Electronic Cigarette Industry Trade Association ECITA The industry standard of excellence

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Summary of legal rulings and case precedents

Germany, Higher Administrative Court of North Rhine-Westphalia, Case numbers: 13 A 2448/12, 13 A 2541/12 and 13 A 1100/12, September 17th 2013

The court upheld three previous decisions that electronic cigarette products containing nicotine were not medicines, unless presented as such. A translation of the actual decision was not available at the time of writing, however the following translated excerpt from the Administrative Court's press release provides a clear indication of the courts thinking:

"*In support of the three judgments, the Supreme Administrative Court has essentially decided that nicotine-containing liquids are not a medicinal product by presentation because they are not indicated or recommended as a means to cure, mitigate or prevent disease. But also the liquids are not a medicinal product by function. According to settled case law of the European Court had to decide whether a product is a medicinal product by function, are taken on a case by case basis, taking all the features of the product are considered, i.e. composition, methods of use, volume of distribution, brand awareness among consumers and risks of use. The application of these criteria leads to the conclusion that nicotine-containing liquids are not medicinal products.*"[i]

Estonia, Tartu Administrative Court, Case No. 3-12-2345, March 2013

The Court found that the State Agency of Medicine had incorrectly compared E-Lites' products with medicinal NRT products without explaining why tobacco cigarettes are excluded from medicinal regulation:

"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." (*paragraph 27*)

The Judge further expanded on the concept of 'quitting smoking' as a medicinal process:

"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. 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 cannot 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 mediation 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. […]

…people who have given up smoking tobacco cigarettes in favor of e-cigarettes for health reasons do not use nicotine as a medicinal product, but as a drug which is less detrimental to the health instead of a more hazardous cigarette." (*paragraphs 28 and 29*)

The judge went on to give her ruling on the amounts of nicotine in the products:

"Regarding the quantity of nicotine, the respondent has noted, when defining the product as a medicinal product, that the active dose of a single e-cigarette capsule exceeds the dose necessary for treatment or alleviation of a condition and that in the products' user information, consumers have not been warned of the dangers that may arise from using the product or the risk associated with using the product are not generally known to the consumers. The fact that one of the e-cigarette capsules contains the amount of the active agent which is equivalent to an average of 40 normal cigarettes is not disputed. But there is a serious and logical explanation of the complainant that administration of the active ingredient of a capsule does not take place at the same time, it is used in analogy to conventional cigarettes according to each smoker's needs. Although the amount of nicotine in one conventional cigarette is significantly smaller than in the e-cigarette capsule, there is nothing to prevent a smoker from smoking conventional cigarettes more than one cigarette at a time, as in case of conventional cigarettes, the smoker usually has a whole pack, not just one cigarette." (*paragraph 30*)

On how the products are used by consumers, the Judge observed the following:

"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. 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." (*paragraph 31*)

In conclusion, the Judge stated:

"The court is of the opinion that it 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. Upon definition of the product as a medicinal product within the meaning of Directive 2001/83/EC should be taken into account all the characteristics of the product - the composition, pharmacology, disposition and the extent of use of the product, awareness of the consumers of the product and the risks which may be associated with using the product. The court agrees with the complainant that the respondent has not taken into account all these circumstances in the decision of definition of the product as a medicinal product, or has done so inadequately. The complainant has also referred to the decision of European Court of Justice in Case No. C-140/07 (Hecht-Pharma vs Lüneberg) in which the court has decided when interpreting Directive 2001/83/EC, Article 2, paragraph 2, that the directive does not apply to the product, for which there is no scientific evidence that it is a medicinal product by function, but for which it cannot be excluded. It is therefore not legitimate to define the product as a medicinal product in any doubt. Regarding E-Lites products, taking into account the specific characteristics and features of these products, there is no such scientific studies." (*paragraph 31*)

The Estonian State Agency of Medicines was ordered to pay costs.[ii]

http://www.ecita.org.uk/kohtuotsus_e-sigaretid_zandera%20vs%20ravimiamet_ha-3-12-2345_07032013_en-us.pdf

The Netherlands, s-Gravenhage Court, Case No. 414117, March 2012

The s-Gravenhage Court in the Netherlands unambiguously concluded in its ruling of 13 March 2012 that "the state will be required to provide evidence that upon the use of an e-cigarette the pharmacological properties are, for that purpose, stronger than those observed when the original product (cut tobacco leaves) is used. The state has failed to supply any scientific evidence to prove its allegations" (see page 1 and more specifically, page 5 of the ruling).

