking prevalence. A recent study from Oxford Economics analysed whether, globally, there is any statistically significant relationship between the market share of menthol cigarettes and youth (aged 13-15) smoking rates.[13] Their analysis of a sample of 52 countries worldwide shows that "*…there is no evidence to support the hypothesis that greater availability of menthol cigarettes (as represented by market share) is associated with higher youth smoking prevalence – overall, male and female*."[14] The authors conclude: "*Our results do not support the notion that menthol cigarettes contribute to an increased smoking prevalence among young people, neither male, nor female*."

2. The proposed packaging standardisation <u>will lead to a fall in prices and increased illicit trade, impacting the UK economy</u>

While the Commission's proposal does not include full plain packaging, it still introduces a very substantial degree of pack standardisation: it more than doubles the total size of the current health warnings by introducing 75%/75% combined health warnings (pictorial and textual) on the front and back, and 50% textual warnings on both side panels. In the thus reduced space left for manufacturers, the proposed measures will further restrict the scope for branding by, e.g. prohibiting product descriptions that refer to flavour and taste and banning "misleading colours". In addition, the new packaging requirements also mandate the shape, format, layout, fabric and design of the pack, and, de facto, its dimensions (through the introduction of specific minimum sizes for health warnings).

As per our discussion on January 30th, we have provided a detailed response on standardised (plain) packaging in our 2012 UK consultation submission, including several expert reports and studies on the topic. As you know, this will be shortly complemented by our response to the questions the DH raised in the impact assessment. We believe that the information on standardised packaging in the UK substantially applies also to the new labeling and packaging standardisation measures proposed by the Commission.

For example, the sweeping standardisation measures will make it more difficult for tobacco companies to sell more expensive premium brands, which will put pressure on prices. The

[11] Smoking drinking and drug use among young people in England in 2011, The Information Centre for Health and Social Care, 2012.

[12] PMI data; 2001 earliest year available.

[13] Oxford Economics, The influence of the availability of menthol cigarettes on youth smoking prevalence, December 2012, Commissioned by Philip Morris International. Attached as Appendix 1.

[14] The data used (Tobacco Atlas Fourth Edition) also shows that, in the EU, UK has the lowest youth smoking rate (13-15) in 2011. Many countries with much lower menthol presence have much higher youth smoking rates, e.g. 20% in the Netherlands (menthol: 4%); 18.9% in Spain (menthol: 0.2%); 20.7% in Italy (menthol: 0.3%).

Commission failed to consider this possibility. Lower prices can result in higher consumption. Lower prices are also very likely to impact tax revenues as well as the income of virtually all economic actors in the tobacco sector, including hundreds of thousands of small retailers. Accordingly, lower prices will also mean less employment across the EU and in the UK.

Indeed, the Commission's own consultant RAND Europe had discussed that "*with possibly less or no space on the pack to display brand logos and recognizable graphical features, it will become difficult for tobacco companies to sustain their brands and sell their products at a premium rate*." Furthermore, PMI had submitted a range of studies and data on this topic, including upon specific request of the Commission. Against this backdrop, it is not conceivable how the Commission could have failed to look at such scenarios of falling prices and how they negatively impact employment and tax revenues.

3. In violation of fundamental principles of European law and governance, the proposal seeks to shift competences from Member States to the EU, and at EU level from the Parliament and Council to the Commission

a. No legal basis for the EU to introduce the proposed measures

The Commission proposes far-reaching changes to the TPD. Indeed, as the Commission itself states, "*in many areas very substantial changes are proposed and some are added to the Directive.*"[15] Without exception, all proposed changes are pursuing public health objectives. The Commission is quite explicit about this, for instance, when it articulates the overarching problem: "*The lack of EU action negatively affects EU citizens in terms of premature mortality, expensive health care treatment and inadequate consumer information.*"[16] However, the EU is not competent to regulate in public health matters.

b. The Union may only act within the powers conferred on it by the Member States

According to Article 5(1) of the Treaty on European Union (TEU), "*the limits of Union competences are governed by the principle of conferral*". This principle means that the EU is able to legislate only on the basis and within the limits of the competences specifically conferred on it by the Member States in the Treaties. National competence remains the rule, whereas EU competence is the exception. Public health is not a power conferred by the Member States to the Union. It is a genuine national competence (see Article 168(7) Treaty on the Functioning of the European Union – TFEU).

The Commission seeks to circumvent this competence rule by artificially constructing an internal market competence under Article 114 TFEU. This must be rejected for overstepping the boundaries set by the Treaties and for the damage it would do to the balance of competences between the UK and other Member States and the EU.

[15] Explanatory Memorandum, p. 3.

[16] Impact Assessment, p. 22.

c. *The Commission's proposal fails to meet the internal market standard under Article 114 TFEU*

The EU is competent to adopt harmonisation measures under Article 114 TFEU only when they are "*intended to **improve** the conditions for the establishment and functioning of the internal market and must **genuinely** have that object, actually contributing to the elimination of **obstacles to the free movement of goods** … or to the **removal of distortions of competition***".[17]

The Commission's proposal does not begin to meet this standard. Consider some of the "*very substantial changes*" such as the ban of menthol cigarettes, the ban of slims cigarettes and the proposed pack standardisation measures: Does the Commission explain and provide evidence that these are in fact "*obstacles to the free movement of goods*" or "*distortions of competition*"? It does not. Does the Commission explain and provide evidence how its proposed measures actually contribute to improving competition and/or the free movement of goods? It does not. There is no substantive, concrete analysis. Instead, the Commission merely invokes vague and abstract language such as "*heterogeneous development*", "*fragmentation of the internal market*", and "*legislative divergence*" to describe the status quo, and similarly empty phrases such as "*more homogenous development*" and "*level playing field*" to state what it seeks to achieve.

