Position on the EU-Commission's Proposal for the Revision of the Tobacco Products Directive

Smoking is the greatest avoidable health risk, not only in Germany but across the whole of Europe. Approximately one third of the European population smokes. Each year around 695.000 people within the European Union die from tobacco-associated diseases, half of these aged between 25 and 69 years.[1]

The European Commission has therefore made it its objective to improve health protection in the area of tobacco consumption at the same time as and within the framework of regulating the internal market (cf. Article 114 of the Treaty on the Functioning of the European Union/TFEU).

A whole bundle of measures is intended to make the consumption of tobacco less attractive as a whole. This also corresponds to the wishes of the majority of the population in the EU: According to a current EU-wide survey, the majority of EU citizens are in favour of increased measures to combat tobacco consumption.[2]

Planned amendments to the Tobacco Products Directive

Part of the European Commission's comprehensive strategy is the revision of Directive 2001/37/EC, the so-called Tobacco Products Directive.[3] The Proposal for the Tobacco Products Directive (the proposal) was presented by the EU-Commission on 19.12.2012. As part of this planned review, stricter regulation with regard to the following points is provided for[4]:

1. Changes to the packaging of tobacco products: From now on, packaging should have larger pictorial health warnings (obligatory instead of voluntary as to date) that cover 75 % of the external area of both front and back surfaces of the packets. In addition the packaging will include smoking cessation information. The requirements regarding product description are also becoming stricter: "Packaging of tobacco products, or the products themselves, shall not include any elements that promote tobacco products or mislead consumers to believe that the product is less harmful than others, refer to flavours or tastes or resemble a food product".[5] The Member States would retain their power to implement full standardisation of packaging (plain packaging).

2. New regulations with regard to ingredients: An electronic format for reporting ingredients and emissions is to be introduced. Cigarettes, roll-your-own and smokeless tobacco products with characteristic aromas are to be banned, as are products with increased toxicity and elevated addictive potential.

3. Maintaining the sales ban on smokeless tobacco products such as the Swedish SNUS.

4. Extending the scope of the Directive: Nicotine Containing Products – NCP (e.g. E-Cigarettes) the nicotine content of which is above a determined threshold must be registered as medicinal products. Nicotine Containing Products with a lesser nicotine content may be sold as consumer products provided they carry a health-related warning.

5. Cross-border distance sales: Provisions have been made for notification obligation for Internet-retailers and a mechanism for verifying age in order to guarantee that tobacco products are not being sold to children and adolescents.

6. Illegal trade: Traceability and security features are provided for to ensure that only those products are sold in the EU, which meet the provisions of the Directive.

The German Smoke-Free Alliance – ABNR (Aktionsbündnis Nichtrauchen) supports the further development of the Tobacco Products Directive. The planned measures are, to a large extent, sensible amendments for the improvement of health protection and are in accordance with modern European public health policy, which is increasingly taking the promotion of the health of its citizens and the prevention of diseases into account.

A large number of smokers are suffering from an addiction requiring treatment. We cannot speak of a free decision to "enjoy" smoking here. In addition, non-smokers are also subjected to the health risks by way

Legal background: Procedure for the review of the Tobacco Products Directive

The Tobacco Products Directive issued in 2001, regulates the manufacture, presentation and sale of tobacco products. In 2005, the European Union ratified the Framework Convention on Tobacco Control (FCTC), the first health protection treaty under international law. In addition, all EU-Member States have ratified the WHO-Framework Convention, the last being the Czech Republic on 01.06.2012. As part of this framework convention the parties commit to comprehensive protection from the dangers of passive smoking. These obligations relate, inter alia to the packaging and labelling of tobacco products (Art. 11 FCTC), as well as tobacco advertising, promotion of the sale of tobacco and tobacco sponsoring (Art. 13 FCTC). Thus, even against this backdrop, a review of the Tobacco Products Directive has become necessary.

