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## **E-Cigarettes – Unresolved Questions regarding Regulatory Options within the Framework of the Tobacco Products Directive**

In the course of the planned revision of the Tobacco Products Directive, various legal issues have arisen, especially in the field of e-cigarettes. In summary, the expert assessment that follows has concluded the following:

1. E-cigarettes containing nicotine may be classified as both “medicinal products by presentation” and “medicinal products by function”.
2. The inhaler for the liquid which contains nicotine is to be classified as a medical device.
3. There is to be clarification with regard to the differentiation of “NCPs” in the context of Food Law.
4. E-cigarettes without nicotine are to be classified as “medicinal products by presentation”. If this view cannot be accepted, e-cigarettes without nicotine are to be classified as consumer products (and not as tobacco products). Clarification in this regard should be made as part of the Directive proposal.

The question as to whether fundamental rights would be contravened by the planned new regulation of e-cigarettes has not been explored as part of this evaluation.

## I. Fundamental Aspects on the “Extension of the Product Scope of the Directive”

The EU-Commission has extended the product scope of the Directive to include new products.<sup>1</sup> The scope extension is subject to discussion in connection with new “nicotine containing products” (NCPs) such as the e-cigarette. According to Article 18 of the EU-Commission proposal, NCPs (i.e. e-cigarettes, for example) that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy and have a positive risk/benefit balance.<sup>2</sup> In the legal elements of the proposal it is stated that products with a lower nicotine content “can be sold as consumer products provided they feature an adapted health warning.”

### 1.1 Legal Competence to Extend the Scope of the Directive

With regard to NCPs above the aforementioned threshold there is talk of an “extension of the product scope” of the Directive. For all Member States, the NCPs will then bindingly be subject to the Medicinal Products Directive 2001/83/EC (or any national legislation such as the German *Arzneimittelgesetz* (German Medicinal Products Act), via which the requirements under European law are implemented in Germany).

The differences in classification for e-cigarettes in the various Member States require standardisation and this therefore definitely represents an approximation of laws in the region of the internal market (Article 114 TFEU). In this respect, it is understandable and to be welcomed that harmonisation will be effected in the course updating the Tobacco Products Directive.

Occasionally the opinion has been voiced that with regard to the e-cigarette the EU lacks the **regulatory competence** against the backdrop of the Amendment of the Treaty of Lisbon.<sup>3</sup> This is justified on the grounds that the risks of tobacco consumption were mentioned for the first time in the Treaty of Lisbon and explicitly regulated in Article 168.<sup>4</sup> This means – by implication – that the Union cannot (any longer) refer to the more general competence standards (i.e. Article 114 TFEU) for the regulation of this task.<sup>5</sup> Therefore there is currently a different starting position than existed in 2001.<sup>6</sup>

This opinion cannot be endorsed. No such limitation of the competences of the Union – especially in the field of the internal market – can be gathered from the synopsis of various competences as detailed in Article 114 TFEU (cross-sectional competence) and Article 168 TFEU (field-related competence standard) even after the Treaty of Lisbon came into force in 2009:

*“If Article 114 TFEU is to be relevant, the measure concerned must actually have the purpose of improving the conditions for the establishment and functioning of the internal market. If it is a matter of eliminating distortions of competition, these have to be noticeable. The realisation of the objectives of Article 26 TFEU must therefore be the main purpose and not merely an incidental or supplementary aim of the measure to approximate laws. If this is the case, then the protection of health may also be of decisive importance, even if the harmonisation measure provides for a complete marketing ban.”<sup>7</sup>*

*“Regulations that have both health protection and the functioning of the internal market as their objective (e.g. concerning medicines, dangerous products etc.), may be based on the considerably more extensive Article 114 TFEU, provided that they – unlike the case of the Tobacco Products Directive [comment: which was then changed accordingly] – are required in order to remove concrete restrictions on fundamental freedoms and noticeable distortions of competition in the context of Article 114 TFEU. The Tobacco Products Directive which is based on Articles 95 and 133 ECT (Article 114 and 207 TFEU) contains the upper limits for tar, nicotine, and carbon monoxide, as well as regulations for health warnings and other mandatory information on the packaging. It is intended to remove barriers to the internal market (Recitals 2, 3) and has been confirmed by the European Court of Justice (ECJ) with regard to the choice of legal basis regarding its competence. Only in the area of determining quality and safety standards for blood, blood derivatives, human organs and substances of human origin is Article 114 TFEU superseded by the more specialised standard of Article 168 Paragraph 4 lit. a) TFEU...”<sup>8</sup>*

The reasons why an approximation of laws in the field of NCPs such as the e-cigarette has become necessary is also explained in detail in the proposed Directive.<sup>9</sup> In so far no objections exist with regard to legal competence.