In essence, all the Commission is able to point to are some differences in national legislation.[18] That, however, is not enough. As the Court of Justice of the European Union (Court of Justice or CJEU) has held, if mere findings of disparities were enough to justify Union competence under Article 114 TFEU (formerly Article 95 EC), then "*the powers of the Community legislature would be practically unlimited.*"[19]

It is therefore not surprising that the Impact Assessment Board, in its second opinion on the Directorate General for Health & Consumers' (DG SANCO) Impact Assessment dated 12 July 2012 raised strong doubts about the internal market competence:

> *"[T]he evidence presented, in terms of concrete obstacles for economic operators affecting the functioning of the relevant markets, remains weak*."
>
> *"[T]he presented evidence does not suggest any significant negative impacts of the current situation on the functioning of the internal market.*"[20]

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[17] CJEU, C-491/01 British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd, judgment of 10 December 2002, paragraph 60 (emphasis added); C-58/08 Vodafone Ltd and Others v Secretary of State for Business, Enterprise and Regulatory Reform, judgment of 8 June 2010 (Roaming Decision), paragraph 32; Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 15696/10, 5 November 2010, p. 5, paragraphs 13/22.

[18] On many measures, the Commission is unable to even point to differences in legislation. E.g. no Member State has banned menthol cigarettes, no Member State has banned slims cigarettes.

[19] CJEU, C-376/98 Federal Republic of Germany v European Parliament and Council of the European Union, judgment of 5 October 2000, paragraph 107.

[20] Impact Assessment, 12 July 2012, available at http://ec.europa.eu under 2012 impact assessment (IA) reports / IAB opinions.

The Foreign Secretary in his Call for Evidence as part of the Government's review of the balance of competences between the UK and the EU describes the internal market as follows:

> "*The Internal Market of the EU is an area without internal frontiers designed to ensure the free movement of goods, services, capital and persons: the so-called Four Freedoms. Greater integration within an Internal Market reduces the autonomy of Member States to act independently,* ***but can bring significant benefits as the barriers to trade between Member States are removed***."

The Foreign Secretary goes on to explain: "*The* ***economic gains*** *from a single market in principle come in many ways, notably from* ***economies of scale*** *due to the* ***creation of a larger market than the purely national one***."[21]

The proposed measures, however, do not lead to any economic gains. There are no "*economies of scale*" and no such "*significant benefits*". Measures such as standardising the size and shape of the pack or banning products do nothing to further the internal market by creating a larger market than the national one. In fact, far from improving the internal market, the measures proposed by the Commission will result in *creating obstacles* to trade as well as *reducing competition*. Clearly, prohibiting outright 10% of the current EU cigarette market (menthol and slims cigarettes) erects the most drastic and insurmountable obstacle to trade for such cigarettes: their trade will cease to exist. Standardising the packaging of tobacco products and drastically reducing the space available for branding will limit product differentiation and competition.

Again, this is something the Impact Assessment Board had pointed out already. In its first opinion dated 20 April 2012, the Impact Assessment Board had urged DG SANCO to "*reconsider presenting as an enhancement of the internal market measures aimed at* ***removing products from the market****, banning cross-border distance sales or* ***limiting product differentiation***."[22]

The Court of Justice and the Commission have recognised the importance of branding to the proper functioning of competitive markets, including those for tobacco products.[23] The Court of Justice has emphasised that using trademarks is an "*essential element in the system of undistorted competition which the Treaty seeks to establish and maintain*".[24] Measures that eliminate branding and other elements of product differentiation will eliminate this "*essential element*". They will undermine the internal market which, according to the Treaty, "*includes a system ensuring that competition is not distorted*".[25]

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[21] Department of Business Innovation & Skills, Government Review of the Balance of Competences Between the United Kingdom and the European Union, November 2012, paragraph 10 (emphasis added).

[22] Available at http://ec.europa.eu under 2012 impact assessment (IA) reports / IAB opinions (emphasis added)

[23] See, for example, CJEU, C-10/89 SA CNL-SUCAL NV v Hag GF AG, judgment of 17 October 1990, paragraph 13; C-487/07 L'Oréal v SA v Bellure NV, judgment of 18 June 2009, paragraph 58; C-491/01 British American Tobacco (Investments) and Imperial Tobacco, judgment of 10 December 2002; Case No COMP/M.2779, Imperial Tobacco/Reemtsma Cigarettenfabriken, 08 May 2002, paragraph 54; and Case COMP/M.4581, Imperial Tobacco/Altadis, 18/10/2007, paragraph 68.

[24] CJEU, C-10/89 SA CNL-SUCAL NV v Hag GF AG, judgment of 17 October 1990, paragraph 13.

[25] Lisbon Treaty Protocol (no. 27) on the Internal Market and Competition.

d. Damage to the balance of powers under the Treaties

The UK Government should be concerned about the Commission's attempt to assert competence on what clearly are health matters. Article 114 TFEU must have teeth in order to protect the balance of powers between the Member States on the one hand and the EU on the other hand. If the Commission can establish competence through blanket assertions of "*heterogeneous developments*" and "*level playing field*" then Article 114 TFEU will become an empty shell. It will only be up to the discretion of the Commission whether or not to invoke its newly established super-competence, which of course will extend beyond tobacco and beyond public health to any field of Member State competence.