In the first instance, this task is the responsibility of the Directorate General for Health and Consumers (DG SANCO) as part of the European Commission. It suggests legal regulations, political measures and programmes of action and is responsible for implementing the decisions of the Parliament and of the Council in the field of Health and Consumer Protection. On 19.12.2012 the EU-Commission, under the new Commissioner for Health and Consumer Protection, Tonio Borg, presented the proposed directive. This proposal is now being debated under the legislative process between the European Parliament and the Council of the European Union (the so-called Council of Ministers) in a first and, if required, second reading, although in view of the current controversies it is unrealistic that agreement will be reached before the second reading in the course of the legislative process.

"The earliest we can expect adoption is in 2014. Within a transition period Member States are then obligated to transpose the Directive into national law. The European Commission is assuming that the Directive could come into force in 2015 or 2016.

Even if the Tobacco Products Directive is passed in 2014 with stricter regulations, it is to be expected that that the tobacco industry will go before the European Court of Justice (ECJ) against a tightening of the Tobacco Products Directive. In the past nearly all legal initiatives by the EU on the topic of tobacco have been taken to law, albeit rarely with a successful outcome for the plaintiff: Generally the ECJ has supported the Commissions line to date."

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of passive smoking, without effectively being able to defend themselves. This is particularly true in the case of children and adolescents. In the following, the aforementioned planned amendments to the Tobacco Products Directive will be explained. In addition it will be shown – and scientifically proven – why these planned changes are advisable and necessary from a legal and public health point of view.

Proposed measures from a Public Health perspective

"Tobacco is the only legal product that when used as directed, is lethal".[6] Tobacco products are therefore not to be equated with normal consumer products. Against this background it is clear that tobacco products must be subject to particularly strict regulation not only to protect the health of consumers but also to protect non-consumers affected by passive smoking.

1. Regulation of Ingredients (Article 6 of the proposal)

The Commission's proposed Directive intends to more strictly regulate the ingredients of tobacco products. Accordingly the placing on the market of tobacco products with a characterising flavour is prohibited (Article 6 Para. 1 line 1 of the proposal). In addition, it is intended to prohibit the following additives in tobacco products (Article 6 Para. 4 of the proposal):

- vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards,
- caffeine and taurine and other additives and stimulant compounds that are associated with energy and vitality,
- additives having colouring properties for emissions.

According to Article 6, Paragraph 5 of the proposed Directive the Member States shall prohibit the use of flavourings in the components of tobacco products such as filters, papers, packages, capsules and adhesives and any technical features allowing modification of flavour or smoke intensity. Filters and capsules shall not contain tobacco.

In addition, the proposal provides that Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase - in an appreciable manner at the stage of consumption, the toxic or addictive effect of a tobacco product (Article 6 Para. 7 of the proposal).

The ban (for example with regard to placing on the market of tobacco products with a characterising flavour) shall not apply to cigars, cigarillos or pipe tobacco[7] (cf. Article 6 Para. 10 of the proposal).

ABNR Position

Until now, it has been possible to mix over 600 additives to tobacco products in order, for example, to preserve the products, change the flavour or to make smoking easier.[8] The partial guidelines for the implementation of Articles 9 and 10 of the international "Framework Convention on Tobacco Control" (FCTC) address, amongst other things, the use of additives. Therein it states, "Tobacco products are commonly made to be attractive in order to encourage their use. From the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive" (Point 1.2.1.1 "Attractiveness").

In the Directive proposal the relevance of the regulation of additives, which make the tobacco product more attractive for consumers, is not taken into account. The regulation of additives is important because they not only make it easier to start consuming tobacco – they also help the continued consumption of a product that is damaging to health.

The use of additives serves to make tobacco products more attractive – particularly for children and adolescents.[9] The use, especially, of flavours based on foodstuffs that are not harmful to health such as coffee, sugar, cocoa and honey result in the fact that, "the unpleasant odour of tobacco smoke is reduced, so the smoke together with its health hazards is hardly perceived." [10]

The German Cancer Research Centre (DKFZ) has emphatically illustrated increasing the attractiveness of a harmful product using the example of the additive menthol: Menthol has a cooling, but also pain-relieving and slightly numbing effect. This permits deeper inhalation so that the lungs are subjected longer to the toxic and carcinogenic components of tobacco smoke. New technologies such as embedding capsules in the cigarette filter, which may be filled with menthol or other flavouring agents and allow consumers to adjust the taste of the cigarette individually, make cigarettes interesting - especially for young people and those starting smoking.[11]