## **1.2 Legal Classification of Products below the Threshold Value**

According to Article 18 of the EU-Commission proposal, nicotine containing products that have a nicotine level exceeding 2 mg or a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance.<sup>10</sup>

The classification of products below the lowest threshold value is not entirely clear in the proposed Tobacco Products Directive.

In part the proposal is interpreted in such a way that products below the lowest nicotine content threshold fall within the regulatory scope of the Directive.<sup>11</sup> This statement is to be understood in such a way that these products would then be classified as “tobacco products”.

However, it appears questionable whether products with a nicotine content below the threshold value actually fall within the scope of the Tobacco Products Directive. Legislation states that products below the threshold can be sold as “consumer products.” In Germany, a “consumer product” in principle is governed by the Law on Product Safety (*Produktsicherheitsgesetz - ProdSG*), which is used to implement EU legislation. In the Law on Product Safety, a “consumer product” is also clearly defined: According to Section 2, No. 27 ProdSG, consumer products are new, used or refurbished products which are intended for consumers or can be used by consumers under reasonably foreseeable conditions even if they were not intended for them.

NCPs below the threshold value (e.g. those with a threshold value of “zero”) can also be subsumed under this definition. The fact that NCPs below the threshold value come under the Product Safety Law also makes sense fundamentally. In accordance with Section 3 ProdSG a consumer product may only be placed on the market if when used **under normal, intended or reasonably foreseeable conditions**, it does not endanger the safety and health of any person. There is no such regulation in the Tobacco Products Directive with regard to tobacco products, since it would mean that (given current knowledge) tobacco products - including cigarettes - would no longer be permitted to be put on sale. Given this background, a special arrangement with regard to tobacco products evidently exists. To make new products such as e-cigarettes below the threshold values subject to the requirements of the Tobacco Products Directive thus appears to be inexpedient and would also not correspond to the sense and purpose of the updated Directive proposal. The fact that the term “consumer product” – which has already been defined in the Law on Product Safety – is used in the proposal, also speaks in favour of making products of this nature subject to the Law on Product Safety.

However, the wording of the proposal is not completely unambiguous here, especially since e-cigarettes can also (according to the opinion of some) be classified as “goods similar to tobacco products.”<sup>12</sup>

### 1.3 Differences in Definition of NCPs in Food and Tobacco Product Legislation

A market opening for nicotine containing foodstuffs is not to be expected. Sweets or juices containing nicotine would also continue to be assessed according to the Food Law. According to Article 2 of the Basic Regulation (*BasisVO*), foodstuffs are all substances or products which are intended to be - or which can reasonably be expected to be - ingested by humans in a processed, partially processed or unprocessed condition. By this is meant uptake via the gastrointestinal tract.<sup>13</sup>

In the field of Food Law there is a general ban qualified with reservation of authorisation, i.e. all substances are banned unless they are expressly approved. This means: nicotine would have to be permitted in the Ordinance on Registration of Additives (*Zusatzstoff-Zulassungsverordnung*) in order that a foodstuff containing nicotine could be placed on the market. However, this is not the case with regard to nicotine. Consequently it is not to be expected that the Directive proposal will lead to an approval for foodstuffs with artificially added nicotine being made possible.

However, the new definition of an NCP means that the differentiation from foodstuffs is not absolutely clear. According to the Article 2, Definition 22 of the Common Provisions of the Directive proposal, an NCP is “a product usable for consumption by consumers via inhalation, ingestion or in other forms and to which the nicotine is either added during the manufacturing process or self-administered by the user before or during consumption.”<sup>14</sup> The term “ingestion” - but also the catch-all element “or in other forms” - could also in principle be applied with regard to a foodstuff. In this respect there should be clarification in the wording of the law.

## **II. E-Cigarettes containing Nicotine**

In the proposal, provision is made to classify e-cigarettes above a certain nicotine content threshold as medicinal products.