Much has been written about how citizens in the UK and elsewhere are concerned about treaty after treaty changing the balance between what the EU can do Union-wide and what is left to the prerogative of the Member States to regulate. In a way, what's happening here is even worse. Completely unnoticed, without a treaty change, the EU is in the process of usurping legislative power that the Treaties unequivocally reserved for the Member States. This is a slippery slope, and the UK Government should be very concerned even if it believes that on the substance of the proposal its views are broadly aligned with the Commission.

e. The proposed measures do not stand scrutiny under the principle of subsidiarity

In his recent speech on the EU, David Cameron, the British Prime Minister, in simple and clear terms said what many people think: "*Countries are different. They make different choices. We cannot harmonise everything*." But the EU sometimes does harmonise for the sake of harmonisation without any real benefit for the internal market (see above) and without regard to the Member States' national affairs. That is why – in the words of the Prime Minister: "*People feel that the EU is heading in a direction that they never signed up to. They resent the interference in our national life by what they see as unnecessary rules and regulation. And they wonder what the point of it all is.*"[26]

It is precisely the principle of subsidiarity that protects the diversity of Member States and in particular Member States' ability to make different policy choices.

Article 5(3) TEU establishes that the Union may "*act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States … but can rather … be better achieved at Union level*". The principle of subsidiarity reflects the view that Member States should have priority over the Union in taking actions to the extent they have the capability to do so. It also reflects the view that decisions should be taken as closely as possible to the citizens, i.e., whenever possible at national level.

Accordingly, with respect to the new TPD, even if EU competence were established pursuant to Article 114 TFEU (which it is not), the Union would still have to show that its action adds value and produces benefits that cannot be achieved at local level.

This requirement is not theoretical. Article 5 of Protocol No. 2 annexed to the TFEU on the Application of the Principles of Subsidiarity and Proportionality requires that draft legislative

[26] David Cameron's speech on the EU, 23 January 2013

acts be justified with "*detailed statements making it possible to appraise compliance with the principles of subsidiarity and proportionality*". This justification should be substantiated by "*qualitative and, wherever possible, quantitative indicators*".

However, neither the Explanatory Memorandum nor the Commission's Impact Assessment provides such a detailed justification. Again, the Commission limits itself to generic references to "*heterogeneous developments*" and "*fragmentation*", arguing the blatantly obvious, namely that only the EU can impose rules for the entire EU. For example:

- On Nicotine Containing Products: "*only an initiative at EU level is capable of preventing further diversity and legal uncertainty*"[27]
- On health warnings and packaging requirements: "*only EU action can ensure homogeneous development*"[28]
- On additives: "*Only an initiative at EU level is capable of removing the current and expected diversity in terms of regulation and provide a standardised format for reporting of additives*."[29]

The lack of reasoning constitutes a major procedural flaw in that – contrary to Protocol No. 2 – national parliaments are not given the information they need to appraise whether the new TPD complies with the principle of subsidiarity.

Substantively, too, the Commission's proposal disrespects the principle of subsidiarity:

First, in emphasising the differences in national legislation (so-called "fragmentation"), the Commission ignores the simple fact that countries are different in terms of their tobacco markets. Consumers have different preferences, taxes and prices differ greatly, distribution systems vary from country to country, available brands are different, and attitudes towards smoking have been changing in different ways. Sweden's tobacco market is very different from Germany, and Bulgaria is different from the UK.

The Commission's Impact Assessment itself acknowledges the existence of "*national/cultural differences*" and "*different economic situation*[s]" in the Member States,[30] but ignores that it is quite normal, indeed desirable, that in an area where Member States have exclusive competence, they have chosen different approaches in how to regulate tobacco. The UK is a prime example for taking its own, national approaches to tobacco control. Indeed, in its White Paper *Healthy Lives, Healthy People: Our strategy for public health in England*, the UK Government takes subsidiarity even one step further by putting a particular focus on empowering local communities.

Second, the test applied by the Commission is circular and wrong. They say that "*Only a harmonised approach at EU-level in such areas can remove obstacles to cross-border trade and avoid fragmentation, while ensuring a comparable high level of health protection.*"[31] However, the test must be whether the public health objectives can be better achieved at national level. If the test were to ask at what level, EU or Member States, one can better

[27] Impact Assessment, p. 85.

[28] Impact Assessment, p. 97.

[29] Impact Assessment, p. 105.

[30] Impact Assessment, Annex 5, p. 3.

[31] Expl. Mem. paragraph 3.9.2.

achieve the harmonisation of laws then the subsidiarity test would be completely obsolete in Article 114 TFEU cases, because obviously it is not possible for individual Member States to harmonise laws across the EU.

Subsidiarity also means applying common sense in examining what the EU should be doing and what it should not be doing. For instance:

- Should the EU prescribe for everybody that a pack of cigarettes can be 55 mm wide, but not 54 mm?
- Should the EU prescribe for everybody that an individual cigarette can have a diameter of 7.5 mm, but not 7.4 mm?
- Should the EU prescribe for everybody that only so-called flip top boxes can have a pack opening and closing mechanism, but not soft packs?
- Should the EU prescribe for everybody that cigarette packs must have a "cuboid" shape?

