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Subject: Revision of TPD - E-cigarettes - TVECA (80 % of e-cigarettes stakeholder organisations) - Position Paper+Amendments
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Dear Mr Singhofen

It was a pleasure having you on the phone on 9 April concerning the revision of the Tobacco Products Directive (TPD). As indicated, we represent the **Tobacco Vapour Electronic Cigarette Association (TVECA)** during the ongoing revision of the Tobacco Directive (Ms McAvan's Report). TVECA represents approximately 80 % of EU e-cigarettes stakeholder organisations (please note that British ECITA is not part of TVECA).

As promised, and ahead of the AMs deadline on 6 May, please find attached the following documents:

- 1) TVECA Short position papers + proposed amendments
- 2) TVECA Comprehensive position paper (for a more detailed argumentation)

In brief, TVECA's position is as follows:

- 1) E-cigarettes are *less harmful substitutes* to conventional tobacco products (e.g. there is no combustion, hence no smoke and no passive smoking).
- 2) The Commission's proposal proposes to classify e-cigarettes as medicinal products (art. 18). This is a de-facto ban. E-cigarettes will simply never fulfil the *safety* (1) and *efficacy* (2) criteria in order to receive approval under the indicated legislation. Furthermore e-cigarettes are not medicinal products by presentation (1) and by function (2) which was ruled by courts of a number of EU member states, including Germany, the Netherlands and Estonia.
- 3) TVECA supports a level playing field between tobacco products and e-cigarettes. It is therefore proposed to include e-cigarettes in the scope of TPD and subject them to e-cigarettes-specific requirements.

We hope that your group would eventually support our position and Mr Slyter would consider tabling and/or co-signing some of the proposed amendments.

Please do not hesitate to contact us, should you have any further questions on TVECA position.

Kind regards

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Avoiding the *de facto* ban of electronic cigarettes as less harmful alternatives to conventional cigarettes in the EU Tobacco Products Directive

About TVECA

The Tobacco Vapor Electronic Cigarette Association (TVECA) is a non-profit association of private sector companies. Its members are involved in all sectors of the creation and promotion of electronic cigarettes. TVECA's membership includes companies in Germany, Italy, the UK and the Netherlands, with membership pending for more European companies in other EU Member States. It also represents all existing vendors' associations including in Italy, France and Germany. It no longer represents ECITA (UK).

TVECA represents approximately 80% of organised e-cigarette stakeholders in Europe.

TVECA's aim is to provide the tools and information necessary for policy-makers, media and private sector companies to make informed decisions, and to dispel highly inaccurate views and opinions.

TVECA is registered in the Transparency Register of the European Parliament and the European Commission under identification number 169778610761-14.

Further information on TVECA and its activities as well as a more extensive position paper and analysis on e-cigarettes in the EU Tobacco Products Directive can be found on the official website of the association via the following link: <http://www.tveca.com>.

E-cigarettes as less harmful alternatives to conventional cigarettes

E-cigarettes can be a viable and less harmful alternative to conventional smoking as in their presentation and user experience they mimic conventional smoking. In an e-cigarette a nicotine liquid is vaporised and then inhaled through the mouthpiece of the device. E-cigarettes therefore can satisfy smokers' nicotine craving while avoiding the risks associated with the process of combustion of tobacco that takes place in conventional tobacco products. Retailers all over the world have already sold millions of e-cigarettes (there are currently an estimated 3.5 million users), yet there is no evidence that these products have endangered anyone in case of normal use. Electronic cigarettes have been the focus of over 21 studies, including an FDA study in the U.S. Never has there been reported a single chemical or toxin at any levels harmful to humans.¹ Moreover, the e-cigarette causes no third party harm, as there is no second- or third-hand smoking, while more than 79,000 adults are said to die each year in the EU alone due to passive smoking. To date,

¹ See: <http://www.tveca.com/science.php> for the details of these studies.

despite the millions of users worldwide, there has been no harm detected from second- or third-hand vaping.

Need for strict and uniform regulation across the EU

As nicotine is known to be addictive, it is necessary to establish, for e-cigarettes, a strict and uniform regulatory framework that ensures a high level of protection as well as a level playing field across the EU. This means, among other things, that e-cigarettes should not be marketed or advertised to children and that their packaging should carry an appropriate health warning as regards the addictiveness of nicotine.

E-cigarettes cannot qualify as medicinal products under EU legislation and risk *de facto* to be banned

E-cigarettes are not currently regulated under a specific harmonised EU legislation but the Commission proposal of 19 December 2012 for the revised Tobacco Products Directive under Article 18 stipulates that all nicotine-containing products (thus including e-cigarettes, nicotine patches, lozenges, sprays, etc.), with the exception of those with very low nicotine content, must be authorised as medicinal products under Directive 2001/83 before they can be placed on the EU market.

This will mean a *de facto* ban on e-cigarettes as this nicotine-containing product category cannot qualify under EU legislation as a medicinal product.²

E-cigarettes are not presented as smoking cessation aids, contrary to nicotine replacement therapies (NRTs). As stated by the Court of Justice of the EU in *Commission v Germany*³ with regard to the presentation criterion, “a product is ‘presented for treating or preventing disease’ within the meaning of Directive 2001/83 when it is expressly ‘indicated’ or ‘recommended’ as such, possibly by means of labels, leaflets or oral representation”.⁴ The e-cigarette is neither recommended as a product for treating or preventing disease, nor is there any indication as such, whether by means of the label, the information printed on the external packaging, or in any other way. The e-cigarette is presented as a pleasure product for smokers who wish to continue their nicotine intake, and it does not claim to have any preventative or treatment properties for smoking cessation and/or nicotine addiction.

E-cigarettes also do not have any physiological effect on the human being. Indeed, the European Court of Justice has ruled that a product must have “a significant effect on the metabolism”, and

² More specifically, the definition of medicinal products under Directive 2001/83, Article 1(2), reads as follows: “Medicinal product:

Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

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.”

³ Judgment of the Court of 15 November 2007, *Commission of the European Communities v Federal Republic of Germany*, Case C-319/05.

⁴ *Idem*, paragraph 44. See also, to that effect, Judgment of the Court of 30 November 1983, *van Bennekom*, Case 227/82, paragraph 18, and Judgment of the Court of 21 March 1991, *Monteil and Samanni*, Case C-60/89, paragraph 23.

only then may it be classified as a product “capable of restoring, correcting or modifying physiological functions within the meaning of the second paragraph of Article 1(2) of Directive 2001/83 [quoted at footnote 1]”.⁵ The Court of Justice of the European Union rejects a broad interpretation of the term medicinal product by function, as the Court recognises that such an interpretation would have significant adverse effects on the free movement of goods in the EU. Indeed, a broad interpretation of the term medicinal product by function would then lead to paradoxical findings, as products such as alcoholic drinks, energy drinks, coffee, tea, and, indeed, conventional cigarettes would qualify as medicinal products by function.

Thus, as the e-cigarette cannot be defined as a medicinal product, the Commission’s current proposal would lead to a *de facto* ban of e-cigarettes across the EU.

It is added here that the courts in the Netherlands, Germany and, most recently Estonia, as well as the U.S., have all ruled that e-cigarettes cannot be classified as a medicinal product. This is due, essentially, to the reasoning provided above. Moreover, this is set to remain unchanged in the future, as there is absolutely no reason or movement at EU level to amend the definition of medicinal product (under Directive 2001/83), nor is there any justification to do so.

The Commission proposal as regards e-cigarettes in the future Tobacco Products Directive creates a perverse situation leading to the opposite effect of the EU’s public health objective: it blocks rather than stimulates the marketing of less harmful alternatives to conventional smoking products. If less harmful alternatives are effectively banned from the market, smokers in the EU will be deprived from choosing a viable alternative to conventional cigarettes. As a result the public health of the EU’s citizens will continue to suffer, with conventional cigarettes having far fewer market barriers than the more worthy alternative.

Lastly, the prohibition on flavourings should not apply to e-cigarettes. The reasoning here is that the vapour emitted by e-cigarettes is naturally flavourless. Precluding e-cigarettes from containing flavours would strongly undermine their attractiveness and therefore their potential as a less harmful alternative to conventional cigarettes. On the contrary, allowing e-cigarettes to contain flavouring would clearly enhance their attractiveness vis-à-vis conventional cigarettes. In addition, this would ensure that a large number of people currently smoking flavoured cigarettes (such as menthol) are more likely to definitively switch over to e-cigarettes.

In addition, while there may be evidence that the use of flavourings seems to favour smoking initiation in young people (in other words, cigarette flavourings are perceived as a “gateway” to smoking for young people), the same cannot be said about e-cigarettes. There is no evidence adduced by the European Commission or anybody that flavours in e-cigarettes have led to young people taking up vaping. Thus, it would be unjustified to simply apply the gateway argument to e-cigarettes in order to prohibit the use of flavourings in this product.

A more extensive position paper on e-cigarettes in relation to the draft EU Tobacco Products Directive can be found on the TVECA website: http://www.tveca.com/PDF/tveca-position-paper.pdf .

⁵ *Idem*, paragraph 68.

AMENDMENT 1

**INCLUDE ELECTRONIC CIGARETTES IN THE SCOPE OF
'TOBACCO PRODUCTS' AND 'SMOKELESS TOBACCO PRODUCTS'**

Amendment

**Proposal for a Directive
Article 2 (34)**

Text proposed by the Commission

(34) 'tobacco products' means products usable for consumption by consumers and consisting of, even partly, tobacco, whether genetically modified or not;

Amendment

(34) 'tobacco products' means products usable for consumption by consumers and consisting of, even partly, tobacco ***or products derived from tobacco***, whether genetically modified or not;

Justification

This definition is almost identical to the one currently proposed, and reflects the US Tobacco Act definition ("any product made or derived from tobacco that is intended for human consumption"). This definition would be slightly broader than the currently proposed one insofar as it would include products derived from tobacco. This amendment would bring electronic cigarettes within the scope of the definition of "tobacco product" since electronic cigarettes contain nicotine derived from tobacco leaves. The amendment also would bring e-cigarettes within the scope of the definition of "smokeless tobacco product" in Article 22 (29) of the draft Directive as it then can be considered also as a "tobacco product not involving a combustion process".

AMENDMENT 2

SPECIFIC LABELLING FOR ELECTRONIC CIGARETTES (PART I)

Amendment

**Proposal for a Directive
Article 11.1**

Text proposed by the Commission

Amendment

Labelling of smokeless tobacco products

Labelling of smokeless tobacco products

1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning:

1. Each unit packet and any outside packaging of smokeless tobacco products, *other than electronic inhalers that vaporise a liquid solution simulating the act of smoking*, shall carry the following health warning:

This tobacco product can damage your health and is addictive

This product can damage your health and is addictive

Justification

Tabled together with amendment [3]. It is appropriate to subject electronic cigarettes to a health warning which is similar to that required under the proposed Directive for NCPs below certain thresholds. A specific labelling for electronic cigarettes would inform consumers and the public at large that electronic cigarettes are a less harmful alternative to conventional tobacco products.

AMENDMENT 3

SPECIFIC LABELING FOR ELECTRONIC CIGARETTES (PART II)

Amendment

**Proposal for a Directive
Article 11.1a (new)**

Text proposed by the Commission

Amendment

Labelling of smokeless tobacco products

Labelling of smokeless tobacco products

1a. Each unit packet and any outside packaging of electronic inhalers that vaporise a liquid solution simulating the act of smoking, shall carry the following health warning:

This product contains nicotine and can be addictive

Justification

Tabled together with amendment [2]. It is appropriate to subject e-cigarettes to a health warning which is similar to that required under the proposed Directive for NCPs below certain thresholds. A specific labelling for electronic cigarettes would inform consumers and the public at large that electronic cigarettes are a less harmful alternative to conventional tobacco products.

AMENDMENT 4

FLAVOURING OF ELECTRONIC CIGARETTES

Amendment

**Proposal for a Directive
Article 6.10**

Text proposed by the Commission

Amendment

Regulation of ingredients

Regulation of ingredients

10. Tobacco products other than *cigarettes, roll-your-own tobacco and smokeless tobacco products* shall be exempted from the prohibitions laid down in paragraphs 1 and 5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is a substantial change of circumstances as established in a Commission report.

10. Tobacco products other than *the following* shall be exempted from the prohibitions laid down in paragraphs 1 and 5:

(a) cigarettes;

(b) roll-your-own tobacco;

(c) smokeless tobacco products, not including electronic inhalers that vaporise a liquid solution simulating the act of smoking.

The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is a substantial change of circumstances as established in a Commission report.

Justification

The prohibition on flavourings should not apply to electronic cigarettes. As the vapour emitted by electronic cigarettes is naturally flavourless, precluding electronic cigarettes from containing flavours would strongly undermine their attractiveness and therefore their potential as a less harmful alternative to conventional cigarettes.



E-cigarettes in the Draft Revised Tobacco Product Directive

Avoiding a ban on a less harmful alternative

TVECA Position Paper

The Tobacco Vapor Electronic Cigarette Association (TVECA) is a non-profit association of private sector companies. Members are involved in all sectors of the creation and promotion of electronic cigarettes. TVECA's membership includes companies in Germany, Italy, the UK and the Netherlands, with membership pending for more European companies in other EU Member States. It also represents all existing vendors' associations including in Italy, France and Germany. It no longer represents ECITA (UK). Overall, TVECA represents approximately 80% of e-cigarette organised stakeholders in Europe.

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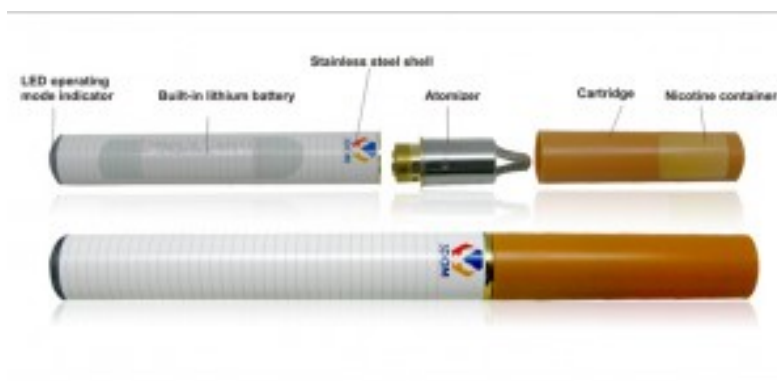


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1. WHAT IS AN E-CIGARETTE?