In principle, the ABNR supports more stringent regulation of ingredients. Across Europe there have to be rigorous and uniform regulations with regard to which additives are prohibited or permitted in tobacco products. In several points the proposal shows significant weaknesses which block the path to the desired objective:

- Flavours should be banned without exception. The Proposal only prohibits tobacco products with a "characterising flavour". The restriction to a "characterising flavour" is an unsuitable criterion and means, for example, that menthol can be used in small quantities provided the amount does not lend the tobacco product any characterising flavour.[12]

- Independent panels should be used by the Member States and by the Commission to assist in such decision-making.[13] It is unclear from which (scientifically independent) organisations or persons any such panel shall be comprised and according to which criteria a "characterising flavour" is to be determined? Any such determination is not possible on a scientifically-founded basis. In so far, the regulation with regard to any maximum levels is also meaningless (cf. Article 6 Para. 3 of the proposal).

- In addition to the above, the impression is created for the consumer that the use of additives below a detectable "characterising flavour" is harmless to health. However, this is not the case. Due to the aforementioned (legal) uncertainties, the use of flavours should be subject to a general ban.

- Furthermore, the regulation according to which additives (based on scientific evidence) can then be prohibited if they increase in an appreciable manner – at the stage of consumption, the toxic or addictive effect of a tobacco product (Article 6 Para. 7 of the proposal). It is debatable – in the case of an already toxic, addictive product – what is to be understood by "increase in an appreciable manner?" The scientific investigation of additives is also problematic since there are no recognised test or measurement methods in this regard. Concerning this, SCENIHR (European Scientific Committee on Emerging and Newly Identified Health Risks) – founded in 2004 by the European Commission[14] – established that it is difficult to investigate the addictive potential of additives since "Human testing of different tobacco products for addictiveness faces severe ethical problems, especially if information is sought about effects on children or non-smokers".[15] Considering the aforementioned difficulties, the regulation may well prove futile.

- Furthermore, the fact that the ban only refers to cigarettes, roll-your-own and smokeless tobacco products is also to be criticised. Cigars, cigarillos and pipe tobacco are, however, excluded from these regulations. From a health perspective there is no reason for any such exception. Prohibition of additives should extend to all tobacco products.

All additives which are in themselves toxic, carcinogenic or addictive or which contribute to a toxic or addictive effect would rightly have to be prohibited. In addition, only those additives should be permitted, which are harmless to health (i.e. additives that are in themselves non-toxic, non-carcinogenic and non-addictive) or which when consumed in line with the regulations, especially when burned, form no toxic, carcinogenic or addictive substances.

2 Changing labelling and packaging (Articles 7 to 13 of the proposal)

One of the most important opportunities for the cigarette industry to advertise its products is the packaging: "Besides being appealing, its brand name, logo, colours and configuration create a specific brand image which shape consumer expectations about the product." [16] "... the brand image is most important for the tobacco industry. It not only creates a difference between several brands, but it is the definitive reason for new customers to opt for a certain brand." [17] The

tobacco industry itself confirms the great significance of packaging as an advertising and marketing instrument: "Our final communication vehicle with our smoker is the pack itself. In the absence of any other marketing messages our packaging (...) is the sole communicator of our brand essence. Put another way – when you don't have anything else – our packaging is our marketing".[18]

2.1 Pictorial Warnings

The proposal intends that combined warnings (picture and text) – that are to cover 75 % of the external area of both the front and back surface of the unit packet – be mandatory for the Member States (Articles 7 – 9 of the proposal). Also the warnings must not be hidden or interrupted by any type of wrapper or the like (Article 7 Para. 3 and 4 of the proposal).