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

The import ban was removed and the Dutch health ministry was ordered to pay costs.[iii]

Germany, Administrative Court of Köln, Case No. 7 K 3169/11, March 2012

The Administrative Court of Köln in Germany unambiguously stated in its ruling of 20 March 2012 that "the obligation to prove pharmacological properties lies with the defending party (i.e. the respective competent state authority), as it has alleged that we're dealing with a functional medicinal product [see clauses 111-113 jj of the ruling]. We need confirmation that the use of an e-cigarette would not just only wean smokers from their smoking habit, but also treat nicotine addiction [see clause 130 of the referred ruling]. There is no scientific evidence to show whether this specific product is suitable for the treatment of nicotine addiction. Above all, the Court has found that we're not speaking of nicotine addiction, as long as nicotine is obtained from electronic cigarette instead of a tobacco cigarette. The nicotine addiction will then prevail. Nicotine addiction is satisfied, not treated" [see clause 132 of the ruling].

The Administrative Court of Köln ruled that "when observing the products that serve as the object of the dispute, we can't ignore the fact that the

definition of a functional medicinal product usually covers authentic medicinal products and therefore, products that serve a therapeutic of prophylactic purpose. We have to distinguish products that have a different primary objective, for example, nourishment or getting a satisfaction" (see clause 171 of the ruling).[iv]

Germany, Supreme Court of Sachsen-Anhalt, Case No. 3 M 129/12, June 2012

The Supreme Court of Sachsen-Anhalt State of Germany stated in its ruling of 5 June 2012: "We must not ignore the main function of a substance considered as a potential functional medicinal product. Regardless of pharmacological properties, a product is not considered as a functional medicinal product solely because it contains some substance – nicotine, in given case – that is accompanied by health risks when used, as a definition of a functional medicinal product includes fighting against diseases or undesirable physical conditions of reaching a medical diagnosis as a function of the medicinal product." /…/ "Pure physiological effect of nicotine is not sufficient to classify something as a functional medicinal product. Usually, only products that have either therapeutic or prophylactic purpose can be therefore functional medicinal product. The Medicinal Products Act does not cover products with different main objectives, for example, being used for nourishment or as substances for pleasure and gratification." /…/ "The Medicinal Products Act can only be applied if it's definitely known, as a product is manufactured, that it's future purpose will be, without exception, medicinal function inhuman body – even where combined effect with some other substance will be needed for that purposes. As for the object of dispute – a liquid that contains nicotine – this can't be assumed. Weaning from the use of tobacco cigarettes or alleviation of nicotine addiction do not take the front stage".

In the final part of the ruling the Supreme Court of Sachsen-Anhalt State of Germany also explained: "This would mean, above all, that the regulation applicable under the Medicinal Products Act can only be implemented if the suitability of a product as a medicinal product has been identified. Otherwise, the stricter rules, arising from the Medicinal Products Act, would be applicable also to other circumstances and this would prohibit the free movement of products in the European Union without the situation being sufficiently justified by health protection requirements".[v]

European Court of Justice, Case No. C-140/07, January 2009, preliminary ruling in the case of Hecht-Pharma GmbH –vs- Staatliches Gewerbeaufsichtsamt Lüneburg

The Court ruled:

"1. Article 2(2) of 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, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as meaning that Directive 2001/83, as amended by Directive 2004/27, 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 its being possible to exclude that possibility.

2. Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27, must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to determining whether that product falls within the definition of a medicinal product by function.

3. Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27, must be interpreted as meaning that, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, a product cannot be regarded as a medicinal product within the meaning of that provision where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action."[vi]

Commission of the European Communities –v- Federal Republic of Germany, Case No. C-319/05, November 2007

In case C-319/05 (Commission of the European Communities v Federal Republic of Germany, classification of a garlic preparation as a medicinal product)[1], the Court of Justice concluded, among other things, that

"*the generic reference made to the risks that taking garlic may have for health in very specific circumstances is not sufficient, to justify a measure such as making the product subject to the particularly strict procedure for a marketing authorisation for a medicinal product, and that such a restriction on the free movement of goods must therefore necessarily be*

[1] See footnote 2.

based on a detailed assessment of the risk (to public health) alleged by the state."[vii]