### **1. Classification as Medicinal Product**

Clarification is required as to whether e-cigarettes can be classified as a medicinal product.

Direct application of Directive 2001/83/EC is out of the question<sup>15</sup>, since Directives – as a matter of principle – have no direct effect but have to be implemented by the Member States in national legislation. Consequently the only binding legislation is Section 2 of the German Medicinal Products Act (*Arzneimittelgesetz -AMG*), which if required would have to be interpreted to conform to the Directive.<sup>16</sup>

Section 2 AMG differentiates between medicinal products by presentation and medicinal products by function.

#### **1.1 Medicinal Products by Presentation**

Medicinal products by presentation in the context of Section 2 Paragraph 1 No. 1 AMG (German Medicinal Products Act) are all substances and preparations of substances intended for

application in or on the human body and which are intended as a medium with properties for curing or alleviating or preventing human or animal diseases or pathological conditions. As such it is important how the products are 'labelled or - more appropriately - presented on the market' by the producer/vendor."<sup>17</sup>

A product is assumed to be a medicinal product by presentation if "the description, layout or other presentation of the product creates the logical impression in an averagely well-informed consumer that the product, on consumption/use will have the effect detailed in Paragraph 1, No. 1".<sup>18</sup> This impression may also be created if recommendations are made by third parties, for example by specialist medical companies.<sup>19</sup> It is by no means a question as to whether the product also actually has the appropriate effect with regard to the suitability qualities mentioned in the above<sup>20</sup>, and in this respect so-called "pseudo-medicinal products" are also included. This is intended "to not only protect the consumer from harmful or poisonous medicines as such but also from products that are used in place of suitable cures or more effective (even non-medicinal) medical treatment options."<sup>21</sup> In order to assume a product is medicinal by presentation no 'explicit statement' on the part of the manufacturer is necessary, in fact an indirect expression of intention suffices."<sup>22</sup> The fact that the manufacturer claims that the product is not a medicinal product is irrelevant with regard to classification.<sup>23</sup>

E-cigarettes may well be viewed as medicinal products by presentation since for the averagely well-informed consumer the way in which they are presented often creates the impression that the e-cigarette is a medicinal product to help smoking cessation.

Even though it is not possible to generalise, reference is made here to the web advertising presence for the e-cigarette "SNOKE" as an example<sup>24</sup>:

The e-Cigarette SNOKE is promoted - in a manner questionable in professional law - by a professor in the field of nuclear medicine, dressed in a trust-inspiring white coat and standing in front of a medical device.<sup>25</sup> On the homepage reference is made to the fact that, "A German pharmaceutical laboratory, as well as a German pharmacy both process..... the certified and listed ingredients and flavours .....all staff entrusted as part of the manufacturing process are highly qualified and undergo continuous further training and are all familiar with holistic preventive health care. The pharmacy has been producing sterile infusion solutions since 1998, which is an ideal prerequisite for the manufacturing process required for our SNO-Caps."<sup>26</sup> The drop-down under the menu item "*Gesundheit*" (health) reveals a detailed statement on "Harm Reduction".<sup>27</sup> In a "Factsheet" by the Institute for Future Policies (*Institut für Zukunftspolitik*) entitled "Thank you for Smoking" there is a specific reference to the possibility of withdrawal treatment.<sup>28</sup>

One further example to mention is that on its homepage, the German Diabetes Union recommends the use of e-cigarettes if you are not able to stop smoking.<sup>29</sup> Many references to smoking cessation and/or to the alleviation of complaints are to be found on the Internet, among manufacturers as well.<sup>30</sup>



Until now, classification as medicinal product by presentation has not been taken into consideration by the German courts or has not been affirmed. However, classification as medicinal product by presentation is completely appropriate<sup>31</sup> – especially since it suffices that the medicinal product creates the impression that it helps alleviate the condition.

## 1.2 Medicinal Products by Function

According to Section 2 Paragraph 1 No. 2 AMG (German Medicinal Products Act) medicinal products by function are deemed to be all substances and combinations of substances intended for use in or on the human body or which can be administered to a person in order to either restore, correct or influence the human physiological function through a pharmacological, immunological or metabolic effect (1<sup>st</sup> alternative) or in order to make a medical diagnosis (2<sup>nd</sup> alternative).