1.1 Components

An electronic cigarette contains three essential components: (1) a plastic cartridge that serves as a mouthpiece and a reservoir for liquid, (2) an "atomizer" that vaporizes the liquid, and (3) a battery.



1.1.1 Cartridge

The cartridge, a small plastic container with openings on each end, serves as both a liquid reservoir and mouthpiece. It allows the passage of liquid to the atomizer and vapour from the atomizer back to the user's mouth, without leaking liquid into the mouth.

Most models adopt a plastic sponge to keep the liquid in place, but it is also common to use a refillable tank to hold the liquid, with a separate tunnel connecting to the atomizer. When the liquid is depleted, users can refill it or replace with another pre-filled cartridge.

E-cigarettes can be disposable or rechargeable. An E-cigarette cartridge typically contains a nicotine content of upwards of 0mg/ml up to 36mg/ml¹. By way of comparison, a conventional cigarette contains up to 1mg of nicotine².

¹ An example of a low dosage of nicotine is 6mg/ml, which is the strength commonly used by light smokers of conventional cigarettes. Examples of medium-level dosages typically range from 12mg/ml – 18mg/ml, and a high-level dosage, which is usual for heavy smokers of conventional cigarettes, is considered to be 36mg/ml.

1.1.2 Atomizer

This is a battery connected to a USB charger. The atomizer contains a small heating coil that vaporizes the liquid, and generally consists of a simple filament and wicking metal mesh or silica wick to draw the liquid in. It is positioned in the center of the three components that make up the entire electronic cigarette cylinder, as the cartridge attaches to one end, and the power unit to the other. The atomizer's filament will lose efficiency over time due to a buildup of sediment, or "burns out" entirely, requiring replacement. In some models, the cartridge and atomizer component are integrated, known as a "cartomizer".

1.1.3 Battery

Most portable power units contain a lithium-ion rechargeable battery which constitutes the largest component of an electronic cigarette. This may contain an electronic airflow sensor so that activation is triggered simply by drawing breath through the device. Other models come with a power switch, which must be held during operation.

Batteries are usually charged via AC outlet, car or USB. Some manufacturers also offer a cigarette-pack-like portable charging case (PCC), which contains a larger battery to charge smaller batteries of individual e-cigarettes.

1.1.4 Liquid

The liquid, which produces vapour in electronic cigarettes, known as "e-juice" or "e-liquid", is a solution of propylene glycol (PG) and/or vegetable glycerin (VG) and/or polyethylene glycol 400 (PEG400) mixed with concentrated flavours, and optionally, a variable percent of a liquid nicotine concentrate.

The liquid is often sold in a bottle or as pre-filled disposable cartridges. Many manufacturers offer various flavours which resemble the taste of regular tobacco, menthol, vanilla, coffee, etc., but nicotine concentrations vary by manufacturer. The standard notation "mg/ml" is often used in labelling, sometimes shortened to a simple "mg". Nicotine-free solutions are also available.

² In accordance with Article 3.1 of the current 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 (*TPD*).

1.2 Types of e-cigarettes

The most common types of e-cigarettes on the market are disposable e-cigarettes and rechargeable/refillable e-cigarettes³.

2. CURRENT SITUATION WITHIN THE EU

The current TPD does not cover e-cigarettes, which are therefore regulated generally by Directive 2001/95/EC on general product safety, among others.

Meanwhile, the treatment of e-cigarettes at Member State level is widely disparate. In several EU countries including Germany, the UK, the Netherlands, Ireland, Spain, Italy, and Poland, there is no specific legislation on e-cigarettes, which in principle means that e-cigarettes are treated as consumer products and regulated as such (in essence, by product safety laws). Yet, in other countries, such as Belgium, Finland, Sweden, and Denmark, e-cigarettes are regulated as pharmaceutical products, and at least one country, Greece, actually prohibits e-cigarettes.

As mentioned in the IA Report⁴, the market for e-cigarettes is growing rapidly in the EU and there is a growing interest from bigger cigarette manufacturers (including the big four FMC⁵ producers) to enter the market.

The diversity in the way national Member State laws treat e-cigarettes creates significant barriers to the trade of e-cigarettes, hinders their free movement in the EU, and partitions the EU market. Therefore, there is an urgent need to replace the diverse national laws and to harmonise the legislation on e-cigarettes at EU level, as well as, more particularly, to recognise e-cigarettes as a viable and less harmful substitute to conventional cigarettes.

³ There also exist so-called "EGO"-models and variable voltage personal vaporizers, which are both heavier and more expensive and do not look like a traditional cigarette. Their market share is smaller. .

⁴ Commission Staff Working Document Impact Assessment accompanying the document 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 (the "**IA Report**").

⁵ Factory Manufactured Cigarettes.

3. TREATMENT OF E-CIGARETTES IN THE DRAFT DIRECTIVE

The e-cigarette does not fall into the definition of tobacco products currently proposed in the draft Directive⁶, even though it contains a substance (nicotine) derived from tobacco plants. E-cigarettes currently fall within the proposed definition of nicotine-containing products (“NCPs”).

However, the proposal fails to differentiate between NCPs that are medicinal products for smoking cessation (Nicotine Replacement Therapies, “NRTs”), and e-cigarettes. For all such products, except in cases of very low nicotine content, the proposal requires authorisation under Directive 2001/83/EC.⁷

The grouping of e-cigarettes with NRTs is erroneous. E-cigarettes and NRTs are very different in their nature, target group, objectives and aims.

3.1 NRTs

On the one hand, NRT (in the form of, e.g., patches or gum) is *“the remedial administration of nicotine to the body by means other than tobacco, usually authorised under the pharmaceutical legislation as part of smoking cessation”*⁸. Cessation of smoking leads to symptoms of nicotine withdrawal such as anxiety and irritability. Smoking cessation support methods generally endeavour to address both nicotine addiction and nicotine withdrawal symptoms.

Common forms of NRT are nicotine patches and nicotine gum which, respectively, transdermally or orally, administer nicotine in small, steady doses. The primary benefit of NRT is that it prevents nicotine cravings and relieves withdrawal symptoms in a smoker whilst allowing him to abstain from tobacco and thus avoid the harmful effects of smoking. In other words, the delivery of nicotine to the body by an NRT is intended as a remedy to help the user gradually reduce and then permanently stop his nicotine addiction and thus quit smoking conventional tobacco products. Moreover, NRTs are intended only for *temporary* use (usually up to 2 or 3 months, sometimes up to 6 months).

⁶ Namely, the Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products, presented on 19 December 2012.

⁷ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (**Directive 2001/83/EC**).

⁸ This is the definition of NRT used in the IA Report.

The above can be illustrated by referring to the “Indications and Clinical Uses” and “Posology” sections of the Summary of Product Characteristics (**SPC**) of some of the NRTs on the EU market:

- NICORETTE 2mg gum: *“indicated for the relief of nicotine withdrawal symptoms as an aid to smoking cessation in adults and children over 12 years of age. [...] In smokers currently unable or not ready to stop smoking abruptly, the gum may also be used as part of a programme to reduce smoking prior to stopping completely. If possible, Nicorette 2mg Gum should be used in conjunction with a behavioural support programme”*

“Continue use for up to three months to break the habit of smoking, then gradually reduce gum use. When daily use is 1-2 gums, use should be stopped”.

- NIQUITIN 7 mg transdermal patches: *“relieve and/or prevent craving and nicotine withdrawal symptoms associated with tobacco dependence. They are indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them. [...] If possible, when stopping smoking, NiQuitin patches should be used in conjunction with a behavioural support programme”. Users in all categories in any event are “encouraged to stop smoking completely as soon as possible”.*

“For optimum results, the 10 week treatment course (8 weeks for light smokers or patients who have reduced strength as above), should be completed in full”.

- NICOTINELL TTS 20 patch: *“relieve and/or prevent cravings and nicotine withdrawal symptoms associated with tobacco dependence. They are indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them. [...] Nicotinell patches should preferably be used in conjunction with a behavioural support programme”. Users in all categories in any event are “encouraged to stop smoking completely as soon as possible”.*

“The treatment is designed to be used continuously for 3 months but not beyond”.

Importantly, as can be seen from the SPCs (and also from the patient leaflets, advertising, etc.), NRTs are *presented* as smoking cessation medicinal products, and are thus regulated as such in accordance with the presentation criterion under Article 1.2 of Directive 2001/83/EC (See, below sub 5.1).

3.2 Electronic cigarettes

On the other hand, an e-cigarette (or Electronic Nicotine Delivery System, ENDS) is an electronic inhaler that vaporizes a liquid solution into an aerosol mist, simulating the act of tobacco smoking, or, to use the Commission's definition in the IA Report, "*an electronic device typically consisting of a mouth piece (containing an electronic evaporator) and a cartridge (typically replaceable) and designed to deliver nicotine to the lung through inhalation of a mixture of air & vapours into the respiratory system*". Electronic cigarettes (or e-cigars, e-pipes) are very similar to conventional cigarettes in their physical design, in the nicotine release, in the emitted smoke-like vapour and in gesture.

The aim of e-cigarettes is to *compete* with traditional tobacco and to have as many smokers as possible switch from conventional tobacco products to e-cigarettes. E-cigarettes are *not* intended as a remedy to help the user gradually reduce and then stop his nicotine craving and thus quit smoking. On the contrary, e-cigarettes are intended to satisfy the user's nicotine craving and do not intend to reduce or stop it, so they are not intended for temporary use.

The WHO Study Group on Tobacco Product Regulation emphasizes that "*ENDS are not nicotine replacement therapy. ENDS should not be confused with NRT products approved for the treatment of tobacco dependence. ENDS and conventional NRT products may differ in design, content and the mode of delivery of nicotine and other chemicals. [...] ENDS might be used to perpetuate smoking by what has been termed 'dual use', that is, sustaining nicotine dependence in environments where smoking is prohibited. [...] ENDS may discourage people from quitting, as users can maintain their nicotine addiction despite smoking restrictions and resume smoking where such restrictions are absent*"⁹.

Importantly, as is confirmed by the IA Report, e-cigarettes are "*marketed*" (and thus *presented*) as "*consumer/leisure products*" (and thus not as smoking cessation products).

4. **E-CIGARETTE IS NOT A MEDICINAL PRODUCT**

Below we provide a detailed explanation of the reasons why e-cigarettes are not medicinal products and therefore why their grouping with NRTs in the draft Directive is fundamentally flawed.

⁹ WHO Study Group on Tobacco Product Regulation, Report on the Scientific Basis of Tobacco Product Regulation, WHO Technical Report Series, No. 955.

4.1 Definition of “medicinal product” at EU level

According to Article 1.2 of Directive 2001/83/EC, a medicinal product is:

- “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”.*

In other words, a product can qualify as a medicinal product in the following two cases. First, when it is a medicinal product by presentation, *i.e.*, when that product is presented as having medicinal properties. Second, when it is a medicinal product by function, *i.e.*, when that product exerts a pharmacological, immunological or metabolic action and is administered to humans with a view to restoring, correcting or modifying physiological functions or when it is administered with the purpose of making a medical diagnosis.

Below, we will show that the e-cigarette does not fall into either of the above two categories and therefore does not and cannot qualify as a medicinal product.

4.2 Marketing authorisation procedure for a medicinal product in the EU

No medicinal product (with the exception, under certain conditions, of radiopharmaceuticals prepared at the time of use) may be placed on the market of a EU Member State unless an authorisation has been issued by the competent authorities of that Member State or by the European Medicines Agency (**EMA**) (Article 6.1 of Directive 2001/83/EC).

Certain particulars and documents must be included with the authorisation request, including:

- therapeutic indications;
- posology; and
- the results of pharmaceutical, pre-clinical and clinical tests (Article 8.3 of Directive 2001/83/EC).

Pursuant to Annex 1 to Directive 2001/83/EC (Analytical, Pharmacotoxicological and Clinical Standards and Protocols in respect of the Testing of Medicinal Product), the clinical tests must include *inter alia* efficacy studies (Section 5.2.5 of Annex 1), *i.e.*, clinical studies that demonstrate in a scientifically proper manner the efficacy of the product concerned for the therapeutic indications for which a marketing authorisation is sought.

The marketing authorisation application will be rejected *inter alia* if it appears that:

- the **risk-benefit ratio** is not considered to be favourable (safety criterion); or
- its therapeutic effect is insufficiently substantiated by the applicant (**efficacy** criterion) (Article 26.1 of Directive 2001/83/EC).

4.3 E-cigarette is not a medicine by presentation

Various courts, including the Court of Justice of the European Union, have been seized already in cases where a Member State (or its regulatory Medicines Agency) had qualified a product as a medicine and the manufacturer of this product disputed this qualification.

As stated by the Court of Justice of the European Union in *Commission v Germany*¹⁰ with regard to the presentation criterion,

*“a product is 'presented for treating or preventing disease' within the meaning of Directive 2001/83 when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation”.*¹¹

The e-cigarette is not recommended as a product for treating or preventing disease, nor is there any indication as such, whether by means of the label, the information printed on the external packaging, or in any other way. The e-cigarette is presented as a pleasure product for smokers who wish to continue their nicotine intake, and it does not claim to have any preventative or treatment properties for smoking cessation and/or nicotine addiction. This is explicitly acknowledged by the Commission in the IA Report: *“Electronic cigarettes are most often marketed by their producers as an alternative to FMC rather than a smoking cessation aid”.*

In a recent judgement of 7 March of the Tartu Administrative Court in a legal proceeding brought by Zandera Ltd. against the Estonian State Agency for Medicines (which has now become final as no appeal was lodged by the deadline of 8 April 2013), the Court ruled that:

“The nicotine products cited by the respondent are manufactured and marketed for the treatment of nicotine dependence; E-Lites do not bear this objective”.

In addition, e-cigarettes mimic conventional cigarettes: they have a very similar appearance to conventional cigarettes, they emit a smoke-like vapour and - frequently - they have a tobacco flavour. E-cigarettes are presented as a direct substitute to conventional cigarettes.