ABNR Position

In its attempt to change the packaging, the EU-Commission is picking up on a trend which is emerging internationally but also particularly within the EU. Obligatory pictorial health warnings have been introduced, amongst others, in Spain, France, in the United Kingdom and Belgium.[19] With its proposals, the EU-Commission is in accordance with the obligations determined in Articles 11 and 13 FCTC, as well as the recommendations of the Guidelines to the FCTC. In addition, they are viewed positively by the majority of the EU population: 80 per cent of non-smokers and 61 per cent of smokers are in favour of pictorial health warnings. [20]

According to the WHO, picture and text warnings are amongst the most effective methods with which people can be sensitised to the health risks associated with smoking. A reduction in tobacco consumption can be achieved in this manner.[21]

International studies on this subject[22] have proven the effectiveness and the cost-effectiveness of warnings, whereby combined health warnings using text and large shocking pictures have been proved to be more effective than text warnings alone.[23] Pictorial warnings attract greater attention and lead to better processing of information than solely textual warnings, smokers are also more likely to remember larger than smaller warnings and tend to equate the size of the warning with the extent of the risk.[24] In addition to the above, pictorial health warnings (as opposed to purely textual warnings) may cancel out linguistic barriers so that the content of the warnings – especially amongst socially disadvantaged groups – can be understood regardless of command of the respective national language.[25]

One recent study has confirmed that the small, solely textual warnings used in Germany, tend to be less effective.[26] A summary of the most recent study results on the effectiveness of pictorial health warnings can be found in a recent publication by the German Cancer Research Center.[27]

For the reasons stated in the above, the ABNR supports the introduction of tobacco product packages with large pictorial health warnings on the front and back of the packaging, which in addition may not be hidden or interrupted by any type of wrapper. However, criticism is levelled at the fact that this regulation does not apply to pipe tobacco, cigars and cigarillos and water-pipe tobacco.

2.2 Information on tobacco withdrawal

The Commission's proposal intends that new packaging must include smoking cessation information (Article 9 Para. 1 lit. b). The information shall include phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking.

ABNR Position

This also meets the recommendations under international law: Article 14 Para. 1 FCTC requires the parties to adopt effective measures to encourage the cessation of tobacco consumption and appropriate treatment of tobacco dependence. The parties are encouraged to have the quit line number printed on tobacco product packaging (Guidelines for the implementation of Article 14: No. 46).

ABNR fully supports this part of the Commission's proposal.

2.3 Product description requirements

Article 12 of the proposal regulates more stringent product description requirements. According to this, the labelling of a unit packet and any outside packaging and the tobacco product itself shall not include any element or feature that:

- promotes a tobacco product by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;
- suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health or social effects;
- refers to flavour, taste, any flavourings or other additives or the absence thereof;
- resembles a food product.

Prohibited elements and features may include – but are not limited to – texts, symbols, names, trademarks, figurative or other signs, misleading colours, inserts or other additional material such as adhesive labels, stickers, inserts, scratch-offs and sleeves [that] relate to the shape of the tobacco product itself. Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.

ABNR Position

The regulation is to be endorsed: Already prior to the publication of the proposal for the Tobacco Products Directive the tobacco industry was preparing its consumers as a precaution for future changes, for example a ban on additives: This was done by promoting their tobacco products with a label "without additives" on the unit packets and in advertising campaigns – a practice that still goes on. Any kind of reference for the consumers that these are not lower risk cigarettes is not always immediately apparent (for example on the product packaging). This could therefore be seen as a conscious misleading of consumers, to whom the suggestion is being made that a tobacco product "without additives" is less damaging to health than a tobacco product with additives. Any deception of this kind would already be illegal under existing legislation according to the German Unfair Competition Act (UWG). The Commission's proposal now explicitly forbids any such deception since the packaging may no longer bear any feature that refers to flavour, taste, any flavouring or other additives or the absence thereof (Article 12 Para. 1 lit. [c] of the proposal).

This clarification is to be welcomed. This is also true with regard to the prohibition of additional requirements concerning product description as designated in the draft law.

2.4 Appearance and content of unit packets (Article 13 of the proposal)

The proposal stipulates, inter alia, that a unit packet of cigarettes shall have a cuboid shape and include at least 20 cigarettes (Article 13 Para. 1 of the proposal).