A stringent assessment of whether or not a proposed EU Directive complies with the principle of subsidiarity is warranted especially in areas where competence lies originally with the Member States. That is why the Impact Assessment Board asked DG SANCO to clarify "*to what extent the principle of establishing equality in health protection is compatible with the discretion of Member States in defining their health policies.*"[32]

The UK in the past has not been shy to raise concerns when it thought that the principle of subsidiarity is being disrespected. The House of Commons, for example, has criticised that the Commission

> "*has failed to adduce clear evidence of the necessity for EU legislative action, which should include how it will achieve its stated objectives. …necessity is a pre-requisite both for action at EU level and for conformity with the principle of subsidiarity. …The perception of a need for the Commission to "express a more committed political approach" should not, in our view, be a replacement of evidence of necessity for the EU to act.*"[33]

In another case, the House of Commons again was not satisfied with vague assertions, but rather demanded real evidence:

> "*the Commission's explanatory memorandum and impact assessment are largely based on perceptions of a need to act, which are necessarily subjective, in contrast to objective evidence of a need to act.*"[34]

[32] IAB Opinion, 12 July 2012.

[33] Reasoned Opinion by the House of Commons on Proposal for a Council Regulation on the right to take collective action within the context of the freedom of establishment and the freedom to provide services across the EU (COM/2012/0130), 22 May 2012, paragraphs 4/15/23.

[34] Reasoned Opinion by the House of Commons, on Proposal for a Council Regulation on the right to take collective action within the context of the freedom of establishment and the freedom to provide services across the EU (COM/2012/0130), 22 May 2012, paragraph 17.

Indeed, the House of Commons requirements are crystal clear:

> "*The presumption in Article 5 TEU is that decisions should be taken as closely as possible to the EU citizen. A departure from this presumption should not be taken for granted but be justified with sufficient detail and clarity that an EU citizen can understand the qualitative and quantitative reasons leading to a conclusion that EU action rather than national action is justified.*"[35]

If the Commission's logic prevails, subsidiarity no longer means anything. It is the very nature of subsidiarity that countries have different rules in the area of health which is their primary competence. In essence, what the Commission claims is that (1) such differences are enough to take away competence, and (2) since only the EU can eliminate the differences through EU-wide regulation, EU action is consistent with the principle of subsidiarity. This is the exact opposite of what the Treaties intend in establishing the principles of conferral and subsidiarity. If the Commission has its way, the new (unwritten) rule will be: Member States can adopt national legislation only as long and insofar as the EU, at its sole discretion, does not impose harmonising Union-wide legislation.

f. Excessive use of delegated powers

Not only does the Commission's proposal seek to shift the balance of powers from the Member States to the EU, it also seeks to grant broad powers to the Commission – to the detriment of the Parliament and the Council and of Member States' national parliaments. Indeed, the Commission proposes to grant itself the power to adopt delegated acts for an indeterminate period of time and in no less than 16 different areas,[36] many of which relate to core elements of the TPD. In contrast, the current Directive contains only three references to comitology relating to the implementation of technical aspects.[37]

Pursuant to Article 290 TFEU, "*A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain* ***non-essential elements*** *of the legislative act.*" (emphasis added). The Commission's proposal fails to meet this requirement. To provide only a few examples:

- Articles 3(2) and (3) of the draft proposal allow the Commission to change the maximum level of tar, nicotine and carbon monoxide in cigarettes as well as the maximum level of other emissions both from cigarettes and other tobacco products that are marketed or manufactured in Member States in order to adapt them to scientific developments and international standards. The tar, nicotine and carbon monoxide ceilings were a major component of the current Directive when adopted in 2001. Allowing the Commission to change them through delegated act would mean giving the Commission the power to amend an essential element of the Directive. In fact, since the power would include the power to set nicotine levels at zero (see explicitly Article 2(19) draft proposal), the Commission could even ban the entire legal tobacco market in the EU by way of delegated act.

[35] Reasoned Opinion by the House of Commons on Proposal for a Council Directive on a Common Consolidated Corporate Tax Base, (COM/2011/0121), 12 May 2011, paragraph 19.

[36] See Article 22 of draft proposal.

[37] See Articles 9, 10 TPD regarding graphical health warnings; Article 5(3) regarding product identification and traceability; Article 5(9) regarding TNCO measurement methods.

- Article 9(3) of the draft proposal allows the Commission to modify the combined health warnings, both wording and photos, in order to adapt these in line with developments in science and on the market, plus the definition of the position, format, layout, design, rotation and proportions of these warnings. There can be no doubt that the content, proportions and design of health warnings are a central component of the current and the new TPD. Yet, under the proposal, the Commission would have the power to adopt new health warnings without recourse to the ordinary legislative procedure.

Again, the UK has not shied away from expressing concerns on legislative proposals that exceeded the Treaties' confines on delegation of powers. The UK Government, for example, took issue with the number and substance of delegated acts contained in a Commission proposal seeking to establish a general EU framework for data protection.[38] It expressed reservations that there "*is an excessive number of delegated … acts, which often does not constitute a correct exercise of the power conferred in the parent legislation – for example there are many instances in the instruments where the Commission has powers to impose further criteria or requirements which cut across essential aspects…*"[39]

In sum, the excessive use of delegated acts in the Commission's proposal should be rejected. The Court of Justice has recently confirmed that delegated powers find their limits for measures which "*entail*[s] *political choices falling within the responsibilities of the European Union legislative, in that it requires the conflicting interests at issue to be weighed up on the basis of a number of assessments.*"[40] It is also politically inappropriate because good law making must be respectful of the role of the Parliament, the Council and the national parliaments – all the more in light of the fact that the primary competence for regulating public health lies with the Member States, and not with the Union, let alone the Commission.