¹⁰ Judgment of the Court of 15 November 2007, *Commission of the European Communities v Federal Republic of Germany*, Case C-319/05.

¹¹ *Idem*, paragraph 44. See also, to that effect, Judgment of the Court of 30 November 1983, *van Bennekom*, Case 227/82, paragraph 18, and Judgment of the Court of 21 March 1991, *Monteil and Samanni*, Case C-60/89, paragraph 23.

According to the Court of Justice of the European Union, a product is also “*presented for treating or preventing disease*”

*“whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question. In that regard, account must be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by proprietary medicinal products, having regard to the safeguards normally associated with their manufacture and marketing. Although the external form given to the product may serve as strong evidence of its classification as a medicinal product by presentation, the ‘form’ must be taken to mean not only the form of the product itself but also that of its packaging, which may, for reasons of marketing policy, tend to make it resemble a medicinal product”.*¹²

No aspect of the e-cigarette or its packaging, nor the marketing used for e-cigarettes, tend to make e-cigarettes resemble a medicinal product. Indeed, the external packaging of e-cigarettes has nothing on it that would even remotely inspire in a reasonably well-informed consumer the confidence as that usually inspired by medicinal products. On the contrary, the appearance of the e-cigarette, itself in a form that, in most cases, intentionally mimics the conventional cigarette, makes it particularly unlikely that a reasonably well-informed consumer would have the impression that the e-cigarette is a medicinal product. The same goes for the fact that e-cigarettes are offered in assorted flavours. The promotional material of the manufacturers of e-cigarettes is not aimed at preventing, mitigating or treating nicotine addiction and the effects of withdrawal, but toward encouraging nicotine use. Smoking e-cigarettes is presented as fun and exciting, the aim being that consumers who already smoke would switch to e-cigarettes for the same recreational purposes and with the same frequency as conventional cigarettes. As rightly stated by The Hague Court of Appeals on 26 June 2012 in summary proceedings between United Tobacco Vapor Group Inc. and the Dutch State (at p. 5): *“The Court considers that the consumer uses the e-cigarette as a pleasure product, in addition to or as a substitute for the conventional cigarette”*.

This is also confirmed by the Tartu Administrative Court in Estonia in its judgement of 7 March 2013:

“E-cigarettes are smoked visually in a similar way to the smoking of a normal cigarette, so it is a replacement product of a normal cigarette, not a medicinal product. Nicotine is received from an e-cigarette instead of a tobacco cigarette. Also, people who have given up smoking tobacco cigarettes in favour 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.

¹² *Idem*, paragraphs 46-47. See also, to that effect, Judgment of the Court of 30 November 1983, van Bennekom, Case 227/82, paragraphs 18-19, and Judgment of the Court of 21 March 1991, Monteil and Samanni, Case C-60/89, paragraphs 23-24.

[..]

[The electronic cigarette] is a feel-good substance with the intention of replacing tobacco cigarettes and allows the consumption of nicotine without the harmful effect of tobacco smoke and tar”.

In contrast to e-cigarettes, NRTs explicitly *present* themselves as an aid to smoking cessation and, as a result thereof, are explicitly qualified as medicinal products by presentation within the meaning of Article 1(2) of Directive 2001/83/EC.

In those circumstances, it must be held that the e-cigarette does not satisfy the criteria laid down in the first paragraph of Article 1(2) of Directive 2001/83/EC. Therefore, it cannot be classified as a medicinal product by presentation within the meaning of that Directive.

4.4 E-cigarette is not a medicine by function

4.4.1 Nicotine in e-cigarettes does not “significantly affect” the metabolism

According to the Court of Justice of the European Union, for the purposes of determining whether a product falls within the definition of a medicinal product by function within the meaning of Directive 2001/83/EC, the authorities

*“must decide on a case-by case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail”.*¹³

In addition, although the definition of a medicine by function 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”.*¹⁴

Importantly, in *Commission v Germany*, the Court clarified under which circumstances a product “*significantly*” affects the metabolism. According to the Court,

¹³ *Idem*, paragraph 55. Emphasis added. See also, to that effect, Judgment of the Court of 9 June 2005, HLH Warenvertrieb and Orthica, Joined cases C-211/03, C-299/03 and C-316/03 to C-318/03, paragraph 51.

¹⁴ *Idem*, paragraph 60. Emphasis added. See also, to that effect, Judgment of the Court of 16 April 1991, Upjohn v Farzoo, C-112/89, paragraph 22.

“[...] 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 product capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83”¹⁵.

It has to be emphasised here as well that the quality of altering physiological functions is not a quality reserved only to medicines. Physiological functions of the body can be influenced by numerous different products that are nevertheless destined for nutrition or pleasure, or even by products that are poisonous to the human body.

However, as seen above, the Court of Justice of the European Union rejects a broad interpretation of the term medicinal product by function, as the Court recognises that such an interpretation would have significant adverse effects on the free movement of goods in the EU. Indeed, a broad interpretation of the term medicinal product by function would then lead to paradoxical findings, as products such as alcoholic drinks, energy drinks such as Red Bull, coffee, tea, and, indeed, *conventional* cigarettes would qualify as medicinal products by function.

As the Court explains, products having pharmacological effects do not automatically qualify as medicinal products by function. Rather, in order for a product to qualify as a medicinal product by function, it should have a significant effect on the physiological functions of a human, and greater than the effect created when the product (be it a foodstuff, ingredient, substance such as nicotine, etc.) is consumed in a reasonable quantity. This principle was acknowledged expressly by the Commission in its “Orientation Note: Electronic Cigarettes and the EC Legislation” of 22 May 2008: *“The electronic cigarette can be regarded as a human medicine by function in so far as it qualifies as ‘restoring, correcting or modifying physiological functions’ in a significant manner”* (emphasis added).

One may argue that e-cigarettes have pharmacological effects as a result of their active ingredient, nicotine. Indeed, in the IA Report, the Commission argues that *“[t]he pharmacological effects of nicotine in NRTs are well documented. Nicotine attaches itself to receptors in the brain [...]”* and that *“most consumers use these products for cessation/limitation purpose, which presupposes a pharmacological reaction, i.e. a certain level of nicotine”*. However, a nicotine containing product would qualify as a medicinal product by function only if the consumption or use of this product creates additional physiological effects as compared to those which are created from the consumption of nicotine in, for example, a conventional cigarette. The Commission correctly states in its “Orientation Note: Electronic Cigarettes and the EC Legislation” of 22 May 2008 that *“the electronic cigarette – with the most intense cartridge – gives about the same yield of nicotine as one cigarette (1 mg)”*. This explains why there is no scientific evidence whatsoever

¹⁵ *Idem*, paragraph 68.

that the effects on the physiological function of the human body resulting from the use of e-cigarettes are any greater or different from the effects created when nicotine is consumed by, e.g., conventional cigarettes. On the contrary, studies have shown that nicotine exposure from e-cigarettes approximates tobacco cigarette use¹⁶. That amount of exposure (quantity) for both conventional cigarettes and e-cigarettes is user dependent as a result of “*the overriding importance of smokers’ tendency to regulate their nicotine intake by modulating puffing and inhalation in response to variations in yield*”¹⁷.

In this respect, The Hague Court of Appeals ruled on 26 June 2012 in summary proceedings between United Tobacco Vapor Group Inc. and the Dutch State (at pp. 4-5):

“It is not, or at least insufficiently, disputed that the e-cigarette possesses some pharmacological characteristics that can influence the physiological functions of the human being. However, this does not suffice to classify a product as a medicine. The same goes, for example, for coffee, wine and a conventional cigarette. None of these products fall within the scope of the Medicines Act. It follows from the case law of the European Court of Justice that it is required that scientific research has properly shown that there is a significant physiological effect. In this respect, it is important to note that no grievances are invoked against the decision of the first judge that it is undisputed that the pharmacological effects of the e-cigarette established in the studies that have been carried out so far, are no greater than those of a conventional cigarette” (translation from Dutch; emphasis added).

At the first instance level in these same legal proceedings, the Dutch Court of The Hague in summary proceeding had ruled already on 13 March 2012 (at page 5) that

“[..], the State has not made it plausible that the use of the e-cigarette has pharmacological effects, in the sense that these effects would be greater than in case of the use of the original product (cut tobacco leaves)” (translation from Dutch).

Importantly, for a product to qualify as a medicinal product by function, its greater pharmacological effects would need to be scientifically proven and not just assumed¹⁸.

¹⁶ See, *inter alia*, A.R. Vansickel, Ph.D, and T. Eissenberg, Ph.D.,, Electronic Cigarettes: Effective Nicotine Delivery After Accute Administration, *Nicotine & Tobacco Research*, 6 February 2012.

¹⁷ *Ibid.*

¹⁸ On this point see also Judgment of the Court of 15 January 2009, Hecht-Pharma, Case C-140/07, paragraph 29, where the Court added that “Article 2(2) of Directive 2001/83 must be interpreted as meaning that that

Due to the absence of scientific observation and evidence that e-cigarettes “*significantly*” affect the physiological functions of the human body, as required by the test developed by the Court for a product to qualify as a medicinal product by function, the proposed classification of the e-cigarette as a medicinal product by function – on the mere basis of the fact that it contains nicotine - is arbitrary and fundamentally flawed.

4.4.2 E-cigarettes have not been scientifically observed and are not designed to restore, correct or modify physiological functions

Furthermore, in order for e-cigarettes to qualify as medicinal products by function, they should at *least* have preventative or curative effects, such as be able to prevent or cure nicotine addiction. This has not been scientifically proven. In fact, it is commonly accepted that such a curative effect does not exist for e-cigarettes. While the nicotine need is being satisfied, the nicotine addiction is neither prevented nor cured. E-cigarettes, just like conventional cigarettes, cannot and do not help against nicotine addiction. Therefore, they cannot be classified as a medicinal product by function within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83/EC.

The Administrative Court of Cologne ruled in this respect in a judgement of 20 March 2012 in case No. 7 K3169/11 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 an electronic cigarette instead of a tobacco cigarette. The nicotine addiction will then prevail. Nicotine addiction is satisfied, not treated. [...] “when observing the products that serve as the object of the dispute, we cannot 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”¹⁹ (translation from German; emphasis added).

In a similar vein, the Supreme Court of Sachsen-Anhalt State of Germany ruled on 5 June 2012 that:

“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

directive does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, without it being possible to exclude that possibility.”

¹⁹ See, also: Higher Administrative Court of Sachsen-Anhalt, judgement of 5 June 2012 in case No. 3 M 129/12.

considered as a functional medicinal product just because it contains some substance – nicotine, in the case at hand – that is accompanied by health risks when used, as a definition of a functional medicinal product includes fighting against diseases or undesirable physical conditions or reaching a medical diagnosis as a function of the medicinal product. [...] The pure physiological effect of nicotine does not suffice to classify something as a functional medicinal product. Usually, only products that have either therapeutic or prophylactic purpose therefore can be functional medicinal products. The Medicinal Products Act does not cover products with different main objectives, for example, nourishment or pleasure and gratification.[...] The Medicinal Products Act can only be applied if it is definitely known, as a product is manufactured, that its future purpose will be, without exception, medicinal function in the human body – even where a combined effect with some other substance will be needed for that purpose. As for the object in dispute – a liquid that contains nicotine – this cannot be assumed. Weaning from the use of tobacco cigarettes or alleviation of nicotine addiction do not take the front stage. [...] 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”.

And on 7 March 2013, the Tartu Administrative Court in Estonia ruled as follows:

“The Court finds that the contested decisions of the State Agency of Medicines do not convince the court unequivocally that in case of the complainant’s E-Lites products it has been proven that they are medicinal products. The respondent has both in the contested decision, as in the court proceedings compared E-Lites products with the medicinal products that contain nicotine and already own the marketing authorization, but 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”.

It is stated in the IA Report that *“low-nicotine’ NCP would not respond to users’ cravings for nicotine”*. The Commission thus acknowledges that all other e-cigarettes (i.e., the majority) respond to users’ nicotine cravings.

In this respect, the fact that, according to the IA Report, some users of e-cigarettes would have stated that they use the product primarily to *“quit smoking”* or to *“reduce their smoking”* does not confer medicine status on e-cigarettes either. Indeed, as stated above, while an e-cigarette user may well intend to quit smoking conventional tobacco products or reduce his smoking habit, he

will achieve this by satisfying his nicotine craving indefinitely by means of an e-cigarette instead of by a conventional tobacco product. The nicotine addiction thus is not treated but maintained. The use of NRTs, on the contrary, is intended to cease the nicotine addiction altogether so cannot be likened to NCPs such as e-cigarettes.

Again, we wish to quote from the judgement of 7 March 2013, the Tartu Administrative Court:

“The court agrees with the complainant that according to the respondent’s approach, all the nicotine-containing products, thus in this case also the normal cigarettes should be defined as a medicinal product on the basis of the effect of nicotine. This, however, does not exclude the possibility that a past smoker can use e-cigarettes as a smoking cessation tool. Quitting smoking is possible for some people and in some cases even without any special equipment or without any assistance of a medicinal product. It is not excluded that, if desired, symptoms of withdrawal can also be alleviated with the help of a normal cigarette, which is not to say that it is a medicinal product”.

The IA Report mentions that some studies have been published *“that highlight the electronic cigarettes’ potential as a smoking cessation aid”* (See, footnote 129 of the IA Report which lists three studies). However, the IA Report fails to specify that:

- the study by Caponnetto *et al.* only shows that some smokers of conventional cigarettes were able to quit smoking conventional cigarettes and remain abstinent for a certain period of time after taking up e-cigarettes. None of these individuals stopped using e-cigarettes so their nicotine addiction was undiminished;
- the same comment also applies to the study by Polosa *et al.* Moreover, these authors even emphasize that *“because of its unusual design (smokers not willing to quit, e-cigarettes were used throughout the entire study period) this is not an ordinary cessation study and therefore direct comparisons with other smoking cessation products cannot be made”*;
- the letter (not a study) of Etter and Bullen only concluded that cotinine levels in ENDS users were similar to levels observed, in previous reports, in smokers and higher than levels usually observed in NRT users. The letter did not contain any relevant findings on smoking cessation.