ABNR Position

Again and again in the past unique packets were developed in order to appeal to specific target groups.[28] Especially girls and women are being targeted, the shape and design strongly resembling perfume and lipstick packs.[29] The package's structure and material influence how the consumer perceives a product's quality by suggesting, for example, a higher level of quality.[30] The design elements of the packaging creates a direct link to the potential customer, plays an essential contribution to the brand image and the attractiveness of a brand and can also manipulate the perception of taste and health risk.[31] Studies conducted by the tobacco industry itself show that the brand image conveyed via the packaging has a particular influence on young people – and at an age at which the decisive brand choice is made.[32] Through standardisation of packaging this is now being used in a manner neutral to advertising and sales. The less brand specific elements are left on a package, the less it is attractive for potential consumers.[33]

The ABNR fully supports the regulation to standardise packaging.

2.5 Plain Packaging

Plain Packaging, i.e. standardised packets with pictorial health warnings without individual branding is not mandatory in the proposal.

ABNR Position

The Member States are nevertheless permitted to introduce plain packaging (cf. Article 24 Para. 2 of the proposal) – and for this reason the advantages of plain packaging should be highlighted once more at this point:

- Plain packaging lessens attractiveness: Plain packaging serves the purpose (as do pictorial health warnings) of minimising the attractiveness of the product packets – especially for children and adolescents.

- Plain packaging is effective: International studies have shown that an even better effect of the pictorial health warnings is achieved if these warnings are combined with standardisation of the packaging.[34] Especially among young people, plain packaging has the effect that cigarette packaging is perceived as less attractive and less appealing.[35] Due to uniform product design it is also no longer possible to subliminally convey the impression that a certain product is less harmful to health.[36]

- Plain packaging does not contravene international law: Both the Ukraine and Honduras have requested the formation of a dispute settlement panel at the World Trade Organisation with regard to the planned introduction of plain packaging in Australia, inter alia due to a supposed contravention of the TRIPS-Agreement.[37] [38] However, internationally renowned legal experts give this line of argument virtually no chance of success.[39] (For further explanation regarding the TRIPS-Agreement see the Chapter "Proposed measures from the legal perspective").

- Plain packaging does not lead to an increase in smuggling: It has been shown that the most effective way of combatting illicit trade is through a combination of measures (e.g. international cooperation, legislative measures).[40] There is no evidence whatsoever that plain packaging would lead to an increase in the illicit trade of tobacco products. Moreover the new EU-Directive provides for an EU-wide system for the tracking and tracing of tobacco products along the supply chain (with the exception of retail trade). In addition to the markings for tracking and tracing, visible security features shall be put on all tobacco products placed on the EU market in order to facilitate the identification of authentic products.[41]

From the ABNR perspective we see nothing against, but everything in favour of the introduction of plain packaging.

3 Prohibiting the placing on the market of tobacco for oral use (Article 15 of the proposal)

The Member States have prohibited the placing on the market of tobacco for oral use (Article 8 of the current Tobacco Products Directive, Article 15 of the proposal). The Kingdom of Sweden has derogation from this prohibition.

ABNR Position

In Sweden the smokeless tobacco product Snus has a long tradition.[42] Nevertheless it has been determined that Sweden is to ensure that Snus is not marketed in other Member States (Article 8 Tobacco Products Directive in conjunction with Article 151 of the Protocol to the Act of Accession of Austria, Finland and Sweden, Annex X). The tobacco industry also went to law against this marketing ban – but without success. The ECJ determined that: "... in the exercise of the power conferred on it by Article 95 (now Article 114 Para. 3 TFEU), the Community legislature is to take as a base a high level of protection of human health" and therefore, without overstepping the boundaries of the discretionary power it enjoys, "was entitled to consider that a prohibition on the placing on the market of tobacco for oral use was necessary and that, in particular, there was no alternative measure which allowed its objective to be achieved as effectively."[43]

Under no circumstances should the risk from smokeless tobacco products be underestimated:

- Smokeless tobacco products contain, depending on the type, different amounts of nicotine. Smokeless tobacco products are harmful, cause dependence and deliver similar amounts of nicotine during consumption as cigarettes.
- Smokeless tobacco products contain carcinogens and toxic substances and cause serious diseases that may be lethal. Smokeless tobacco products can also cause oral cancer and oesophageal cancer but also periodontosis, dental caries, tooth loss and gingival recession.
- In addition, smokeless tobacco products may cause premature birth and pre-eclampsia (pregnancy-related high blood pressure).[44]