Classification as a medicinal product by function, which is suitable for making a medical diagnosis, is out of the question with regard to the e-cigarette from the very outset.

Within the scope of the first alternative there is **impact on physiological function** both as part of a desired influence (healing effect) and an unwanted, damaging impact (toxic effect) on the organism.<sup>32</sup> One qualification – also regarding the differentiation from foodstuffs – is that the product has to be suitable for impacting on the functions in an “appreciable manner”.<sup>33</sup> In order to bring about this, “appreciable impact on the organism, the **pharmacological effect** of the product must also correspondingly exceed a **significance threshold**”.<sup>34</sup>

The question is when does a pharmacological effect exist? Here, for the purposes of differentiating medical devices, reference is made to some extent to the definition in the EU-Commission’s ‘European Medical Device Vigilance Guideline MEDDEV’.<sup>35</sup> It states in this regard:

*“The MEDDEV-Guideline defines pharmacological effect as ‘an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.’ This definition is being used increasingly in jurisdiction and in the institutional practice of the Federal Institute for Drugs and Medical Devices (BfArM) with regard to questions of definition – not just between medicinal products and medical devices.”*

The question concerning the (considerable) pharmacological effect in the case of e-cigarettes (containing nicotine) has so far in part been answered differently by jurisdiction and in legal literature in Germany,<sup>36</sup> without citation of the MEDDEV-Guidelines being evident.

On the other hand, in a recent ruling on 06.09.2012 the ECJ once again clarified the term “pharmacological effect” whilst referring to the guideline. According to this it cannot only be assumed that a pharmacological effect of a substance exists if there is an interaction between the molecules of this substance and a cellular constituent of the user’s body; it is sufficient – according to the ECJ – that the interaction takes place between the substance in question and any cellular constituent that is not actually deemed to be part of the human body (for example bacteria in saliva).<sup>37</sup>

The German Cancer Research Center (*Deutsche Krebsforschungszentrum*) for example, says the following with regard to “pharmacological effect”:

*“In the body, nicotine binds to nicotine receptors (nicotinic acetylcholine receptors) in the brain, on ganglia of the autonomic nervous system (these are ganglia in the part of the nervous system that regulate unconscious processes such as the heartbeat or the digestion), in the adrenal medulla, which produces the stress hormones adrenaline and noradrenaline, as well as on the motor endplates (these are the connection points between nerves and muscles). The effect of the nicotine depends on the one hand on the dose and on the other on the individual constitution of the smoker too. Thus, small amounts of nicotine – such as those absorbed when smoking – increase blood pressure and the frequency of the heartbeat, whereas high doses lower blood pressure and slow the heartbeat.”<sup>38</sup>*

Admittedly, it is not possible to subsume the complex pharmacological effect of nicotine in a simple dose-effect-relationship, since it depends on various factors (pH-conditions of the mucous membrane in the oral cavity, local conditions of the lung alveoli; varying individual ability to rapidly break down nicotine dependent on age, sex, consumption of medicines, physical illnesses – especially of the liver and kidneys, and possible genetic factors). Nevertheless, taking the aforementioned definitions as a basis together with the clarification by the ECJ the view which affirms a pharmacological effect in the case of nicotine is more convincing.

With regard to the question as to whether or not we are dealing with a medicinal product by function we must - according to the jurisdiction of the ECJ- refer to the product features as a whole. In addition to the pharmacological effect these also include the composition, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.<sup>39</sup> In “conjunction with the pharmacological effect characteristic and the respective antitheses (nutritional, cosmetic, physical etc.) the ECJ is thus essentially basing its argument on the **predominant intended purpose** of the product.”<sup>40</sup> The, “objective standard needed to be applied regarding intended purpose bears the particular consequence that the subjective ideas and strategies of the manufacturer have to be disregarded”.<sup>41</sup>

Due to functional similarities with already existing nicotine replacement preparations, it suggests itself to see the objective intended purpose mainly as being smoking cessation. Since



there are similar nicotine replacement preparations, the “consumption for pleasure” of e-cigarettes containing nicotine is to be viewed more as a misappropriation/misuse of what is essentially a (potential) medicinal product than an objective purpose [of the product]. Recent studies suggest that e-cigarettes [can] be used for the purpose of smoking cessation.<sup>42</sup> In addition, the potentially lethal risk of the nicotine-containing liquid has to be considered, which also speaks in favour of more stringent regulation via pharmaceutical legislation. In a synopsis of all circumstances, e-cigarettes containing nicotine are therefore to be classified as “medicinal products by function”.