The IA Report also mentions that some users of e-cigarettes would have stated that they smoke e-cigarettes to reduce harm associated with smoking *“as they felt these products were less toxic than traditional tobacco products”*. Again, the mere fact that a product is, and/or is considered by the user as, a less toxic/less harmful alternative to a conventional cigarette, does not confer medicine status on an e-cigarette. If that were the case, “slim”, “mild” and “low tar” conventional cigarettes, which traditionally were also felt by users to be less toxic than conventional cigarettes, could have been medicines.

It is, likewise, worth noting that *NRTs* also do not have any significant physiological effect on the human body in the manner defined by the Court of Justice of the European Union. Like e-cigarettes, *NRTs* do not have greater pharmacological effects than the effects resulting from the consumption of nicotine e.g., by conventional cigarettes.

It is indicative in this respect that 93% of attempts to stop smoking with the help of *NRTs* have failed within a year.²⁰ Moreover, two studies published in 2012 showed that *NRTs* are no better than willpower at helping smokers to quit. Researchers at the Harvard School of Public Health and the University of Massachusetts studied the attempts of 787 Massachusetts smokers to quit, and found that the use of *NRTs* had no effect on their success.²¹ In the second study, published in the prestigious *Annual Review of Public Health*, lead author John Pierce and his colleagues argued that rather than helping smokers quit, the widespread marketing of nicotine replacement therapy had reduced expectations about how difficult it was to quit.²²

Therefore, as with e-cigarettes, *NRTs* – at least on the basis of the above scientific evidence - are not medicinal products *by function*. However, *unlike* e-cigarettes, *NRTs* are presented as an aid to smoking cessation and thus qualify as medicinal products *by presentation*.

We can take the example of one *NRT*, the nicotine inhaler. The nicotine inhaler releases nicotine but it does not have any significant physiological effects in the terms defined by the Court.²³ Nonetheless, the nicotine inhaler manufacturer presents this product as having medicinal properties and claims that it is effective in weaning smokers of their nicotine addiction for the purpose of smoking cessation. Indeed, because of the nature of the nicotine inhaler, if the manufacturer did not present this product as an aid to smoking cessation and did not make efficacy claims in this regard, then the nicotine inhaler would no longer be attractive to the consumer and it would lose considerable share in the market for smoking cessation products. In contrast to this, e-cigarettes are presented as products for pleasure interchangeable with conventional cigarettes, the use of which implies that the user remains addicted to nicotine.

²⁰ See "A meta-analysis of the efficacy of over-the-counter nicotine replacement", J. R. Hughes, S. Shiffman, P. Callas, J. Zhang, *Tobacco Control* 2003; 12:21-27.

²¹ See "A prospective cohort study challenging the effectiveness of population-based medical intervention for smoking cessation", Hillel R Alpert, Gregory N Connolly, Lois Biener, *Tobacco Control* 2001; 22:1 32-37.

²² See "Quitlines and Nicotine Replacement for Smoking Cessation; Do we need to change policy?", John P. Pierce, Sharon E. Cummins, Martha M. White, Aimee Humphrey, and Karen Messer, *Annual Review of Public Health*, Vol. 33: 341-356.

²³ The fact that a nicotine inhaler does not have any significant physiological effects was recently accepted by the Dutch Court of The Hague in summary proceeding between United Tobacco Vapor Group Inc. and the Dutch State, 13 March 2012, 414117 / KG ZA 12-209 (at page 4), as well as by the Administrative Court of Cologne in a judgement of 20 March 2012 in case No. 7 K3169/11.

Moreover, while e-cigarettes mimic conventional cigarettes, nicotine inhalers contain neither an aroma nor smoke that needs to be inhaled or exhaled. Nicotine inhaling therefore only very remotely (if at all) resembles smoking and it is clearly meant to fight nicotine withdrawal symptoms. Moreover, unlike e-cigarettes, a nicotine inhaler is meant only for temporary use and for the purposes of treating nicotine addiction. For instance, a typical nicotine inhaler is not to be used for more than six months according to the instructions accompanying the product. On the other hand, e-cigarettes closely resemble conventional cigarettes and are sold in the market as substitutes to cigarettes for use during an indefinite period of time.

Furthermore, nicotine inhalers have a metered dosage delivery function, *i.e.*, the amount per intake is fixed. It is a device that delivers a specific amount of nicotine to the lungs, which cannot be varied per “puff”, making it more akin to other medicinal devices (e.g., asthma inhalers). This is not the case for e-cigarettes, where the strength of each intake depends on the individual consumer: there is therefore no question of “dosage” as in some medicinal products; the amount of nicotine that is delivered per “puff” is determined individually by the user.

In sum, while NRTs are correctly classified as medicinal products due to the fact that they are *presented* as such, e-cigarettes neither claim to have medicinal properties for smoking cessation nor do they have any significant effect on the physiological functions of the human body.

In a judgement of 13 March 2012 of The Hague Court in summary proceedings between United Tobacco Vapor Group Inc. and the Dutch State, the Court held that

“[t]he position of the State that the e-cigarette has pharmacological characteristics which influence the physiological functions of human beings and for that reason alone already should be considered as a medicine, provisionally cannot be followed. Indeed, the e-cigarette is not intended to create such effects. The words ‘with a view to being administered or used for’ in the statutory definition exclude pleasure products such as alcohol and tobacco from the application of the law. According to the judge, the same goes for the e-cigarette”.

In its judgement of 7 March, the Tartu Administrative Court ruled that:

“The presented material shows that the use of E-Lites products is designed to replace the smoking habit, i.e., an analogous activity to smoking of regular cigarettes. The nicotine products cited by the respondent are manufactured and marketed for the treatment of nicotine dependence; E-Lites products do not bear this objective. There is also no corresponding scientific research regarding the products in dispute to support their therapeutic properties”.

In a case before the United States District Court for the District of Columbia, the Food and Drug Administration (**FDA**) had argued that, as e-cigarettes are to be used as a means for delivering nicotine and as consumers and scientists widely believe that nicotine has drug-like effects, these products would be intended to affect the structure or function of the human body and thus qualify as a drug-device combination. The Court ruled in this respect:

“Put simply, this argument is bootstrapping run amuck. That electronic cigarettes are devices for delivering nicotine and are intended to have the same effect on the structure and the function of the body as cigarettes is hardly a basis for classifying electronic cigarettes as a drug-device combination, thereby excluding them from the definition of ‘tobacco product’. If it were, then traditional cigarettes would be excluded as well. Indeed, any tobacco product containing nicotine and claiming some pharmacological effect would be excluded.

[..]

In sum, absent substantial evidence of the manufacturer’s objective intent that its electronic cigarettes affect the structure or the function of the body in a way distinguishable from ‘customarily marketed’ tobacco products or that its electronic cigarettes have the therapeutic purpose of treating nicotine withdrawal, there is no basis for FDA to treat electronic cigarettes, as they are marketed by the plaintiffs in this case, as a drug-device combination when all they purport to do is offer consumers the same recreational effects as a regular cigarette²⁴.

It is clear from all the foregoing that the e-cigarette does not satisfy either the definition of medicinal product by presentation nor the definition of medicinal product by function. Therefore, it cannot be classified as a medicinal product within the meaning of Directive 2001/83/EC.

4.5 Applications by e-cigarette manufacturers for a marketing authorisation under Directive 2001/83/EC are doomed to fail

In light of all of the above, requesting a marketing authorisation under Directive 2001/83/EC for e-cigarettes would bring the e-cigarettes industry to a dead-end and would lead to the *de facto* banning of e-cigarettes from the EU market²⁵. Indeed, it is illogical to force manufacturers to go through the cumbersome procedure of applying for a marketing authorisation under Directive 2001/83/EC, if their applications are destined to fail due to the fact that e-cigarettes are *not* presented as medicinal products (which the Commission explicitly acknowledges in the IA Report) and do *not* have any significant pharmacological effects.

More particularly, as already set out above, manufacturers of e-cigarettes would be obliged under Article 8.3 of Directive 2001/83/EC to include *inter alia* the following particulars and documents with their authorisation request²⁶:

²⁴ United States District Court for the District of Columbia, *Smoking Everywhere, Inc. and Sottera, Inc. v. FDA*, ruling of 14 January 2010 of Judge Leon.

²⁵ The Commission confirms in the IA Report that “the majority of [NCPs] currently on the market would be affected”.

²⁶ See also the WHO Study Group on Tobacco Product Regulation: “Although ENDS are promoted as smoking cessation aids in some markets, the manufacturers have not provided evidence-based guidance for their

- therapeutic indications: this means *de facto* for e-cigarettes that the applicants would be forced to allege that their products are indicated for the relief of nicotine withdrawal symptoms as an aid to smoking cessation. This would be absurd as e-cigarettes satisfy the user's nicotine craving indefinitely and are not intended to treat but on the contrary maintain the nicotine addiction (just like a conventional cigarette)²⁷. The Commission thus would force e-cigarette manufacturers to invoke false indications that are impossible to prove.
- posology: as already stated above, in the case of e-cigarettes the strength of each intake depends on the individual consumer: the amount of nicotine that is delivered per "puff" is determined individually by the user. There is therefore no question of "dosage" as in some medicinal products (e.g. nicotine inhalers where the amount per intake is fixed/cannot be varied per "puff"). It follows that no "posology" can be given for e-cigarettes.
- the results of pharmaceutical, pre-clinical and clinical tests: this means *de facto* for e-cigarettes that the applicants would be forced to prove on the basis of clinical trials the efficacy of e-cigarettes for relieving nicotine withdrawal symptoms as an aid to smoking cessation. This is an impossible proof as e-cigarettes *maintain* the nicotine addiction. In the IA Report, the Commission admits on several occasions that "[a]t this stage the evidence on the effectiveness of electronic cigarettes in smoking cessation is inconclusive". This is a euphemism to say the least.

The marketing authorisation application will be rejected *inter alia* if it appears that:

- its therapeutic effect is insufficiently substantiated by the applicant (**efficacy** criterion); or
- the **risk-benefit ratio** is not considered to be favourable (safety criterion):

efficacy, dosing and duration of use, how they should be combined with behavioural strategies for smoking cessation or guidance for discontinuation. This information would be required if WHO or national regulatory authorities were to make even a preliminary evaluation of the safety and effectiveness of ENDS.

In summary, claims for the effectiveness of ENDS for smoking cessation and other health effects must be substantiated by rigorous studies of pharmacokinetics, trials of safety and efficacy and review and approval by major drug regulatory authorities. The types of data and studies that would be required include a complete listing of the chemicals used in ENDS products; a listing and reporting of the concentrations of chemicals delivered to the consumer; comparisons of the effect of ENDS on smoking cessation with that of approved NRTs and placebo; and the adverse effects of these products" (emphasis added, Report on the Scientific Basis of Tobacco Product Regulation, WHO Technical Report Series, No. 955).

²⁷

Incidentally, the IA Report mentions that some users use e-cigarettes "to get around smoke-free environments (including lorry drivers)" (as e-cigarettes do not emit smoke, only a water-based vapour) and that e-cigarettes "are often promoted as an alternative to smoking which allows smokers to keep up nicotine addiction in situations where smoking is prohibited". This shows that e-cigarettes are being used *inter alia* by smokers of conventional cigarettes to satisfy their nicotine craving in areas where the smoking of conventional cigarettes is not allowed. Once outside that smoke-free environment, they revert to smoking conventional cigarettes which is the opposite of smoking cessation.

An application by e-cigarette manufacturers for a marketing authorisation would be rejected on both grounds as these applicants will be unable to substantiate the alleged therapeutic effect of e-cigarettes which in turn will lead to the risk-benefit ratio being considered as unfavourable. Indeed, on which basis would the EMA or a competent national authority of a Member State, following a risk-benefit analysis, authorise a product that is unable to prove its efficacy for relieving nicotine withdrawal symptoms as an aid to smoking cessation and that, moreover, whilst less harmful than a conventional cigarette, contains an addictive substance (nicotine) and thus logically still will be considered as harmful? The IA Report even contains a reference to an article²⁸ in which the authors state that “[s]mokers attempting to use e-cigarettes for smoking cessation will most likely find them ineffective; indeed, their use may instead perpetuate smokers’ addiction. [...] [e]vidence of [...] cessation benefit is lacking”.

Moreover, the Commission even acknowledges in the IA Report (when discussing its “Option 2, i.e., establishing a new authorisation scheme for NCP) that *“the identification of assessment criteria (risk/benefit analysis) is somehow difficult. The pharmaceutical framework provides a safety/efficacy assessment where the efficacy is seen in terms of benefit from smoking cessation. As NCPs falling under this scheme do not claim to assist in smoking cessation, the efficacy assessment is therefore different in particular as the safety consideration needs to take into account that nicotine is a toxic and addictive substance and therefore, per se, not safe”*.

With this in mind, it is quite shocking to read in the IA Report that the Commission:

- on the one hand, explicitly admits on several occasions that “[a]t this stage the evidence on the effectiveness of electronic cigarettes in smoking cessation is inconclusive²⁹” (and even refers to a scientific study in this respect³⁰) and that “In terms of substitution, there is no conclusive evidence at this stage that NCP can be effectively used in smoking cessation, which logically means that these products cannot possibly obtain a marketing authorisation as a smoking cessation medicine, and

²⁸ But only quotes it in the context of its “gateway” argument; See below, sub 8. Cobb NK, Abrams DB. E-cigarette or Drug-Delivery Device? Regulating Novel Nicotine Products. N Engl J Med 2011; 365(3):193-5.

²⁹ This view is shared by the WHO Study Group on Tobacco Products : *“It is possible that at some time in the future ENDS might be developed as smoking cessation aids. [...] However, currently, the evidence is insufficient to conclude that any of the ENDS products is an effective smoking cessation aid or that they deliver sufficient nicotine for them to be used in smoking cessation”* (Report on the Scientific Basis of Tobacco Product Regulation, WHO Technical Report Series, No. 955).

³⁰ Etter JF, Bullen C, Fouris AD, Laugesen M, Eisenberg T. Electronic nicotine delivery systems: a research agenda. *Tob Control* 2011; 20:243-8.