The health risks of smokeless tobacco products have been confirmed by both SCENIHR and the WHO.[45]

Furthermore there is no scientific proof that smokeless tobacco products may be of help in smoking cessation. On the contrary: Smokeless tobacco products are attractive for youngsters and because of their low nicotine content and intense flavours represent initiation products for young people.[46]

Against this backdrop, it is important that the ban on smokeless tobacco products remains in place. It is to be welcomed that smokeless tobacco products must also be printed with health warnings on the two largest (most likely to be visible) surfaces of the unit packet (Article 11 of the proposal).

4 Regulations concerning cross-border distance sales (Article 16 of the proposal)

Until now it has been left to the Member States to regulate Internet sales of tobacco. Nine Member States (including Spain, France and Austria) have already banned Internet sales of tobacco[47]. Admittedly the Commission has recognised the problem of Internet sales of tobacco goods especially to young persons – but it has unfortunately refrained from placing a general ban on Internet sales of tobacco. The proposal now foresees that retailers that wish to sell tobacco products cross-border must notify their activity prior to the first sale to the Member State in which they are located and in those to which they sell tobacco products. They also must ensure that tobacco products are not sold to children and adolescents.[48]

Retail outlets engaged in distance sales shall be equipped with an age verification system, which verifies at the time of sale, that the purchasing consumer respects the minimum age foreseen under the national legislation of the Member State of destination. The retailer or nominated natural person shall report to the competent authorities a description of the details and functioning of the age verification system (Article 16 Para. 4 of the proposal).

ABNR Position

Since the Commission regrettably could not see its way clear to a comprehensive Internet sales ban, it is imperative – as minimum level protection – that sale to minors is ruled out by using the age verification system. However, many age verification systems do not meet this requirement. Consequently further regulation is required with regard to which age verification system is to be employed in concrete terms by the retailers in order to afford the greatest possible level of safety for children and adolescents.

Until now, the legal situation regarding Internet sales of tobacco to children and adolescents has been very unsatisfactory, so a tightening of laws at European level would be welcomed. According to Section 10, Paragraph 1 of the Law for the Protection of Children and Youth (Jugendschutzgesetz), tobacco goods may not be supplied to children or youths in pubs/restaurants, shops or otherwise in public. In jurisdiction and literature it remains disputed whether the shipment of tobacco goods via the Internet actually constitutes "supply in public"[49] and whether any kind of age verification is required – and if yes - which? Against this backdrop, clarification is needed. In the case of age verification systems, the same requirements should be in force as for the supply of publications harmful to young persons. The Federal Court of Justice (BGH) insofar has stated (BGH, Judgement of 18.10.2007, Ref.: I ZR 102/05):

"In the case of mail order with carrier media harmful to young persons, the Federal Court of Justice only recently deemed a two-stage age verification to be necessary. Firstly, prior to dispatch of the media, a reliable age check is necessary – for example using the "Postident" procedure. In addition, it must also be ensured that the goods in question are not received by minors, which can be guaranteed for example by sending the item by personal signed-for registered mail. Correspondingly effective precautions are also to be required by providers of pornographic content on the Internet. The reliability of an age verification system accordingly presupposes that it rules out simple, obvious and apparent circumvention possibilities. (...) In particular, those abuse risks immanent to the Internet – due to the anonymity of the medium – are to be taken into account."

An "age check via the so-called ID-card-check" (i.e. sending a copy/scan/fax of ID papers) is "not sufficient" since it is too susceptible to manipulation. Even the requesting of separate confirmation of the age of majority as part of the order process (e.g. by tick box) is not sufficient, if the retailer does not check the declaration made by the customer."[50]

According to the opinion of the ABNR, consistent child and youth protection can only be guaranteed through a complete ban on the sale of tobacco products via the Internet, as is already the case in some Member States. As long as a sales ban is not regulated in the future as part of the legislative process, guarantees must be in place that any supply to children and adolescents is ruled out by means of a reliable age verification system (e.g. via the "Postident" procedure).