## 2. Classification as Medicinal Product above a certain Threshold

According to Article 18 of the EU-Commission proposal, nicotine containing products that have a nicotine level exceeding 2 mg or a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance.<sup>43</sup>

Evidently the Commission used the threshold values for previously licensed medicines for smoking cessation for orientation. However, the determination of the threshold values is not convincing for the following reasons:

- The lowest threshold value in the proposal is 2 mg per unit. Admittedly those products already available on the market actually mostly have a higher nicotine content than 2 mg per unit (Nicotine chewing gum: 2 mg and 4 mg; nicotine-patch: 8.3 mg for 16 hour patch up to 52.5 mg for 24-hour patch<sup>44</sup>; Nicotine inhaler: 10 mg). However, there are also nicotine-lozenges available with a lower nicotine content (for example: Niquitin Mini 1.5 mg Lozenges, GlaxoSmithKline Cons. Healthcare; Nicotinell Lozenges, 1 mg, 2 mg, Novartis Consumer Health GmbH). In this respect the setting of the threshold at 2 mg is not comprehensible.
- Presuming that it has been assumed that a “pharmacological effect” sets in starting at 2 mg per unit, this is also not comprehensible. It is to be assumed that a pharmacological effect actually exists at very low nicotine doses. There is no evaluation at hand confirming that any such effect is only evident from 2 mg per unit. Against this backdrop, the setting of a high threshold value of 2 mg per unit is incomprehensible.

Consequently classification as a medicinal product should be made without the setting of a particular threshold value.

### 3. Classification as Medical Device

Medical devices differ from medicinal products by virtue of the way they function. Whilst medical devices function in a mechanical-physical manner, the main effect of medicinal products is pharmacological, metabolic or immunological.<sup>45</sup> “The definition is made depending on the function of the product and its principal intended effect.”<sup>46</sup> In so far it is to be “decided” whether the product as a whole is designed to administer a medicinal product/medicine and/or introduce it into the body or whether the medicinal purpose is mainly to be achieved through the functioning of the object in or on the human body. If the principal intended effect in or on the human body is based on the characteristics/qualities of the object, then it is a medical device (for example: a stent)<sup>47</sup>; otherwise (in the case of fixed medicinal product-medical device combinations) it is a medicinal product. If however, the medical device and the medicinal product “are placed on the market together (but as separates) in the form of (sales) unit package (e.g. vaginal ointment with applicator) this is not considered to be a combination in the context of Section 2 Paragraph 3 of the German Medical Devices Act (MPG). Here, on the one hand, the regulations of the law on medical devices, including CE-labelling will be relevant (in this case for the applicator). On the other (with regard to the vaginal ointment) the medicinal product/pharmaceutical regulations - including relevant registration number - will be applicable. These regulations are to be considered independently and observed.”<sup>48</sup>

Accordingly for the ingredients of the e-cigarette – the so-called “liquids” – the medicinal product/pharmaceutical regulations would have to be adhered to. For the inhaler itself, however, it would be the medical devices regulations.

### III. E-Cigarettes without Nicotine

It is to be assumed that there should not be any significant pharmacological effect for e-cigarettes not containing nicotine. The purely psychological aspect of handling, which may be of benefit for nicotine withdrawal, is in itself not sufficient and neither is any placebo effect. Thus any classification as “medicinal products by function” would be impermissible. If necessary, classification as “medicinal product by presentation” could be considered. The prerequisite here however, would be that e-cigarettes without nicotine were also “presented” as medicinal products/medicines (see above). Whether and to what extent this is the case would require even closer investigation. New studies show, however, that e-cigarettes without nicotine are also being used by consumers for the purpose of smoking cessation<sup>49</sup> and that they can lessen the symptoms of withdrawal – albeit to a lesser extent.<sup>50</sup>

With this as a backdrop, the classification of non-nicotine-containing e-cigarettes as medicinal products would seem appropriate. Until now, legislation in Germany has however rejected

classification as “medicinal product by presentation” – even in the case of e-cigarettes containing nicotine.