- on the other hand, proposes that *“NCP with a nicotine level over a certain threshold may only be placed on the market if they have been authorised as medicinal products on the basis of their quality, safety and efficacy”*.

in the full knowledge that, by their nature, it is impossible for e-cigarettes to pass the efficacy test for smoking cessation.

In the same vein, it is startling to read in the IA Report that the Commission:

- on the one hand, as stated above, concedes that the evidence on the effectiveness of electronic cigarettes in smoking cessation is inconclusive at this stage, and
- on the other hand, argues that e-cigarettes are presented as an alternative to FMC rather than a smoking cessation aid *“in order to avoid the relatively burdensome authorisation procedure applicable to medicinal products”*

again in the full knowledge that an e-cigarette applying for a marketing authorisation as a medicinal product is doomed to fail.

In this regard, the Commission’s following arguments are without merit too:

- *“the already on-going development towards bigger companies is expected to continue and at a higher speed due to innovation opportunities and a clear legal framework. Also, bigger companies are more likely to have resources for obtaining market authorisations”*: it is irrelevant whether a manufacturer of e-cigarettes has a lot of money to spend on applications for marketing authorisations for these products or not. The basic problem that e-cigarettes do not meet the conditions for such a marketing authorisation, remains, regardless of the amount of money “thrown at the problem”;
- *“In addition, some adaptations in terms of composition and/or design might be needed to ensure compatibility with the medicinal products framework”*. Again, no amount of adaptation in composition and/or design will transform an e-cigarette into a medicinal product;
- *“It would encourage research and innovation in smoking cessation”*: the same comment applies here as no amount of research or innovation will transform an e-cigarette into a medicinal product.

In sum, the classification of e-cigarettes as medicinal products leads to the absurd result whereby manufacturers would have to (i) either try to prove something that does not exist and consequently cannot be proven (*i.e.*, significant physiological effects and a therapeutic indication for relieving nicotine withdrawal symptoms as an aid to smoking cessation), or (ii) present e-

cigarettes as a smoking cessation product against their will, commercial aims and better judgment. The Commission is attempting to force a peg into a square hole.

This scenario, which is regrettably pursued in the draft Directive, would only benefit conventional tobacco products and the pharmaceutical industry. Meanwhile, it would be detrimental to public health as it would eliminate from the EU market an alternative to conventional cigarettes which – unlike conventional cigarettes – does not have fatal effects (See, below).

It is finally added here that – as shown above – courts in Germany and the Netherlands have ruled that e-cigarettes cannot be classified as a medicinal product the term of which has been defined in Article 1(2) of Directive 2001/83/EC. The ECJ has further clarified this definition, precluding it from being applied to e-cigarettes. This body of case law cannot be dispelled or ignored by the legislator, as the definition is set to remain unchanged in the future: there is absolutely no reason or movement at EU level to amend the definition of medicinal product under Directive 2001/83/EC, nor is there any justification to do so, which means the case law must continue to apply³¹.

4.6 Skewed “level playing field” for e-cigarettes and NRTs, and de facto ban of e-cigarettes

In its IA Report, the Commission repeatedly states that “[n]icotine replacement products (NRTs) considered as medicinal products need to undergo strict marketing authorisation procedures and if other NCP can reach the market without such authorisation, it could lead to an unjustified advantage undermining a level playing field”. In order to address this alleged “undermining of a level playing field”, the draft Directive proposes to subject NCPs, including e-cigarettes, to the same strict marketing authorisation procedures for medicinal products as NRTs.

However, although TVECA recognises that the draft Directive positively aims to remove current legislative divergence between Member States, the draft Directive fails to take into account the crucial fact that the e-cigarette, contrary to NRTs, does not claim to have any medicinal properties and in fact does not have any.

While e-cigarettes are significantly less harmful than conventional cigarettes (See, below sub 7), they do not have any curative or preventative properties. Therefore, e-cigarettes should not and indeed cannot be authorised as medicinal products. It also follows therefrom that the Commission’s policy objectives of (1) “removing differential treatment between NCP and NRT” and (2) “facilitating a level playing field as it would subject all economic stakeholders involved in NCP and NRT to the same rules” are fundamentally flawed. Indeed, the differential treatment of

³¹ Incidentally, this case law is also quoted extensively by the Commission itself in its Orientation Note: Electronic Cigarettes and the EC Legislation of 22 May 2008.



different types of products containing nicotine (NRT's versus NCPs such as e-cigarettes) is perfectly justified. Far from establishing a level playing field within the internal market, the draft Directive would create a market that is unlawfully skewed in favour of NRT's and thus the pharmaceutical industry.

By grouping e-cigarettes with NRTs and by requiring authorisation of e-cigarettes under Directive 2001/83/EC, the draft Directive also results in a *de facto* ban on e-cigarettes. Indeed, e-cigarettes, not being a medicinal product, cannot fulfil the criteria to obtain a marketing authorisation as a medicinal product (See, above sub 5.5). Recent experience from the US confirms this as all applications for e-cigarettes to receive a marketing authorisation as a medicine in the US have failed, and no e-cigarette has obtained authorisation as a medicinal product in the US or in the EU to date.³² In consequence, e-cigarettes would be doomed to exit the market under the current proposal (except for e-cigarettes falling below the particularly low thresholds of Article 18 of the draft Directive; it should be noted that such products have only extremely limited use among smokers wishing to switch, due to their too-low nicotine content.

The TVECA is not the only one who considers the draft Proposal as imposing a *de facto* ban on e-cigarettes. It suffices to "Google" "*draft proposal tobacco product directive de facto ban electronic cigarettes*" and read the resulting articles/documents.

5. OTHER CONSIDERATIONS

In addition to the above, we would like to point out that a vast number of e-cigarettes have a tobacco flavour. The tobacco flavour is closely related to conventional cigarettes and would have a counter-effect, in terms of behaviour, on those trying to quit smoking. This consideration thus further points to the conclusion that e-cigarettes are not medicinal products by either presentation or function.

Indeed, in order to stop smoking there is a need for behavioural change (for example, not "lighting up" and not satisfying the nicotine need by inhaling a product closely resembling a conventional cigarette). This behavioural change is not realised when someone uses e-cigarettes, as the latter mimic conventional cigarettes and prolong the addiction to nicotine.

In contrast, the use of NRTs signifies a visible behavioural change, away from conventional cigarettes.

³² As the Commission acknowledges in the IA Report, "[s]o far, no electronic cigarette has been authorised in the EU under the pharmaceutical regulation".



Finally, the conclusion that e-cigarettes should not be treated as medicinal products for the purposes of the draft Directive is also supported by the fact that e-cigarettes are not treated as medicinal products for other purposes, such as when classifying them under EU's customs law.

Having demonstrated that e-cigarettes do not qualify as medicinal products under Directive 2001/83/EC, we provide evidence in the section below that, unlike conventional cigarettes, e-cigarettes do not constitute a threat to public health.

6. PUBLIC HEALTH ISSUES

6.1 Scientific evidence shows e-cigarettes to be less harmful than conventional cigarettes

We do not dispute that nicotine is an addictive substance³³ but we do dispute that it is a “toxic” substance as the IA Report suggests. The toxicity of a substance depends entirely on the dosage: any substance, consumed in excessive quantities, has the capacity of being toxic – this applies to water as well as nicotine (so-called “the dose makes the poison” principle).

The mere fact that nicotine is an addictive substance (just like caffeine for example) does not mean that e-cigarettes present a “*significant risk to public health*” as suggested by the Commission in the IA Report.

A number of reports available over the Internet have characterized, quite extensively, the components contained in c-cigarette liquid and vapour using gas chromatography mass spectrometry (GC-MS). They demonstrate that the primary components of c-cigarette cartridges are propylene glycol (PG), glycerine, and nicotine³⁴.

Retailers all over the world have already sold millions of e-cigarettes (there are currently an estimated 3.5 million users), yet there is no evidence that these products have endangered anyone in case of normal use. Electronic cigarettes have been the focus of over 21 studies, including an FDA study. Never has there been reported a single chemical or toxin at any levels harmful to humans. See: <http://www.tveca.com/science.php>.

³³ Indeed, under the Membership Agreement of the TVECA, its members agree to show prominently the TVECA approved warning on products that contain nicotine, on print materials, and throughout their website. This warning is: “*Nicotine is a highly addictive substance. Do not use if you are pregnant, nursing, allergic to nicotine or propylene glycol, or have high blood pressure*” (www.tveca.com).

³⁴ Alliance Technologies: Characterization of liquid “smoke juice” for electronic cigarettes. 2009 [http://cdn.johnsoncreeksmokejuice.com/downloads/JCE_GCMS_Report.pdf]. Under the Membership Agreement of the TVECA, its members agree to list all primary ingredients on their website and to reference this webpage on the packaging/instruction card (www.tveca.com).



Moreover, the e-cigarette causes no third party harm, as there is no second- or third-hand smoking, while more than 79,000 adults are said to die each year in the EU alone due to passive smoking.³⁵ To date, there has been no harm detected from second- or third-hand vaping.

The only study known to TVECA that barely suggests that risks for passive smokers cannot be excluded is a study conducted by the German Federal Institute for Risk Assessment (BfR). Even here, the study fails to provide any positive evidence whatsoever to support the vague claim that *“risks cannot be excluded”*. Failing to find any proof that e-cigarettes can harm second- or third-hand vapers, the study makes mere assumptions regarding possible risks arising from potential abnormal use of the e-cigarettes, for example, in case users experiment and apply other concentrates and substances to the e-cigarette.

On the contrary, an increasing amount of studies provide significant positive evidence that vaping is not harmful to second- and third-hand vapers.

The first scientific study to show that the vapour emitted by e-cigarettes contains nothing likely to harm users or bystanders was conducted by Dr. Murray Laugesen of Health New Zealand who tested e-cigarette vapour for over 50 cigarette smoke toxicants. He reported at the April 2009 Society for Research on Nicotine and Tobacco Conference that e-cigarette users do not inhale smoke or smoke toxicants.³⁶

In July 2009, the US Food and Drug Administration (FDA) lab report on the testing of 18 e-cigarette samples revealed that the only potentially harmful element the agency could find in the vapour was a tiny trace of a minor tobacco alkaloid. However, taking into consideration the levels of this chemical in the e-cigarette, the chemical is neither toxic nor carcinogenic to humans.

In another important study in the field, Dr. Michael Siegel of Boston University School of Public Health, along with Berkeley’s Dr. Zachary Cahn, reviewed the results of 16 studies (including the FDA “Final” lab report). TSNAs were reported in two studies, but at trace levels which are similar to those found in a nicotine patch, and, most importantly, about 500-fold to 1400-fold lower than TSNA levels measured in conventional cigarettes. The presence of DEG was reported in the FDA’s report in one of the 18 cartridges, yet none of the other 15 studies found any DEG. The authors stated: *“Although the existing research does not warrant a conclusion that electronic cigarettes are safe in absolute terms and further clinical studies are needed to comprehensively*

³⁵ See:

<http://www.smokefreepartnership.eu/documents/lifting-smokescreen-10-reasons-going-smokefree>

³⁶ See *“Ruyan® E-cigarette Bench-top tests”*, Murray Laugesen, Poster 5-11, Society for Research on Nicotine and Tobacco (SRNT) Dublin, April 30, 2009; updated 27 May.



assess the safety of electronic cigarettes, a preponderance of the available evidence shows them to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products".³⁷

In addition, according to Siegel and Cahn, none of the more than 10,000 chemicals present in tobacco smoke, including over 40 known carcinogens, has been shown to be present in the cartridge or vapour of electronic cigarettes in anything greater than trace quality (i.e., well below the level that could cause even minimal harm).

Laugesen tested e-cigarette mist for more than 50 priority-listed cigarette smoke toxicants and found none³⁸. This report only revealed traces (8.2 ng/g) of TSNAs in the 'high' nicotine cartridge of an e-cigarette. It must be noted that this amount is equal to the quantity reported to be present in a nicotine medicinal patch (NRT).

In addition, a study called by the World Health Organisation concluded in October 2012 that acute active and passive smoking using e-cigarettes does not influence complete blood count indices in either smokers or second- or third-hand smokers. In contrast, the researchers found that acute active and passive tobacco cigarette smoking increase the secondary proteins of acute inflammatory load for at least one hour.³⁹

Another study has found that, while smoking one tobacco cigarette leads to significant acute myocardial dysfunction, e-cigarettes do not have acute adverse effects on cardiac function⁴⁰. Therefore, they do not damage the heart.

As shown above, no specific health risks have been identified to date in relation to e-cigarettes. No specific risk has been identified as a result of e-cigarette overdose either.

³⁷ See "Electronic cigarettes as a harm reduction strategy for tobacco control: A step forward or a repeat of past mistakes?", Zachary Cahn and Michael Siegel, Journal of Public Health Policy (2011) 32, 16–31. doi:10.1057/jphp.2010.41; published online 9 December 2010, Emphasis added.

³⁸ Laugesen M: Ruyan e-cigarette bench top tests. Poster. Society for Research on Nicotine and Tobacco Conference, Dublin, 2009 [<http://www.healthnz.co.nz/DublinEcigBenchtopHandout.pdf>]

³⁹ See "Acute effects of electronic and tobacco cigarette smoking on complete blood count", Flouris A., Poulianiti K., Chorti M., Jamurtas A., Kouretas D., Owolabi E., Tzatzarakis M., Tsatsakis A., Koutedakis Y., Food and Chemical Toxicology, October 2012.

⁴⁰ Farsalinos K *et al*, research results presented at the ESC Congress 2012

([tp://www.escardio.org/about/press/press-releases/esc12-munich/Pages/acute-effects-electronic-cigarettes-heart-damage.aspx](http://www.escardio.org/about/press/press-releases/esc12-munich/Pages/acute-effects-electronic-cigarettes-heart-damage.aspx)).

For this reason, The Hague Court of Appeals ruled on 26 June 2012 in summary appeal proceedings between United Tobacco Vapor Group Inc. and the Dutch State (at p. 5):

"The State has acknowledged that the e-cigarette does not present an acute risk for public health. More generally, it is not demonstrated that the e-cigarette presents (legally relevant) risks for public health. Even if there would be any risks, it appears probable that these risks are smaller than the risks related to the use of a conventional cigarette. This is important because the application of the Medicines Act should not lead to impediments of the free movement of goods that are not proportionate to the intended aim of protection of public health (See, e.g., Commission/Germany)".