Counsel Opinion of Advocate-General Geelhoed on joined cases C-21103, C-299/03 and C-316/03 to C-318/03, February 2005

"The case-law clearly brings out the twofold *ratio legis* underlying Directive 2001/83. On the one hand, the legal regime for medicinal products should be more rigorous than that for food, since their use in consumption may present particular risks. On the other hand, there must be sufficient assurance that products which claim to have medicinal properties do indeed have those properties. The existence of both particular risks and therapeutic efficacy must be demonstrated on the basis of data supported by sound scientific research." (*paragraph 35*)

[…]

"In my opinion, there are three objections to too broad an interpretation and application of the definition of medicinal product. First of all, the concept of 'medicinal product' would cease to have any differentiating effect if it were to include products whose properties and action did not justify their being classified as such. This would harm rather than serve the interests of human health. Secondly, it could result in the specific Community regulations for certain categories of food – containing provisions relating to the particular risks of the products – losing their regulatory object. […] Thirdly, a 'stealthy' extension of the scope of Directive 2001/83 to include extraneous products would be detrimental to the free movement of goods." (*paragraph 36*)

A-G Geelhoed describes how, in the "ongoing process of substantive harmonisation an ever-increasing number of specific Community regulations, intended to remove obstacles to free movement and assure a high level of health protection, are being introduced." (*paragraph 45*)

On the specific point of proportionality, A-G Geelhoed counselled:

"If they succeed in making it seem plausible that dangers or substantial risks to health do indeed exist, then, in accordance with the settled and recently reaffirmed case-law of the Court, the restrictive measures proposed will have to comply with the principle of proportionality. That means that the measures must be appropriate, not go beyond what is strictly required by the interest to be protected and be proportional to the objective pursued, in the sense that the objective could not have been attained by measures which are less restrictive of intra-Community trade." (*paragraph 48*)

He goes on:

"It is forbidden to bring products within the definition of medicinal products if, on the basis of objective criteria, they do not belong in that category" (*paragraph 54*)

and

"… a risk assessment, which must precede the invocation of the precautionary principle, cannot be based on purely hypothetical considerations." (*paragraph 66*)[viii]

[i] The ruling of the Higher Administrative Court of North Rhine-Westphalia, Case numbers 13 A 2448/12, 13 A 2541/12 and 13 A 1100/12
http://www.ovg.nrw.de/presse/pressemitteilungen/27_130917/index.php

[ii] Zandera Ltd (t/a E-Lites) –v- Estonian State Agency of Medicines, in the Tartu Administrative Court of Estonia, 2013, Case No. 3-12-2345
http://www.ecita.org.uk/kohtuotsus_e-sigaretid_zandera%20vs%20ravimiamet_ha-3-12-2345_07032013_en-us.pdf

[iii] United Tobacco Vapor Group Inc. versus the State of the Netherlands (the Ministry of Health, Welfare and Sport and the Ministry of Finance), in the Netherlands Court of the Hague, [2012], Case number 414117
http://zoeken.rechtspraak.nl/resultpage.aspx?snelzoeken=true&searchtype=kenmerken&vrije_tekst=414117

[iv] The ruling of Administrative Court of Köln of 20/03/2012 in case no. 7 K 3169/11
http://www.justiz.nrw.de/nrwe/ovgs/vg_koeln/j2012/7_K_3169_11urteil20120320.html

[v] The ruling of the Supreme Court of Sachsen-Anhalt State of Germany of 05/06/2012
http://www.wahrheit-ueber-ezigaretten.de/images/stories/pdf/OVG-LSA-20120605.pdf

[vi] European Court of Justice, Case No. C-140/07, January 2009, preliminary ruling in the case of Hecht-Pharma GmbH –vs- Staatliches Gewerbeaufsichtsamt Lüneburg
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62007CJ0140:EN:HTML

[vii] Commission of the European Communities –v- Federal Republic of Germany, Case No. C-319/05, November 2007
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62005J0319:EN:HTML

[viii] Opinion of Advocate-General Geelhoed concerning joined cases C-21103, C-299/03 and C-316/03 to C-318/03, February 2005
http://curia.europa.eu/juris/showPdf.jsf;jsessionid=9ea7d0f130d5d013e6947c2045ac811f86d1ae1d9904.e34KaxiLc3eQc40LaxqMbN4Oah8Ne0?text=&docid=49907&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=911565