Should regulation as “medicinal product by presentation” not be possible then e-cigarettes without nicotine should be classified as “consumer products” so that the Product Safety Law would be applicable (see above: **Fundamental Aspects on the “Extension of the Product Scope of the Directive”**). There should be no classification as a “tobacco product”.

ABNR

Signed: Bethke/11.04.2013



<sup>1</sup> Cf. [http://europa.eu/rapid/press-release\\_MEMO-12-1005\\_en.htm](http://europa.eu/rapid/press-release_MEMO-12-1005_en.htm)

<sup>2</sup> Article 18 Tobacco Products Directive–Proposal, 3.7 of the Legal Elements, COM(2012) 788 final, English version P. 9

<sup>3</sup> Prof. Dr. Schwemer: “Unvereinbarkeit des Artikel 18 Abs. 1 E-TPR mit dem Primärrecht” (Incompatibility of Article 18, Para. 1 of Tobacco Products Directive Proposal with Primary Law), [http://www.vd-eh.de/wpcontent/uploads/2013/03/Gutachten\\_Tabakrichtlinie.pdf](http://www.vd-eh.de/wpcontent/uploads/2013/03/Gutachten_Tabakrichtlinie.pdf), downloaded on 26.03.2013

<sup>4</sup> ibidem

<sup>5</sup> ibidem

<sup>6</sup> ibidem

<sup>7</sup> Calliess/Ruffert: *EUV/AEUV: Das Verfassungsrecht der Europäischen Union mit Europäischer Grundrechtecharta, Kommentar*, (TEU/TFEU: The Constitutional Law of the European Union with the European Charter of Fundamental Rights, Commentary) Article 168 TFEU, Recital 30, 2011. Also: Lenz/Borchardt: *EU-Verträge Kommentar*, (EU Treaties – Commentary) Article 168 TFEU, Recital 24, 2012;

<sup>8</sup> Streinz: *EUV/AEUV, Beck'sche Kurzkommentare*, (TEU/TFEU Brief Commentary) Article 168, Recital 31, 2012

<sup>9</sup> Article 18 Tobacco Products Directive–Proposal, 3.7 of the Legal Elements, COM(2012) 788 final, English version P. 9

<sup>10</sup> Article 18 Tobacco Products Directive–Proposal, 3.7 of the Legal Elements, COM(2012) 788 final, English version P.9

<sup>11</sup> Cf. Smoke-free Partnership, “Tobacco Products Directive – Fact Not Fiction”

<sup>12</sup> Zipfel/Rathke: *Lebensmittelrecht, VTabakG*, (Food Law, Tobacco Law) Section 3 Recitals 8, 22, July 2011, 148. *Ergänzungslieferung* (Supplement) 2012

<sup>13</sup> Meyer/Streinz: *LFGB, BasisVO, Kommentar* (German Food and Feed Code, Basic Regulation, Commentary) 2007, Artikel 2 BasisVO, Rn. 7 (Article 2, Basic Regulation, Recital 7)

<sup>14</sup> Tobacco Products Directive–Proposal, Common Provisions, Article 2 Definition 22, COM(2012) 788 final, English version p. 25

<sup>15</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 4, 2010

<sup>16</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 4, 2010

<sup>17</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 7, 2010

<sup>18</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 13, 2010 with further references

<sup>19</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 13, 2010

<sup>20</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 14, 2010

<sup>21</sup> ECJ: Judgement of 15.11.2007 – C-319/05 (“*Knoblauchpräparat*” Garlic Preparations); Deutsch/Lippert: *Kommentar zum AMG*, (Commentary on the Medicinal Products Act), Section 2, Recital 15 with further references on jurisdiction of the ECJ; Kügel/Müller/Hofmann: *Arzneimittelgesetz*, (Medicinal Products Act), Section 2, Recital 20, with further references on jurisdiction of the ECJ, 2012

<sup>22</sup> Fuhrmann/Klein/Fleischfresser (Ed.): *Arzneimittelrecht, Handbuch für die pharmazeutische Rechtspraxis* (Medicinal Products Law, Handbook for pharmaceutical legal practice) Section 2, Recital 85, 2010

<sup>23</sup> ECJ: Judgement of 21.03.1991, C-369/88 (Delattre), Kügel/Müller/Hofmann: *Arzneimittelgesetz* (Medicinal Products Law), Section 2, Recital 22, 2012