In its judgement of 7 March 2013, the Tartu Administrative Court in Estonia ruled that:

"E-Lites products are an alternative for regular smoking, their use is more harmless to health, safer and cleaner and in this regard, it appears that there is no dispute.

[..]

Since e-cigarettes do not contain harmful substances (tar, tobacco), it can be concluded that the use of e-cigarettes as compared to the use of tobacco products is more harmless and safer to public health. Thus the complainant has pointed out on the basis of several studies that the transition from conventional cigarettes to electronic cigarettes because of the elimination of combustion by-products are likely to be at least 99% safer and healthier than continuation of smoking of conventional cigarettes.

[..]

The court finds that treating e-cigarettes as medicinal products and selling them only through pharmacies may limit the use of these products and can lead to a situation where the smoker remains using the previous more hazardous tobacco smoke, rather than using the product that is less hazardous for health. No materials or analysis and studies have been presented to the court which would demonstrate that not allowing e-cigarettes to the free market but selling them as medicinal products would reduce users of tobacco smoke or would reduce the overall number of smokers. Such a conclusion cannot be made on the basis of the contested decisions. As the E-Lites products are designed to satisfy the nicotine addiction for current smokers, it cannot be concluded that selling the E-Lites products would increase the number of persons with nicotine addiction".

The same reasoning was developed by the United States District Court for the District of Columbia in the above-mentioned Smoking Everywhere v FDA case of 14 January 2010:

"While FDA's interest in protecting public health and safety is, in the abstract, paramount to plaintiffs' purely economic interests, given the particular facts and circumstances of this case, I am not convinced that the threat to the public interest in general or to third parties in particular is as great as FDA suggests. Together, both Smoking Everywhere and NJOY have already sold hundreds of thousands of electronic cigarettes, yet FDA cites no evidence that those electronic cigarettes have endangered anyone.

Nor has FDA cited any evidence that electronic cigarettes are any more an immediate threat to public health and safety than traditional cigarettes, which are readily available to the public".

Therefore, since the relevant circumstances have not changed, meaning that no research has identified any risk to public health because of e-cigarettes, the Commission's proposed approach to classify e-cigarettes as medicinal products (except in the case of very low nicotine thresholds) is unjustified and disproportionate to the aim of protecting public health.

The available scientific reports show that e-cigarettes do not have greater pharmacological effects than a conventional cigarette.⁴¹ Moreover, the risks of conventional cigarettes have not led to their general prohibition. Therefore, classifying e-cigarettes as medicinal products would lead to an awkward nicotine regulatory structure where "dirty" tobacco products face few barriers to market entry whereas significantly "cleaner" products are subject to onerous hurdles and de facto banning.

Going forward with the current proposal would mean depriving smokers and the public of a non-fatal substitute to conventional tobacco products. This would run counter to the purpose of achieving a "high level of health protection" as mentioned in the preamble of the draft Directive.

The above also shows the untenability of the Commission's contention in the IA Report that, if NCPs, including e-cigarettes are classified as a medicine, *"the impact on Governments is expected to be positive as NCP could develop their potential as smoking cessation aid and thus lead to improved health outcomes (less premature mortality, health care costs, productivity)"* and *"[c]onsumers would have a more limited choice, but a higher degree of health protection"* and *"[this option] would lead to some reduction of tobacco related diseases and mortality due to the potential of NCP in smoking cessation"*. First, e-cigarettes in their present form have been shown already to be less harmful than conventional cigarettes so are already leading to improved health outcomes. Second, as extensively explained above, if e-cigarettes are classified as medicines for smoking cessation, this will result in a *de facto* ban of these products so at best the benefit to public health will be zero and at worst the impact on public health will be disastrous.

6.2 Alleged health concerns regarding e-cigarettes are unsubstantiated in the IA Report

In the IA Report, the Commission repeatedly refers to *"health concerns"* and *"serious health risks"* regarding NCPs, including e-cigarettes, and declares its intention to stop e-cigarette manufactures from *"misleading consumers to believe they are less harmful or have health benefits"*. We wonder how the Commission can reconcile this position with the scientific evidence listed sub 7.1 above.

⁴¹ See, for instance, *"Electronic cigarettes: Effective nicotine delivery after acute administration"*, Andrea Rae Vansickel and Thomas Eissenberg, *Nicotine and Tobacco Research*, Oxford Journals 2012.



In any event, for the sake of completeness, we will comment below on the sources quoted by the Commission as the basis for its position. Our analysis will show the bias reflected by the IA Report against e-cigarettes: study results are quoted incorrectly or incompletely, conclusions are drawn that do not follow from the quoted sources, etc. This is unacceptable.

First, the Commission states that it has, so far, received 14 notifications concerning (refill) liquids for electronic cigarettes via the RAPEX system, *“indicating serious health risks for consumers”* (17 December 2012).

However, these 14 RAPEX reports do not mention one single incident of human injury or illness. All of the reports relate to incorrect labelling or faulty battery chargers. Taking into consideration that millions of e-cigarettes have been sold already in the EU to date, the aforementioned data do not prove a significant risk to human health, but rather the absence thereof.

Second, the Commission states that *“acute nicotine poisoning has occurred in children who accidentally ingest nicotine”*⁴². This thus concerns harm from accidental ingestion, not from normal use. The harmfulness of a product or substance should be considered in light of its normal use. Nicotine when used/ingested normally can be considered harmful as it contains an addictive substance (nicotine) but the same goes for coffee and wine for example. These products, when ingested accidentally in a large (*i.e.*, abnormal) quantity by a child, will also cause harm but this is no reason to ban them or to submit them to the medicine legislation.

The study quoted in the IA Report examined *“child poisonings resulting from ingestion of tobacco products and assessed the potential toxicity of novel smokeless tobacco product”*. The TVECA wishes to emphasize in this respect that an e-cigarette cartridge is much harder to open than a paper pack of conventional cigarettes and that, therefore, the risk of accidental ingestion is far more limited than in the case of conventional cigarettes. In addition, under the Membership Agreement of the TVECA, its members agree to ensure, when offering eliquid, that all eliquid containers have child-safety caps, the maximum size bottle containing nicotine will be 30ml and the maximum nicotine level sold to consumer is no greater than 36mg/ml or 3.6% of the total volume of the cartridge. In e-cigarettes that comply with these measures, which the whole industry should adhere to, the risk of acute nicotine poisoning in children is nearly non-existent.

The study concerned also mentions that *“[novel smokeless tobacco products] are of concern with their discreet form, candy-like appearance, and added flavorings that may be attractive to young children”*. *“Discreet form”* and *“candy-like appearance”* are two characteristics that arguably do

⁴² Connolly GN, Richter P, Aleguas A Jr, Pechacek TF, Stanfill SB, Alpert HR. Unintentional child poisonings through ingestion of conventional and novel tobacco products. *Pediatrics* 2010; 125(5):896-9

not apply to e-cigarettes as these are very similar to conventional cigarettes in their physical design. In addition, as regards added flavourings, under the Membership Agreement of the TVECA, its members agree not to offer flavours with names that directly appeal to minors (e.g. Cotton Candy, Bubble Gum, etc.).

Lastly, the study only concluded that *“public health authorities are advised to study these products to determine the appropriate regulatory approach”* so it did not contain any conclusive findings whatsoever.

Third, the IA Report points out that some e-cigarettes have been found to be defective (e.g. leaking cartridges, containers with minimal protection against tampering, differences between labelled and true levels of nicotine cartridges and refill solutions).

However, in the case of defective e-cigarettes found on the EU market, it is disproportionate to prevent *all* e-cigarettes from being placed on the market, or do so by making them subject to the requirement of a marketing authorisation which in effect will lead to the same end-result. In the case that a few defective e-cigarettes have been found on the market, the Commission needs to adhere to the principle of proportionality: the least restrictive approach must be taken in order to resolve the issues concerned. This means that, due the principle of proportionality, any measure which the Commission intends to take must be appropriate in order to achieve the objective which is intended, and necessary in order to achieve the objective which is intended, *i.e.*, there are no less severe means of achieving the objective⁴³.

Taking an example of items that are frequently reported in the Commission’s RAPEX system of notifications of dangerous products, if certain children’s toys are found to be defective, all toys will not be prevented (whether *de facto* or otherwise) from being placed on the market, nor even all toys within a particular category. Rather, those which are or could potentially be defective, emanating from a particular source or sources (e.g., manufacturer or supply chain), are dealt with appropriately (e.g., withdrawn from the market or at the last resort recalled) pursuant to the relevant product safety rules (here, the Toy Safety Directive 2009/48/EC, while for other non-sectoral products, Directive 2001/95/EC on General Product Safety (the “**GPSD**”). The same goes for e-cigarettes: we fully agree that all manufacturers of e-cigarettes must ensure that their products comply with the GPSD and that the Commission should take action against those individual products that are found to violate the GPSD.

In this respect, it should be noted that the Membership Agreement of the TVECA expressly contains rules that its members must abide by for the purpose of ensuring that e-cigarettes are guaranteed as non-defective, as any responsible manufacturer would require and ensure:

⁴³ See: http://europa.eu/legislation_summaries/glossary/proportionality_en.htm



- show prominently the nicotine level and expiration dates on individual cartridge plastic wrap (applies also to any eliquid packaging);
- display nicotine levels numerically (e.g. 24mg) and/or show percentage (e.g. 24mg/ml=2.4%);
- submit to, and pay for, cartridge/eliquid random testing once every 6 months and send all samples within 3 days of notification (www.tveca.com)⁴⁴.

As a result of this regular testing, both internally and by external Certification Bodies, the e-cigarettes of all the members of TVECA have been certified by various bodies such as ROHS, CE and SGS.

Such products cannot be hindered from reaching the market on the basis that some examples of, .e.g., defective Chinese e-cigarettes are entering the market.

Should the Commission nonetheless wish to go further in order to ensure that the risks of defective cigarettes are minimised, it has at its disposal the GPSD, whereby it can introduce at short notice a Decision with EU-wide application to ensure that only non-defective e-cigarettes are being placed on the market (Article 13 of the GPSD).

Fourth, the IA Report states that “[a]nalyzes of electronic cigarette samples conducted by the US Food and Drug Administration (FDA) have shown detectable levels of known carcinogens and toxic chemicals; including diethylene glycol, tobacco-specific nitrosamines and tobacco specific impurities”.

In June 2009, the FDA indeed announced in a press conference that “a laboratory analysis of electronic cigarettes samples has found that they contain carcinogens and toxic chemicals such as diethylene glycol (DEG), an ingredient used in antifreeze”. However, the actual lab report revealed that the “carcinogens” referred to in the FDA’s press conference were tobacco specific nitrosamines (TSNAs), but failed to specify the quantity detected. The FDA’s report did state that the quantity of DEG detected in the liquid in one of the 18 samples was 1% (0,01 ml), but did not point out that this is a non-toxic quantity. The FDA did not report finding DEG, or any other harmful chemical, in the vapour.

⁴⁴ Incidentally, the TVECA members are also under an obligation to inform consumers that all cartridges are recyclable and that there is a proper disposal of batteries (www.tveca.com).



Fifth, the IA Report also mentions a recent study that “found immediate adverse physiologic effects (changes in the lung function) after short terms use which is similar to some of the effects associated with tobacco smoking”⁴⁵.

The study design was scientifically curious to say the least. Indeed, the study aimed to “assess whether using an e-cigarette for 5 min has an impact on the pulmonary function tests and fraction of exhaled nitric oxide (Feno) of healthy adult smokers” (emphasis added). There is no such thing as a “healthy” smoker as cigarette smoke is very harmful to *inter alia* pulmonary (and cardiac) function. Therefore, the study population’s pulmonary function was already lightly to severely impaired prior to participation in the study.

It is also interesting to note that, although the study’s declared purpose was to “assess whether using an e-cigarette for five minutes has an impact on pulmonary function tests and exhaled nitric oxide”, the study’s abstract only reported the observed reduction in exhaled nitric oxide, not the lack of any effect on pulmonary function tests. Moreover, the study failed to compare the acute respiratory effects of e-cigarette exposure with those of active smoking, which is the most important comparison that needs to be made. In contrast to what some are reporting, the study found no effect of e-cigarettes on lung function, as measured by spirometry. This is in contrast to tobacco smoking, which does have effects on lung function that can be measured using spirometric testing. While previous research indicates that active smoking and even second hand smoke exposure can affect acute lung function as measured by spirometry, the study demonstrated that e-cigarette use led to no impairment of lung function detectable via spirometric testing.

What the study did show was subclinical evidence of impaired lung function, meaning that the observed (measurable) lung function was unchanged, but that there was evidence of physiologic effects consistent with some bronchial inflammation. What is not known is whether this acute bronchial inflammation has any significance in the long-term. The presence of bronchial inflammation may be a result of propylene glycol having a respiratory irritant effect. But this does not necessarily mean that long-term exposure would lead to any adverse effect on lung function. The authors acknowledge this: “We must state though that while the differences within our study are of statistical significance, the clinical changes may be too small to be of major clinical importance.”

⁴⁵ Vardavas CI, Anagnostopoulos N, Kougias M, Evangelopoulou V, Connolly GN, Behrakis PK. Short-term pulmonary effects of using an electronic cigarette: impact on respiratory flow resistance, impedance, and exhaled nitric oxide. *Chest* 2012; 141(6):1400-6.

Sixth, the IA Report also refers to a recent study that concludes that “passive vaping” must be expected from the consumption of e-cigarettes due to prominent components in the gas-phase, including 1,2-propanediol, 1,2,3-propanetriol, diacetyl, flavorings, and traces of nicotine⁴⁶.