4. The proposal fails to regulate reduced risk products, and instead prevents consumers from getting access to less harmful alternatives to cigarettes

The TPD should be revised to recognise the important role that reduced harm products can play.

a. Tobacco Harm Reduction is an important complementary policy

The best way to reduce the harm of tobacco use is to prevent initiation and encourage cessation. However, despite the well-known health effects of tobacco use, many people continue to smoke and use other tobacco products. While smoking rates have continued to decline over the past decade, 21% of adults in England still smoke[41] . The situation is similar

[38] Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), COM(2012) 11 final, 2012/0011 (COD).

[39] Interinstitutional File: 2012/0011 (COD), p. 138, available at statewatch.org.

[40] CJEU, C-355/10 European Parliament v Council of the European Union, judgment of 5 September 2012, paragraph 76.

[41] HM Government, A Smokefree Future: A comprehensive tobacco control strategy for England, 2010.

across Europe.[42] Moreover, Nicotine Replacement Therapies (NRTs), used with or without counselling, have not meaningfully improved smokers' long-term chances of successfully quitting smoking.[43]

The UK Government has demonstrated leadership among EU Member States by embracing Tobacco Harm Reduction as an essential element of tobacco policy, recognising that smokers who are unwilling or unable to quit should have access to, and should be encouraged to use, reduced harm alternatives to cigarettes.[44] The head of the Cabinet Office's Behaviour Insights Team, David Halpern, explained the rationale in a recent article in *The Telegraph:*

> "*While many countries, unsure about their [electronic cigarettes'] health risks, have moved to ban them, Halpern's team thinks that's a mistake. It's far better, they argue, to ask smokers to adopt a similar behaviour that, while possibly not risk-free, is less dangerous than smoking proper, than to ask them to quit completely.*
>
> *'If you give someone a decent alternative, it's a lot easier," says Halpern. 'There are 10 or 12 million smokers in Britain, of which roughly half die from their habit. So even with a 20 per cent substitution, you're talking about a million lives.'"*[45]

Accordingly, the National Institute for Health and Clinical Excellence (NICE) is currently consulting on Draft Guidance on tobacco harm reduction,[46] and the Medicines and Healthcare products Regulatory Agency (MHRA) plans to announce a regulatory approach to nicotine-containing products such as electronic cigarettes in the coming months.[47] The Cabinet Office and public health experts have suggested taking a "light touch" regulatory approach to potentially safer alternatives to cigarettes.[48]

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[42] 28% of the EU population continues to smoke, despite the fact that over 60% have tried to quit over the past four years. Special Eurobarometer 385, 2012 – Attitudes of Europeans towards tobacco.

[43] HM Government A Smokefree Future: A comprehensive tobacco control strategy for England, 11, 2010 (noting that fewer than 3% of smokers succeed in quitting each year). See, for example, Alpert, H., Connolly, G. and Biener, L., A Prospective Cohort Study Challenging the Effectiveness of Population-Based Medical/Intervention for Smoking Cessation, Tobacco Control, 2012; Ferguson, J. et al, Effect of Offering Different Levels of Support and Free Nicotine Replacement Therapy via an English National Telephone Quitline: Randomised Controlled Trial, BMJ 344:e1696, 23 March 2012.

[44] HM Government, A Smokefree Future: A comprehensive tobacco control strategy for England, 2010; see also Royal College of Physicians Tobacco Advisory Group, Harm Reduction in Nicotine Addiction: Helping people who can't quit, 223, 2007.

[45] Chris Bell, Inside the Coalition's controversial 'Nudge Unit': Deep inside Whitehall, psychologists are finding ways to make you insulate your loft, pay your taxes, and even quit smoking. Is the Coalition's controversial 'Nudge Unit' finally paying off?, The Telegraph, 11 February 2013, available at: http://www.telegraph.co.uk/news/politics/9853384/Inside-the-Coalitions-controversial-Nudge-Unit.html

[46] See http://guidance.nice.org.uk/PHG/52/Consultation/Latest. PMI and PML's input to that consultation is attached as Appendix 2.

[47] The MHRA is currently overseeing a programme of research and information-gathering on the regulation of nicotine-containing products. The results of the programme will be announced in Spring 2013. www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617. A number of public health policy advocates and consumers have expressed concerns, however, that the MHRA's "light touch" will be too heavy. See, for example, Clive Bates, "Medicines regulation for e-cigarettes – when caution can kill", available at: http://www.clivebates.com/?p=787.

[48] See, for example, Cabinet Office, Behavioural Insights Team, Annual Update 2010-2011, p. 9 ("[*P*]*roducts that deliver nicotine quickly in a fine vapour instead of as harmful smoke could prove an effective substitute for 'conventional smoking'. It will be important to get the regulatory framework for these products right, to encourage new products, which smokers can use as safer nicotine alternatives, to be made available in the UK … If more alternative and safe nicotine products can be developed which are attractive enough to substitute people*

However, both the NICE consultation and MHRA research programme focus exclusively on products that do not contain tobacco. We believe that both non-tobacco products and tobacco-containing products can play an important role in harm reduction, and believe that the revised Tobacco Products Directive should reflect that. PMI is developing a range of products which have the potential to reduce the risk of smoking related disease in adult smokers who switch to them from conventional cigarettes. PMI's approach is to eliminate combustion and limit or eliminate pyrolysis while still providing adult smokers with products that they will accept as substitutes for conventional cigarettes. PMI believes that such products have the potential to significantly benefit public health, given that they are likely to be more acceptable substitutes for conventional cigarettes to a much wider group of smokers than current alternatives, because they come close to replicating the sensory experience and ritual of conventional cigarettes without generating many of the harmful compounds found in cigarette smoke.