<sup>24</sup> The OVG (Administrative Appeals Tribunal) for the state of North Rhine-Westphalia as part of interim proceedings ruled that the e-cigarette SNOKE be classified as a “consumable/stimulant” and not as a medicinal product. (Judgement of 23.04.2012, 13 B 127/12)



- <sup>25</sup> Prof. Dr. Ruhlmann in: <http://www.youtube.com/watch?v=7Z76BKzi3Fw>
- <sup>26</sup> <http://isnoke.com/de/gesundheit/apotheke.html>, downloaded on 25.03.2013
- <sup>27</sup> <http://isnoke.com/de/gesundheit/stellungnahme.html>, downloaded on 25.03.2013
- <sup>28</sup> [http://www.zukunftspolitik.de/fileadmin/user\\_upload/Paper\\_E-Zigarette.pdf](http://www.zukunftspolitik.de/fileadmin/user_upload/Paper_E-Zigarette.pdf), P. 7: "Durch den Umstieg soll der langsame Entzug ermöglicht werden." (By changing [to e-cigarettes] slow withdrawal should be made possible)
- <sup>29</sup> <http://www.diabetes-union.de/die-elektrische-zigarette-ist-auch-fuer-diabetiker-eine-brauchbare-alternative/>, downloaded on 25.03.2013
- <sup>30</sup> <http://www.elektronische-zigaretten.net/elektrische-zigarette>, downloaded on 25.03.2013. A specific recommendation for "Vitasmoke" is made here since the company produces its liquids in Germany. On the "Vitasmoke" homepage it is stated: "Chronic bronchitis – which is to be found in most heavy smokers and which is commonly played down as 'smokers' cough,' ranks amongst the group of 'Chronic Obstructive Pulmonary Diseases' (COPD). The main cause of chronic bronchitis is a disturbance of the so-called cilia. (...) Users of our electronic cigarettes have reported that their smokers' cough abated significantly after only a short period of time and that [sic!] their sporting condition had improved." <http://www.elektronische-zigaretten.net/elektrische-zigarette>, downloaded on 25.03.2013
- <sup>31</sup> So too: Dr. Mathias Volkmer: "Nicotin-Depots für elektrische Zigaretten – Arzneimittel wider Willen" (Nicotine capsules for electronic cigarettes – the reluctant medicinal product) in: PharmR 2012, p. 11 ff.
- <sup>32</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 18, 2010
- <sup>33</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 22, 2010
- <sup>34</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 28, 2010
- <sup>35</sup> Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 29-31, 2010; "Medical devices: Guidance Document". MEDDEV 2. 1/3 rev 3
- <sup>36</sup> Administrative Court (VG) Potsdam, Decision of 08.06.2008 (3 L 115/08): Pharmacological effect affirmed. Administrative Court (VG) Frankfurt/Oder, Decision of 14.10.2011 (4 L 191/11): Pharmacological effect affirmed; Intended use, turned down. Administrative Appeals Tribunal (OverwG) for the State of NRW: Decision of 23.04.2012 (13 B 127/12): Pharmacological effect affirmed; Intended use, turned down (Lower Court of Administrative Court (VG) Düsseldorf, Decision of 16.01.2012 (16 L 2043/11) had affirmed pharmacological effect); Administrative Court (VG) Cologne, Judgement of 20.03.2012 (7 K 3169/11): pharmacological effect, questionable. Administrative Appeals Tribunal (OverwG) Magdeburg, Decision of 05.06.2012, 3 M 129/12: pharmacological effect affirmed, Intended use, turned down. Stollmann: "Die E-Zigarette im Spannungsfeld des Gesundheitsrechts" (approx. The e-cigarette in the minefield of health legislation) in: NVwZ 2012, P. 401 ff.: Pharmacological effect affirmed. Kasper/Krüger/Stollmann: "Nikotinhaltige Liquids – Funktionsarzneimittel oder bloße Genussmittel" (Nicotine-containing Liquids – Medicinal Product by Function or simply a stimulant) in: MedR (2012) 30: 495-500: Pharmacological effect affirmed. Krüßen: "Viel Rauch um wenig Dampf." (Lots of smoke about a bit of steam) Comments on Volkmer, *Nikotin-Depots in PharmR* 1/2012, 143: Pharmacological effect affirmed with further references: "Ansonsten besteht weitgehend Konsens, dass Nikotinliquids aufgrund ihrer pharmakologischen Wirkung durchaus die Kriterien für Funktionsarzneimittel erfüllen." (otherwise there is general consensus that nicotine liquids indeed meet the criteria for medicinal products by function because of their pharmacological effect) – Volkmer: "Nicotin-Depots für elektrische Zigaretten – Arzneimittel wider Willen" (Nicotine capsules for electronic cigarettes – the reluctant medicinal product) in: PharmR 2012, 11 ff.: Pharmacological effect affirmed.
- <sup>37</sup> ECJ: Judgement of 06.09.2012, C-308/11 (*Mundspülung als Arzneimittel – Mouthwash as medicinal product*)
- <sup>38</sup> German Cancer Research Center (*Deutsches Krebsforschungszentrum*) (ed.): *Nikotin. Pharmakologische Wirkung und Entstehung der Abhängigkeit* (Nicotine. Pharmacological Effect and the Origins of Addiction), Heidelberg. Further references: Benowitz NL (1988) Drug therapy. Pharmacological aspects for cigarette smoking and nicotine addiction. *N Engl J Med*, 319, 1318-1330; Benowitz NI (2008) Clinical pharmacology of nicotine: implications for understanding, preventing and treating tobacco addiction. *Clin Pharmacol Ther*, 83, 531-541; Singer MV, Batra A, Mann K (ed) (2011). *Alkohol und Tabak. Grundlagen und Folgeerkrankungen*. (Alcohol and Tobacco. Fundamentals and Secondary Diseases) Thieme Stuttgart, New York.
- <sup>39</sup> ECJ: Judgement of 06.09.2012, C-308/11 (*Mouthwash as Medicinal Product*); see also: Deutsch/Lippert: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), § 2 Recital 35 with further references Kügel/Müller/Hofmann: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 28 with further references