The reader is left with the impression that Schripp et al. found chemicals in e-cigarette vapour that would endanger the health of users. However, a bystander would need to “lock lips” with an exhaling e-cigarette user to be exposed to all the “prominent components of the gas phase” measured in the glass chamber experiment, as opposed to the main stainless-steel chamber experiment.⁴⁷

Importantly, the extremely low quantities in the stainless-steel chamber experiment of this study indicate that most of the chemicals found in concentrated captured exhalation (“the gas phase”) disappear in the ambient air. For example, although nicotine was present (at 1.4% of the exposure limit) in the glass chamber experiment, no nicotine at all was detected in the stainless-steel chamber experiment. Similarly, 1,2-propanediol one of the prominent components of the gas phase, was detected in traces only in the stainless-steel chamber experiment.

While of course chemicals can always be found in vaping, these are way too low to cause any harm to human health (or the environment). Specifically, the quantities of released chemicals are so low that they can not present any health hazard to bystanders or to the users themselves. This fact clearly follows from the US and EU occupational exposure limit values for chemicals collected, among others, in the GESTIS database.⁴⁸

The Occupational Safety and Health Administration in the US publishes permissible exposure limits (PELs) for hundreds of chemicals that might be present in the air at workplaces. Similarly, in the European Union occupational exposure limits (OELs) are adopted and published in the Official Journal. The stainless-steel chamber experiment showed that five of the six compounds, that did increase for the vapour of an e-cigarette,⁴⁹ were present in quantities that are less than 1% of the PEL, and less than 2% of the available OEL. The sixth compound, formaldehyde, is

⁴⁶ Schripp T, Markewitz D, Uhde E, Salthammer T. Does e-cigarette consumption cause passive vaping? Indoor Air 2012.

⁴⁷ During the glass chamber experiment, to determine the components in the breath gas directly, an e-cigarette smoker exhaled into a 10 L glass chamber. Differently, the “large scale vaping/smoking experiment” was performed in an 8 cubic meter stainless-steel emission test chamber. Importantly, analysis of the immediately captured breath in the glass chamber resulted in a different list of chemicals than the stainless-steel chamber experiment.

⁴⁸ See the GESTIS database “International limit values for chemical agents, occupational exposure limits (OELs)”, at: http://www.dguv.de/ifa/en/gestis/limit_values/index.jsp

⁴⁹ The six compounds that did increase for vapour sample were 2-butanone (MEK), acetic acid, acetone, isoprene, formaldehyde, and acetaldehyde.



produced naturally by the human body, and it was present at 2.4% of the PEL, corresponding to 6% of the limit value adopted by Germany (in the absence of an EU-wide OEL).

In short, if the researchers had provided this comparison in their data, it would have been obvious that their conclusions did not fit the facts. Moreover, the study confirms that electronic cigarette use greatly reduces the user's exposure to a wide range of chemicals in tobacco smoke. The few chemicals for which exposure remains are at levels well below that of cigarette smoking.

The above analysis of the sources quoted by the Commission in the IA Report to corroborate its warnings about the alleged “*serious health risks*” of e-cigarettes shows that these sources do not support the Commission's position, rather the contrary.

7. **“GATEWAY” ARGUMENT IS UNSUBSTANTIATED**

Manufacturers of e-cigarettes primarily target their products at adult smokers of conventional cigarettes who wish to stop smoking conventional cigarettes. According to the IA Report, e-cigarettes are also used by smokers of conventional cigarettes to satisfy their nicotine craving in smoke-free environments where the smoking of conventional cigarettes is prohibited. Finally, “dual use” of conventional cigarettes and e-cigarettes has also been reported. All of these reported uses relate to adult smokers.

In its judgement of 7 March 2013, the Tartu Administrative Court ruled that:

“Also should be taken into account the fact that e-cigarettes are sold to adults and they are used by people who already have a nicotine addiction. This part is not disputed by the respondent. Thus, a smoker of an e-cigarette has a strong habit and experience and is able to assess their needs.

[..]

As the E-Lites products are designed to satisfy the nicotine addiction for current smokers, it cannot be concluded that selling the E-Lites products would increase the number of persons with nicotine addiction”.

The TVECA does not advocate targeting non-smokers. These individuals do not experience nicotine cravings and should remain that way. Similarly, we do not advocate targeting young people either. In fact, we are very much in favour of introducing an age restriction for electronic cigarettes, more particularly 18 years. Affiliates of the TVECA include:

- The *We Card* Program, Inc., (www.wecard.org): a number of organisations came together with the aim of preventing the underage sale of tobacco in the US. They established the Coalition for Responsible Tobacco Retailing and its now widely recognized *We Card* Program which has blossomed into a nationwide effort to prevent underage tobacco sales. The *We Card* program is now widely accepted across the US as



a premier tobacco sales training and education program. It works with retailers, trade associations, government officials, community groups and others to provide tools and training to retailers large and small. One of the objectives of the TVECA is to also introduce this program in the EU for e-cigarettes.

- Veratad Technologies LLC. (www.veratad.com) is a world class provider of real-time online Identity Verification, Age Verification and Knowledge Based Authentication Solutions. Its solutions can be used *inter alia* for the purpose of preventing the on-line sale of e-cigarettes to minors. Again, one of the objectives of the TVECA is to also introduce this program in the EU for e-cigarettes.

Under the Membership Agreement of TVECA, its members agree to adhere to the following principles, which are all aimed at avoiding the use of e-cigarettes by minors:

- ensure, with reasonable certainty (e.g. verification services), online buyers to be of legal age to purchase in the area where the consumer resides and/or more specifically where the product will be shipped;
- ensure, with reasonable certainty (e.g. state issued photo ID), in-person buyers to be of legal age to purchase in the area where the consumer resides and/or more specifically the area of place of business;
- ensure marketing materials (e.g. BE COOL) and product packaging do not market and/or directly appeal to minors (e.g. cartoons, candy, etc);
- not offer free trials (a money back guarantee is sufficient) (See, www.tveca.com).

It is stated in the IA Report that *“some NCP appear to be subject to vivid and innovative marketing, which could attract young people in particular. For example, e-cigarettes are available in a range of flavours, including coffee and cherry [..]”*. However, the use of flavourings is customary for a leisure product, especially one that does not contain tobacco and thus is obliged to add flavours in order to achieve taste. The purpose of these flavourings, which mimic the flavourings in conventional cigarettes, is to entice smokers of conventional cigarettes to switch to e-cigarettes. Without their flavourings, e-cigarettes will lose their appeal for these smokers, which would be a regrettable consequence from a public health point of view.

As regards the marketing materials, we concur completely and refer in this respect to the membership principles of the TVECA in the preceding paragraph.

There is no scientific evidence whatsoever that the “gateway”-argument applies to e-cigarettes. In particular, the Commission has not invoked any serious scientific evidence that e-cigarettes are a gateway into tobacco use for young people who do not yet smoke conventional cigarettes. The

Commission only quotes one study in this respect, conducted in Poland⁵⁰. This study indeed found that about one in five young people in a sample group had tested electronic cigarettes, but the Commission fails to mention that the study specifies that “*most of them had previously smoked cigarettes*”. Therefore, this study does not substantiate the “gateway-argument” at all.

Similarly, no scientific evidence exists either to suggest that e-cigarettes can become a re-starter product attractive to former smokers. In the single article (not a study) referred to in the IA Report⁵¹, the authors merely opine that “*there is cause for concern that the devices will become ‘bridge products’ [...] that are attractive to [...] former smokers*” but, tellingly, do not offer or quote any scientific evidence whatsoever to corroborate their opinion. Interestingly, the authors also state in the same article that “[s]mokers attempting to use e-cigarettes for smoking cessation will most likely find them ineffective; indeed, their use may instead perpetuate smokers’ addiction. [...] [e]vidence of [...] cessation benefit is lacking”. Why did the IA Report keep silent about this part of the article?

Lastly, there is no scientific evidence to suggest that non-smokers might take up use of an e-cigarette, become addicted to nicotine, and eventually start to smoke conventional cigarettes. In a survey that included 3,037 ever-users of e-cigarettes, only one of the 2,850 respondents who used nicotine-containing e-cigarettes was a never-smoker.⁵² Given the fact that 70% of the ever-users in that survey succeeded in quitting smoking, the e-cigarette would appear instead to be a gateway away from smoking.⁵³

8. UNLAWFULNESS OF THE CURRENT PROPOSAL

If the current proposal is adopted without any amendment regarding the legal regime applicable to e-cigarettes, TVECA is determined to challenge its validity in court as well as the validity of the transposition measures adopted at Member State level.

In that respect, it is hardly disputable that the draft Directive violates a number of core values and principles of the European Union legal order, amongst which are (1) the principle of conferral; (2) the free movement of goods principle; (3) the obligation to ensure a high level of health protection

⁵⁰ Goniewicz ML, Zielinska-Danch W. Electronic cigarette use among teenagers and young adults in Poland. *Pediatrics* 2012;130(4):e879-85.

⁵¹ Cobb NK, Abrams DB. E-cigarette or Drug-Delivery Device? Regulating Novel Nicotine Products. *N Engl J Med* 2011; 365(3):193-5.

⁵² Etter JF, Bullen C : Electronic cigarettes: users profile, utilization, satisfaction and perceived efficacy. *Addiction* 2011, 106:2017-2028.

⁵³ Caponetto *et al.* *Journal of Medical Case Reports* 2011, 5:585.

within the EU; (4) the principle of equality and non-discrimination; and (5) the freedom to conduct one's business.

8.1 Principle of conferral

According to Article 5(2) of the TEU, “[u]nder the principle of conferral, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. Competences not conferred upon the Union in the Treaties remain with the Member States”.

The principle of conferral imposes on the EU authorities an obligation to indicate the legal basis of any act that they adopt. According to the Court of Justice, “[t]he choice of the appropriate legal basis has constitutional significance”.⁵⁴

It appears from the preamble of the draft Directive that it is based on Article 114 TFEU, which gives the EU competence to “establis[h] or ensur[e] the functioning of the internal market” (Article 26(1) TFEU). The internal market can in turn be defined as “an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured” (Article 26(2) TFEU). It is settled case-law that a measure adopted pursuant to that provision, “must genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market. If a mere finding of disparities between national rules and of the abstract risk of obstacles to the exercise of fundamental freedoms or of distortions of competition liable to result therefrom were sufficient to justify the choice of Article [114] as a legal basis, judicial review of compliance with the proper legal basis might be rendered nugatory”.⁵⁵

It is submitted that, insofar as it imposes a *de facto* ban on e-cigarettes, the draft Directive is not properly based on Article 114 TFEU. It is indeed common ground that, far from embracing the free movement of goods principle, a provision precluding the sale of e-cigarettes would severely restrict it. Admittedly, a measure adopted under Article 114 TFEU can provide for the outright prohibition of a category of products under specific circumstances, notably if such ban is justified on public health grounds⁵⁶. However, as explained below, a prohibition on electronic cigarettes cannot be justified out of public health concerns given that such a measure would actually decrease the general level of health protection in the European Union.

⁵⁴ Opinion 2/00 [2001] ECR I-9717, para. 5.

⁵⁵ C-376/98 *Germany v. Parliament and Council* [2000] ECR I-8419, para. 84.

⁵⁶ See, in that respect, C-434/02 *Arnold André* [2004] ECR I-11825 ; C-210/03 *Swedish Match* [2004] ECR I-11900 ; C-154 and 155/05 *Alliance for Natural Health* [2005] ECR I-6451.

In any event, even if such a measure were adopted as part of a genuine public health policy, it would not withstand judicial scrutiny considering the fact that the EU lacks competence to harmonise Member State legislations in the field of public health (see, Article 6 and 168 TFEU).

8.2 Free movement of goods

According to Article 34 TFEU, “[q]uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States”. As is well known, all trading rules “which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade, are to be considered as measures having an effect equivalent to quantitative restrictions”⁵⁷.

This provision bars the EU authorities from imposing obstacles on the free movement of goods insofar as “the prohibition on quantitative restrictions and measures having equivalent effect applies not only to national measures but also to measures adopted by the [EU] institutions”⁵⁸. Article 34 TFEU also prohibits the EU legislature from allowing Member States to violate the free movement of goods principle considering that “a rule of secondary legislation (...) cannot be interpreted as authorizing the Member States to impose or to maintain conditions contrary to the Treaty rules on the free movement of goods”⁵⁹.

In light of the above, it is hardly disputable that the draft Directive flies in the face of Article 34 TFEU.

First, the draft Directive entails a *prima facie* breach of Article 34 TFEU insofar as it imposes – whether directly or indirectly (through the application, by Member States, of the EU legislation on medicinal products) – a *de facto* ban on the marketing and sale of e-cigarettes in the European Union.

Second, such a restriction does not rest on any objective justification. More in particular, the prohibition on e-cigarettes is not suitable for the attainment of public health objectives. As explained above, it is plain that e-cigarettes constitute a less harmful alternative to conventional cigarettes. As a result, by depriving smokers of the opportunity to switch to less toxic tobacco products, the draft Directive actually undermines the very objective that it purports to achieve.

⁵⁷ Case 8/74 *Procureur du Roi v. Dassonville* [1974] ECR 837, 852.

⁵⁸ See, e.g., cases C-51/93 *Meyhui* [1994] ECR I-3879, para. 11; C-469/00 *Ravil v. Bellon* [2003] ECR I-5053 ; C-108/01 *Asda Stores* [2003] ECR I-5121, para. 53.

⁵⁹ C-12/00 *Commission v. Spain* (chocolate) [2003] ECR I-459, paras 65-66.

It follows that the draft Directive is at variance with Article 34 TFEU insofar as (1) it precludes the sale of e-cigarettes; and (2) this restriction on the free movement of goods is not warranted by any mandatory requirement of general interest.

8.3 Health protection

Article 35 of the EU Charter of fundamental rights and Article 168(1) TFEU provide that “a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”. A similar requirement is contained in Article 9 TFEU. In the same vein, when drafting a piece of legislation based on Article 114 TFEU, the Commission is called upon to “take as a base a high level of protection [of public health]” (Article 114 (3) TFEU).

These provisions must, at a minimum, be understood as precluding the EU authorities from adopting measures which would jeopardise the level of human health protection already reached within the European Union. This is particularly true for the principles contained in the EU Charter of fundamental rights, including the principle of a high level of health protection enshrined in Article 35 of the Charter. Such principles are interpreted as imposing a « standstill » obligation on the EU, namely as prohibiting the EU from *lowering* the general level of protection already achieved for each of these principles⁶⁰.