We believe that if robust evidence substantiates that a product is less risky than conventional cigarettes, the new TPD should allow the product to be marketed accompanied by information which will allow adult smokers to make an informed choice about switching to that product.

b. The proposed Directive should encourage Tobacco Harm Reduction, not obstruct it

The current Tobacco Products Directive[49] recognises the importance of Tobacco Harm Reduction. Recital 8 of the Directive provides that *"[a] revision of the regulatory framework needs to evaluate evidence-based claims for tobacco products designed and/or marketed to 'reduce risk', or for which harm reduction is claimed by the manufacturer*." Similarly, Article 11 of the Directive calls for special attention to developments in scientific and technical knowledge with regard to "*tobacco products which may have the potential to reduce harm*."

The Commission's proposal, however, does not even mention reduced-risk tobacco products, much less make adequate progress in this important area. To the contrary, public health advocates have observed that "*[t]he proposed directive contains measures that could make it harder or impossible for smokers to switch from cigarettes to much less dangerous nicotine products – an approach that will cause more death and disease than it prevents."*[50] We think that is the wrong approach. We concur with the view that the new TPD should "*create an 'enabling framework' for … new, much less risky, alternatives to smoking to enter the market in a way that gives consumers confidence in switching from smoking."*[51] In the

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away from traditional cigarettes, they could have the potential to save tens of thousands of lives a year"); A. Stratton, Try smokeless nicotine cigarettes, says government: Cabinet office 'nudge unit' encourages use of product banned in many countries, in bid to reduce smoking-related deaths, The Guardian, 14 September 2011 (quoting Prof John Britton) ("*What we're asking for is a regulation change to bring all nicotine products into a light-touch regime that will guarantee reasonable purity and safety standards but make them as available as cigarettes in a shop."*).

[49] Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

[50] Clive Bates, EU draft Tobacco Products Directive: who to write to and what to say (a short guide), available at: http://www.clivebates.com/?p=739.

[51] Clive Bates, European Union making bad policy on nicotine – five ways to make it better, December 5, 2012, available at: http://www.clivebates.com/?p=697.

sections that follow, we set out some specific suggestions that can be accomplished in the revised Directive.

c. Article 17 should permit substantiated communication to allow consumers to make informed decisions

The Commission's proposal recognises the concept of novel products,[52] but it does not recognise the possibility that some novel products may be scientifically substantiated as reduced-risk. Article 17 would require manufacturers to notify Member States of any novel tobacco product they intend to place on the market and, as part of that notification, provide evidence including:

- Available scientific studies on toxicity, addictiveness and attractiveness of the product
- Available studies and market research on preferences of various consumer groups, including young people
- Other available and relevant information, including a risk/benefit analysis of the product, the expected effects on cessation of tobacco consumption, the expected effects on initiation of tobacco consumption and other predicted consumer perception

The Directive should permit novel products to be marketed as *reduced risk products provided that the lower risk is* scientifically substantiated, including by non-clinical, clinical and behavioural evidence.

Instead of facilitating consumer access to reduced risk products, Article 17 would mandate that all novel tobacco products "*respect the requirements set out in this Directive*," and would therefore:

- Prohibit any element or feature on product packaging that "*suggests that a particular tobacco product is less harmful than others*" (Article 12) regardless of whether such communication is accurate, non-misleading and scientifically substantiated
- Require that the products bear the same warning label requirements as conventional tobacco products intended for smoking (Article 10) or smokeless tobacco products (Article 11), regardless of the appropriateness of such warnings to the product

As drafted, Article 17 of the proposed Directive would "*den[y] consumers the most relevant information about lower risk tobacco products – information they could use to reduce their own risk and protect their health. This is misleading by omitting the most important information.*"[53]

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[52] Article 2(23) defines a "Novel tobacco product" as "*a tobacco product other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use placed on the market after entry into force of this Directive.*" It does not contain any separate provision for novel products which are substantiated to reduce risk.

[53] Clive Bates, EU draft Tobacco Products Directive: who to write to and what to say (a short guide), available at: http://www.clivebates.com/?p=739.

The new TPD should be regarded as an opportunity to provide consumers access to and information about reduced risk tobacco products, not to deny them such access. The Court of Justice in its judgment validating the current TPD already recognised the role that labelling requirements can have in communicating reduced risk when finding that, "[t]*hose obligations in fact constitute a recognised means … of guiding* [consumers] *towards such of those products as pose less risk to health."*[54] If the scientific evidence submitted by the manufacturer substantiates that a novel tobacco product reduces the risk of smoking-related disease, Member States should be able to permit the manufacturer to market the product as reduced-risk.

d. Article 18 should recognise that nicotine-containing products can play a role in harm reduction

Article 18 of the proposed Directive would regulate nicotine-containing products[55], and prohibit nicotine-containing products that exceed certain nicotine thresholds unless the products are approved as medicines.[56]

We believe that nicotine-containing products have a role to play in harm reduction. However, nicotine-containing products will only be effective substitutes for cigarettes if they are accepted by adult smokers.[57] Many existing Nicotine Replacement Therapies and other nicotine-containing products fail to replicate the sensory experience and ritual of smoking; as a result, many smokers do not accept them.[58] An additional limitation of existing products is "*the fact that no available licensed nicotine-containing product mimics the pharmacokinetic nicotine delivery characteristics of the cigarette*."[59]

The proposed Directive would prohibit nicotine-containing products unless they were approved as medical devices. A number of public health advocates have observed: "*The very weakest form of e-cigarettes … might escape medicines regulation. But these are extremely weak in e-cigarette terms, and not regarded as adequate substitutes for conventional cigarettes and unlikely to do much to help people switch from smoking*."[60] Confronted with that paradox, a number of public health advocates have questioned, "*Why*

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[54] CJEU, C-491/01 BAT, judgment of 10 December 2002, paragraph 131.