- <sup>40</sup> Kügel/Müller/Hofmann: *Kommentar zum Arzneimittelgesetz* (Commentary on the Medicinal Products Act), Section 2, Recital 28 with further references
- <sup>41</sup> Kügel/Müller/Hofmann: *Kommentar zum Arzneimittelgesetz* (Comments on the Medicinal Products Act), Section 2, Recital 113 with further references
- <sup>42</sup> Etter/Bullen: Electronic cigarette users profile, utilization, satisfaction and perceived efficacy, *Addiction Research Report*, 2011; Bullen: effect of an electronic nicotine delivery device (e-cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: *Tob Contr.* Published on November 7, 2011).
- <sup>43</sup> Article 18 Tobacco Products Directive–Proposal, 3.7 of the Legal Elements, COM(2012) 788 final, English version P. 9
- <sup>44</sup> German Cancer Research Center (DKFZ): *Nikotinersatz und andere Medikamente zur Rauchentwöhnung*, (Nicotine replacement and other medicines for smoking cessation) [http://www.dkfz.de/de/rauchtelefon/NRT\\_Medikation.html](http://www.dkfz.de/de/rauchtelefon/NRT_Medikation.html), downloaded on 25.03.2013
- <sup>45</sup> Baierl/Kellermann: *Arzneimittelrecht* (Medicinal Product Law), P 21, 2011
- <sup>46</sup> Fuhrmann/Klein/Fleischfresser: *Arzneimittelrecht* (Medicinal Product Law), Section 2, Recital 151
- <sup>47</sup> Fuhrmann/Klein/Fleischfresser: *Arzneimittelrecht* (Medicinal Product Law), Section 2, Recital 151
- <sup>48</sup> Ratzel: *Handbuch Medizinrecht* (Handbook of Pharmaceutical Law), p. 1350
- <sup>49</sup> Etter/Bullen: Electronic cigarette users profile, utilization, satisfaction and perceived efficacy, *Addiction Research Report*, 2011
- <sup>50</sup> Etter/Bullen: Electronic cigarette users profile, utilization, satisfaction and perceived efficacy, *Addiction Research Report*, 2011; Bullen: effect of an electronic nicotine delivery device (e-cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: *Tob Contr.* Published on November 7, 2011). Dawkins L, Turner, J., Hasna, s. & Soar, K., The electronic-cigarette: effects on desire to smoke, withdrawal symptoms and cognition, *Addictive Behaviors* (2012), doi: 10.1016/j.addbeh.2012.03.004