The draft Directive does not conform to such a requirement. By *de facto* precluding the marketing and sale of e-cigarettes, the draft Directive brings about a decrease in the level of protection of public health. As explained above, it is indeed beyond doubt that electronic cigarettes are significantly less harmful than conventional tobacco products. On the one hand, they cause no third party harm, as there is no second- or third-hand smoking. On the other hand, there are no risks to users that are associated with vaping. Electronic cigarettes have been the focus of over 20 studies, including an FDA study. Never has there been reported a single chemical or toxin at any levels harmful to humans. In addition, electronic cigarettes are a natural alternative to smokers as they usually have strong similarities with conventional cigarettes (or cigars, pipes) in the physical design, in the nicotine release, in the emitted smoke-like vapour and in gesture.

It follows from the above that the draft Directive intends to deprive smokers and the public of a less harmful alternative to conventional tobacco products. By so doing, the draft Directive violates

⁶⁰ See, e.g., O. De Schutter, "Les droits fondamentaux dans le projet européen. Des limites à l'action des institutions à une politique des droits fondamentaux", in O. De Schutter and P. Nihoul (eds), *Une Constitution pour l'Europe. Réflexions sur les transformations du droit de l'Union européenne*, Larcier, 2004, p. 113 ; L. Burgorgue-Larsen, "Article II-112", in L. Burgorgue-Larsen, A. Levade, F. Picod (eds), *Traité établissant une Constitution pour l'Europe. Commentaire article par article. Partie II*, Bruylant, 2005, p. 688 ; A. Bailleux & E. Bribosia, "La Charte des droits fondamentaux de l'Union européenne", in S. van Drooghenbroeck, P. Wautelet (eds), *Droits fondamentaux en mouvement*, Anthémis, 2012, p. 94. At the time of the drafting of the Charter, the Economic and Social Committee already warned that the EU could not adopt "measures which would lessen the degree to which principles have already been put into effect" (CES 1005/2000 – SOC/013).

the principle of a high level of human health protection contained in Article 35 of the Charter and in Article 9, 114(3) and 168(1) TFEU.

8.4 Equality and non-discrimination

The principle of equality and non-discrimination “*is a general principle of European Union law, enshrined in Articles 20 and 21 of the Charter of Fundamental Rights of the European Union. According to settled case-law, that principle 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*”⁶¹.

The draft Directive breaches the principle of equality and non-discrimination insofar as :

- It introduces a difference of treatment between e-cigarettes – which are subject to a *de facto* ban – and conventional tobacco products, which are not so subject;
- E-cigarettes and conventional tobacco products are comparable categories of product given that e-cigarettes were precisely designed to be used as substitutes for conventional tobacco products: they purportedly target the same category of consumers (i.e., smokers), contain nicotine, work in the same way (inhalation through suction) and bear a close physical resemblance with cigarettes (or cigars or pipes);
- This difference in treatment does not rest on any objective justification considering that, as explained above, e-cigarettes are significantly less toxic than conventional cigarettes.

On the other hand, the draft Directive once again infringes the principle of equality and non-discrimination by treating *different* products in the *same* way:

- E-cigarettes and NRTs, being grouped together under draft Article 18 as “nicotine containing products”, are, thereby, both required to obtain authorisation as medicinal products (unless they fall below very low nicotine thresholds) even though they are not comparable;
- They are not comparable because they fulfil different aims and objectives as already amply noted above in this paper;
- And, as a result, there is certainly no objective justification to treat them in the same way.

⁶¹ C-550/07 *Akzo Nobel Chemicals v. Commission* [2010] ECR I-8301, paras 54-55.

8.5 Business freedom

Article 16 of the EU Charter of fundamental rights recognises the freedom to conduct business. This freedom has long been recognised as a general principle of EU law⁶². Admittedly, “restrictions may be imposed on [its] exercise” but only “provided that the restrictions correspond to objectives of general interest and do not constitute in relation to the aim pursued a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed”.⁶³

It is self-evident that, by organising a *de facto* ban on the marketing and sale of e-cigarettes, the draft Directive seriously undermines the freedom to conduct the business of the e-cigarettes industry. As a matter of fact, this restriction impairs the very substance of that freedom considering that it basically deprives e-cigarette manufacturers from any opportunity to market their product in the European Union. In addition, such an encroachment upon a fundamental right does not correspond to objectives of general interest. As explained above, the public health justification is absolutely unconvincing insofar as the draft Directive has the effect of driving out of the market less harmful substitutes for conventional cigarettes while maintaining full market access for the latter.

It follows from the above that the draft Directive breaches the freedom to conduct a business enshrined in Article 16 of the EU Charter of fundamental rights.

9. PROPOSED AMENDMENTS

For the reasons set out above, TVECA is of the opinion that the most appropriate way forward, which will both ensure a high level of public health and the attainment of the EU’s internal market harmonisation objectives, is to put e-cigarettes under the umbrella of (smokeless) tobacco products within the future Directive, albeit with some carve-outs. Taking into account the specific characteristics of e-cigarettes, it follows that the following amendments should be brought to the draft Directive⁶⁴:

⁶² See e.g. C-184/02 and C-223/02 *Spain and Finland v. Parliament and Council* [2004] ECR I-7829, para. 51 and references contained therein.

⁶³ *Ibid.*, para. 52.

⁶⁴ It appears from the IA Report that one of the options examined by the Commission in the framework of the revision of the TPD was to subject NCP to labelling and ingredients requirement under the TPD. More particularly, “NCP placed on the market are subject to adapted health warnings, ingredients reporting and a prohibition to place on the market NCP with characterising flavours (glossary). Delegated/implementing power

1) The definition of tobacco products should be amended as follows in Article 2 (34) of the draft Directive: “‘Tobacco products’ means products usable for consumption by consumers and consisting of, even partly, tobacco or products derived from tobacco, whether genetically modified or not”.⁶⁵

This definition is almost identical to the one currently proposed, and reflects the US Tobacco Act definition (“*any product made or derived from tobacco that is intended for human consumption*”). This definition would be slightly broader than the currently proposed one insofar as it would include products *derived* from tobacco. This amendment would bring e-cigarettes within the scope of the definition of “tobacco product” since e-cigarettes contain nicotine derived from tobacco leaves. The amendment also would bring e-cigarettes within the scope of the definition of “*smokeless tobacco product*” in Article 22 (29) of the draft Directive as it then can be considered also as a “*tobacco product not involving a combustion process*”.

It should be noted in this respect that the IA Report has itself considered, as an option, that e-cigarettes should become a TPD product.⁶⁶ Unfortunately, the option is then rejected in the IA report, but without sound argumentation: the IA Report states, *inter alia*, that “*Option 1 would contribute to a more homogenous development, but some Member States are expected to continue to consider NCP as medicinal products by function, which would maintain legal uncertainty and two parallel legal systems. Overall, it is therefore expected that the functioning of the internal market is not improved in a satisfactory manner.*”⁶⁷

This statement can be easily rebutted. Not only would use of the option (of allowing – in this case e-cigarettes – to fall within the umbrella of tobacco products) *increase*, and not compromise, legal certainty, as well as respond to the need for clarification of this issue by Member States, it would also allow the Commission to bring infringement proceedings against Member States who “go their own way” (by maintaining a parallel legal system) and fail to implement that part of the Directive.

to adapt health warnings and act on products with characterising flavours, on products with increased toxicity or addictiveness and to regulate additives that cause characterising flavours”.

⁶⁵ It is acknowledged that NRTs would also fall within this proposed definition. However, NRTs will continue to be governed by the marketing authorisation route of the current proposal, largely on the basis of their claims of curing addiction, and will therefore continue to be regulated under the relevant Directive, namely, 2001/83/EC.

⁶⁶ See: IA, section 5.2.2.1. *PO1: Subject NCP to labelling and ingredients requirement under TPD.* The option states: “*NCP placed on the market are subject to adapted health warnings, ingredients reporting and a prohibition to place on the market NCP with characterising flavours (glossary). Delegated/implementing power to adapt health warnings and act on products with characterising flavours, on products with increased toxicity or addictiveness and to regulate additives that cause characterising flavours.*”

⁶⁷ See, page 77 of the IA Report, first paragraph under “*Economic Impacts*”.



2) Article 11.1 of the draft Directive should be amended as follows: *“Each unit packet and any outside packaging of smokeless tobacco products, **other than electronic inhalers that vaporise a liquid solution simulating the act of smoking**, shall carry the following health warning [..]”.*

A new Article 11.2 should then be inserted in the draft Directive: *“**Each unit packet and any outside packaging of electronic inhalers that vaporise a liquid solution simulating the act of smoking, shall carry the following health warning: “This product contains nicotine and can be addictive”.**”.*

The reason is that it is appropriate to subject e-cigarettes to a health warning which is similar to that required under the proposed Directive for NCPs below certain thresholds. In this respect, an accurate health warning would read as follows: *“This product contains nicotine and can be addictive.”* It would be unjustified to state (as proposed in draft Article 11.1) that the product *“can damage your health”*, as there is sufficient evidence showing that e-cigarettes do not damage health.⁶⁸

TVECA is therefore not seeking to obtain a special status or to obfuscate the fact that e-cigarettes are (smokeless) tobacco products. On the contrary, TVECA wants its products to be regarded by consumers and the public at large as being what they are, i.e., an alternative tobacco product to conventional ones, which are not designed to “cure” smokers or to free them from their nicotine addiction but which can be used as a less harmful alternative to conventional tobacco products.

3) Article 6.10 of the draft Directive should be amended as follows: *“Tobacco products other than **the following** shall be exempted from the prohibitions laid down in paragraphs 1 and 5:*

(a) cigarettes;

(b) roll-your-own tobacco; and

*(c) smokeless tobacco products, **not including electronic inhalers that vaporise a liquid solution simulating the act of smoking**”*

The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is substantial change of circumstances as established in a Commission report.”

⁶⁸ See: <http://www.tveca.com/science.php>

Under Article 6.10 of the draft Directive the prohibition on tobacco products with a characterising flavour (prohibition on flavourings) applies *inter alia* to smokeless tobacco products and so also would apply to electronic cigarettes which under our first proposed amendment would fall within the scope of the broadened definition of “tobacco product”. However, e-cigarettes should be exempted from the prohibition. This is fully justifiable, as the vapour emitted by e-cigarettes is naturally flavourless. Precluding e-cigarettes from containing flavours would strongly undermine their attractiveness and therefore their potential as a less harmful alternative to conventional cigarettes. On the contrary, allowing e-cigarettes to contain flavouring would clearly enhance their attractiveness *vis-à-vis* conventional cigarettes. In addition, this would ensure that a large number of people currently smoking flavoured cigarettes (such as menthol) are likely to definitively switch over to e-cigarettes.

In addition, while there may be evidence that the use of flavourings seems to favour smoking initiation in young people (in other words, cigarette flavourings are perceived as a “gateway” to smoking for young people), the same cannot be said about e-cigarettes. There is no evidence adduced by the European Commission or anybody that flavours in e-cigarettes have led to young people taking up vaping. Thus, it would be unjustified to simply apply the gateway argument to e-cigarettes in order to prohibit the use of flavourings in this product.

10. CONCLUDING REMARKS

As a concluding remark, we would like to quote a recent article entitled “Electronic cigarettes: No smoke. Why the fire” – The world should welcome the electronic cigarette” in The Economist (edition of 23 March 2013):

“Some inventions are so simple, you have to wonder why no one has come up with them before. One such is the electronic cigarette. Smoking tobacco is the most dangerous voluntary activity in the world. More than 5m people die every year of the consequences. That is one death in ten. People smoke because they value the pleasure they get from nicotine in tobacco over the long-term certainty that their health will be damaged. So it seems rational to welcome a device that separates the dangerous part of smoking (the tar, carbon monoxide and smoke released by the process of combustion) from the nicotine. And that is what an e-cigarette does. It uses electricity from a small battery to vaporise a nicotine-containing solution, so that the user can breathe it in.

E-cigarettes do not just save the lives of smokers: they bring other benefits too. Unlike cigarettes, they do not damage the health of bystanders. They do not even smell that bad, so there is no public nuisance, let alone hazard, and thus no reason to ban their use in public places. Pubs and restaurants should welcome them with open arms.

No wonder the e-cigarette market is growing. Though still small compared with that for real smokes, it doubled in America last year and is likely to do so again in 2013 (see [article](#)).



Who could object? Quite a lot of people, it seems. Instead of embracing e-cigarettes, many health lobbyists are determined to stub them out. Some claim that e-cigarettes may act as “gateways” to the real thing. Others suggest that the flavourings sometimes added to the nicotine-bearing solution make e-cigarettes especially attractive to children—a sort of nicotine equivalent of “alcopop” drinks. But these objections seem to be driven by puritanism, not by reason. Some health lobbyists are so determined to prevent people doing anything that remotely resembles smoking—a process referred to as “denormalisation”—that they refuse to endorse a product that reproduces the pleasure of smoking without the harm.

In some places politicians and other busybodies are listening. Several countries (including Austria and New Zealand) restrict the sale of e-cigarettes, for example by classifying them as medical devices; others (Brazil and Singapore) ban them altogether. Some airlines, too, ban passengers from using e-cigarettes on their planes.

This is wrong. Those charged with improving public health should be promoting e-cigarettes, not discouraging their use. Of course, e-cigarettes should be regulated. Nicotine is an addictive drug, and should therefore be kept out of the hands of children. E-cigarettes should be sold only through licensed outlets, and to adults. It would also be a good idea to do some proper research on them. Nicotine is, after all, a poison (its real purpose is to stop insects eating tobacco plants), so there may be some residual risk to users. But nicotine poisoning is pretty low on the list of bad things that ordinary cigarettes are accused of. Some researchers reckon nicotine to be no more dangerous than caffeine, which coffee plants similarly employ as an insecticide.

The right approach is not to denormalise smoking, but to normalise e-smoking. Those who enjoy nicotine will be able to continue to use it, while everyone else will be spared both the public-health consequences of smoking and the nuisance of other people’s smoke. What’s not to like?”

*

Thank you in advance for your consideration of TVECA’s position, as detailed above. For any further information, the following persons may be contacted:

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