[55] Article 2(22) of the proposed Directive defines a "nicotine-containing product" as "*a product usable for consumption by consumers via inhalation, ingestion or in other forms and to which nicotine is either added during the manufacturing process or self-administered by the user before or during consumption*."

[56] Article 18 of the proposed Directive provides that "*The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:*

(a) products with a nicotine level exceeding 2 mg per unit, or

(b) products with a nicotine concentration exceeding 4 mg per ml or

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml."

[57] Cobb, C., Weaver, M., Eissenberg, T., Evaluating the Acute Effects of Oral, Non-Combustible Potential Reduced Exposure Products Marketed to Smokers, 19 Tobacco Control 367-73, 2010,; see also Le Houezec, J., Mcneill, A., and Britton, J., Tobacco, Nicotine and Harm Reduction, 30(2) Drug & Alcohol Review, 119-23, 2011.

[58] UK Centre for Tobacco Control Studies, Response to Consultation, MLX 364: Regulation of Nicotine Containing Products, available at: http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con102949.pdf.

[59] UK Centre for Tobacco Control Studies, Response to Consultation, MLX 364: Regulation of Nicotine Containing Products, available at: http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con102949.pdf.

[60] Clive Bates, EU draft Tobacco Products Directive: who to write to and what to say (a short guide), available at: http://www.clivebates.com/?p=739.

would governments make it harder to put these products on the market than the much more dangerous products they are designed to replace or compete with?"[61]

We are encouraged by the UK Government's desire to regulate nicotine-containing products under the medicines regime with a "light touch"; we think that the revised TPD should provide a regulatory pathway for nicotine-containing products which are not intended or marketed for use as medicines or medical devices, and should take a "light touch" in regulating them. Given existing uncertainty about the safety and quality of nicotine-containing products, we would recommend that e-cigarettes and other nicotine-containing products should be subject to quality control standards, ingredient disclosure requirements, and the requirement that any express or implied claim should be scientifically substantiated and not misleading.

5. The Commission's Impact Assessment is fundamentally flawed

We believe it is important that the UK Government critically review the Commission's Impact Assessment given it is the basis for the Commission's proposal and given the significant impacts the proposed measures will have on the UK. As you advised at our meeting on the 30th of January, a UK-specific impact assessment would be completed only at the transposition stage of the TPD, which as we both agreed at the meeting would be too late.

Therefore, we strongly encourage the UK Government to complete an impact assessment of their own, following the criteria set out in and by:

1. The Coalition – Reducing regulation made simple
2. Treasury – Green Book
3. The Coalition – IA Toolkit
4. The UK courts

This approach was explained by Rupert Darwall in his report; "Selecting the Evidence to Fit the Policy - *An Evaluation of the Department of Health's Consultation on Standardised Packaging",*[62] which we believe applies equally to the review of the TPD proposal by the UK Government.

In the following, we highlight certain key deficiencies of the Commission's Impact Assessment:

a. *The Impact Assessment fails to meet the evidentiary standards set in the Commission's own Impact Assessment Guidelines*

The Commission's Impact Assessment contains almost no consideration of empirical evidence and hard data, although such data is available. Instead, the Commission resorts to basing its assumptions and projections on speculative, soft "evidence", and dressing up mere guesswork as quantification.

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[61] Clive Bates, EU draft Tobacco Products Directive: who to write to and what to say (a short guide), available at: http://www.clivebates.com/?p=739.

[62] Rupert Darwall, Selecting the Evidence to Fit the Policy - An Evaluation of the Department of Health's Consultation on Standardised Packaging, provided to the DH on 30th January 2013.

The Impact Assessment Guidelines emphasise that an impact assessment should be based on comprehensive evidence, good quality data and robust analysis. Accordingly, evidence must be "*transparent, comprehensive and balanced*", and should provide "***sound analysis** supported by the **best data available**.*"[63] Indeed, "*the credibility of an IA depends to a large extent on providing results that are based **on reliable data and robust analysis**.*"[64] "*It must be clear that all these* [impact] *assessments are **based on evidence, including quantitative data.**"*[65] (emphasis in original).

The Guidelines are abundantly clear that quantification of the impacts is the cornerstone of the assessment process. Thus, the Guidelines expressly require "*quantitative estimations of impacts: the impacts are estimated using quantitative techniques, varying from simple extrapolation … through statistical inference on the basis of similar impacts and occurrences elsewhere (e.g., impact assessment work in Member States and other countries) to full-fledged quantitative modelling*."[66] *I*ndeed, quantification of impacts is the default position under the Guidelines, and deviations from it need to be justified: "*it is desirable to use quantitative approach where possible,*" and "[i]*f quantification is not possible* [the researcher should] *explain why.*"[67]

The approach followed by the Commission falls far short of the Guidelines' requirements. It is neither "*based on sound analysis*" nor "*supported by the best data available*."

For instance: The Impact Assessment Board stated in its first opinion that "*a more detailed analysis of trends and underlying drivers in smoking prevalence, particularly of young people*" was needed. However, no such analysis is included in the final Impact Assessment, which limits itself to vague assertions of how new products and packaging are particularly attractive to minors. The Commission failed to analyse readily available data of EU Member States, which would have allowed concrete conclusions as to whether the presence or absence of certain packaging or additives is correlated to patters of declining or growing (youth) smoking prevalence.

The Commission also failed to consider empirical studies and data which demonstrate that larger pictorial health warnings do not reduce smoking rates. These include studies that had been provided to the Commission upon its request.[68] Instead, the Commission relied only on a biased selection of published studies that have already been deemed speculative and inconclusive by many regulators, courts, and often enough even their own authors.

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[63] Impact Assessment Guidelines, 15 January 2009 (afterwards referred to as "Impact Assessment Guidelines"), p. 6. Note: emphasis is added in quotations throughout this document unless stated otherwise.

[64] Impact Assessment Guidelines, p. 32.

[65] Impact Assessment Guidelines, p. 45.

[66] Impact Assessment Guidelines, p. 38.

[67] Impact Assessment Guidelines, p. 5; Annex 9, p. 39.

[68] See, for example, Kleijnen Systematic Reviews Ltd, Systematic review of the effectiveness of an increase in the size of tobacco health warning labels on cigarette packs in reducing smoking, June 2011; Mulligan, C., Smoking Behavior in Canada: Before and After the 2000 Tobacco Warnings, University of Chicago, 2011; Gospodinov, N. et al., Global health warnings on tobacco packaging: evidence from the Canadian experiment, B.E. Journal of Economic Analysis & Policy, Vol. 4, No. 1, 2004, p. 1-21.

b. *The Commission presents false choices and disregards viable alternative options*

For instance: On packaging and labelling, the choice given is essentially between the status quo, 75/75 pictorial health warnings, and full plain packaging. It excludes deliberately the option of 50/50 health warnings with mandatory pictorials, although 50/50 pictorial health warnings would still be a substantial increase from the sizes under the current TPD. RAND Europe, in the initial impact assessment, specifically discussed this option, and found no quantitative difference between 50/50 and 75/75. Why has the Commission dropped this 50/50 option from the Impact Assessment, but then emphasises that "*There is no less stringent measure available*"?[69]

Another example: No alternatives at all are given to the complete ban of slims cigarettes, although this measure will remove from the market more than 5% of all cigarettes legally sold in the EU.[70] The slims cigarette ban is treated as an annex to the packaging and labelling options, lumped together with measures on product descriptions (Article 12). Given its huge impact, there should have been a separate analysis and presentation of possible policy options on how to regulate the marketing of slims cigarettes, if at all.

c. *The Commission failed to establish a proper baseline scenario*

In its assessment of the baseline (status quo) option, the Commission takes two different positions. On the one hand, it states that "[i]*n the absence of further tobacco control measures at EU level, it is likely that the trend in prevalence would revert, at least in those Member States not taking actions under the baseline scenario*."[71] On the other hand, "*it is assumed that the overall smoking prevalence will remain at the current level if no EU action is taken.*"[72] These are of course very different baseline scenarios, and, contrary to the assertions of the Commission, are not irrelevant for the assessment of the various options. Either way, no factual basis is provided for one or the other position, and the Commission makes no attempt to quantify its baseline scenario.

This is all the more remarkable because the Commission's assumption of reverting trends is in stark contrast to the projection that RAND Europe (i.e. the Commission's own consultant) had made for the initial impact assessment in 2010. RAND Europe estimated that under the baseline scenario (no changes in regulation) smoking prevalence would continue to decline, with an aggregate reduction of 7-8 percentage points over a period of 17 years.[73]

At a minimum, the Commission should have explained why its own assumptions for the baseline scenario are so dramatically different from the projections its consultant made two years ago.

[69] Impact Assessment p. 97.

[70] In the UK, slims cigarettes have a 0.1% market share.

[71] Impact Assessment p.43.

[72] Impact Assessment p. 43.

[73] RAND Europe, p. 88, figure 6.1.

d. The commission failed to consider the effects on price and illicit trade

Ignoring the effects on price and on illicit trade (as described in sections 1 and 2 above) threatens to compromise central elements of the Commission's assessment, in particular with respect to its estimates of smoking prevalence. On the one hand, lower prices can result in higher consumption thus changing the central metric of the Commission's assessment. Lower prices are also very likely to negatively impact tax revenues and employment across the EU. On the other hand, just because a particular measure causes a decline in legal sales says little about the measure's effectiveness in reducing smoking – in many instances, observable legal sales are simply being replaced by illicit sales not captured in the official statistics. Moreover, that decline in legal sales also means less tax revenues and fewer jobs.

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The discussion above is by far not exhaustive. The deficiencies we highlighted are illustrative for an overall misguided approach, which selects the evidence to fit the policy and fails to provide a data-driven, fair and transparent analysis and discussion of all relevant aspects.

We feel it is important that the UK reviews the TPD proposal and the Commission's Impact Assessment and completes its own impact assessment of the proposed measures, given the significant impact they will have on the UK – both in terms of economic impact (tax revenues, employment) and the infringement upon basic fundamental rights such as property and free speech. And as explained above, it will also severely limit the UK's competence and ability to regulate on public health matters, shifting significant powers to the EU and further to the Commission, all in violation of the EU Treaties.

Appendix 1 - Oxford Economics, The influence of the availability of menthol cigarettes on youth smoking prevalence, December 2012

Appendix 2 – PML Submission to NICE Consultation – December 2012