5 Extension of the scope of the directive to nicotine-containing products (Article 17-19 of the proposal)

The EU-Commission has recognised the need to act to regulate nicotine-containing products (for example E-Cigarettes). Until now, there has been legal uncertainty as to whether E-Cigarettes are to be classified as a medicine, medicinal product, as a "normal" consumer product or – in certain individual cases – as a tobacco product. The situation brought with it a great deal of uncertainty for the citizens, manufacturers and distributors, but also for the authorities.

According to the proposal, Nicotine Containing Products are now to be regulated as follows:

Nicotine Containing Products, with a nicotine content 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 of nicotine per ml, may only be placed on the market if they have been authorised as a medicine under Directive 2001/83/EC (Article 18 of the proposal).

Any unit packet and any outside packaging of nicotine-containing products below the thresholds is in fact permitted as a "normal consumer product", these must however carry the following health warning: "This product contains nicotine and can damage your health".

ABNR Position

The ABNR is of the opinion that all nicotine-containing products, regardless of the amount of nicotine contained, as well as all nicotine-containing and nicotine-free products that are consumed in the manner of smoking tobacco, should be regulated through Directive 2001/83/EC. The rationale for this is that one possibility of smoking cessation exists on the one hand in the staged reduction of nicotine uptake. On the other hand, however, both nicotine-containing and nicotine-free products can also be used for tobacco withdrawal on the basis of the type of application where the habits of smoking are maintained. Thus products without nicotine may also alleviate the symptoms of withdrawal.[51]

Given this background, products with low or no nicotine content should also be regulated in the same way as products with high nicotine content.

6 Introduction of a Display Ban

The EU-Commission has refrained from including a Display Ban in the proposal.

ABNR Position

It is necessary from a health policy perspective to reduce the incentive to buy tobacco products. Any such measure would conform to Article 13 FCTC and its respective recommendations: Display of tobacco products at points of sale in itself constitutes advertising and promotion. Display of products is a key means of promoting tobacco products and tobacco use, including by stimulating impulse purchases of tobacco products, giving the impression that tobacco use is socially acceptable and making it harder for tobacco users to quit. Young people are particularly vulnerable to the promotional effects of product display. (cf. Guidelines for the Implementation of Article 13 FCTC, No. 12). Display and visibility of tobacco products at points of sale constitutes advertising and promotion and should therefore be banned (cf. Guidelines for the Implementation of Article 13 FCTC, recommendations for "Retail Sale and Display").

Accordingly, in 2009 Ireland became the first EU State to introduce a display ban.[52] In the United Kingdom there has been a display ban in large stores since 06.04.2012; from 06.04.2015 this also comes into effect for small stores.[53] On no account does the tobacco industry want to forgo this form of sales promotion aimed at (new) consumers and is clearly adopting a position against the more stringent regulations. This has already led to a legal dispute between Philip Morris and Norway, the country having introduced a display ban in 2010. However, Philip Morris lost all proceedings.[54] The introduction of display ban is supported by the majority of the population.[55]

The ABNR therefore continues to demand the introduction of a display ban.

Proposed measures from a legal perspective

In conclusion we would like to respond to some of the points within the proposal that are of significance as part of the legal discussion.

1 Regulatory Powers of the EU

The EU has the legal powers to regulate the manufacture, presentation and sale of tobacco products.

The EU is governed by the "principle of conferral" (Article 5 Para. 1 line 1 and Para. 2 line 1, EUT[56]). This means that the EU can only act if the Member States have transferred the competences for it to do so. For the enactment of the Tobacco Products Directive, two competences come into discussion: Article 168 TFEU[57] ("The EU contribution to ensuring a high level of human health protection") and Article 114 TFEU ("The approximation of laws in the Internal Market"). Competence is based primarily on Article 114 TFEU, i.e. on the approximation of the laws in the internal market. At first glance this may seem surprising or even paradoxical[58], but has the following background:

The European Parliament and the Council may adopt measures designed to protect and improve the health of the population from the risks of tobacco consumption. However, it is expressly determined that there may be no harmonisation of the laws and regulations of the Member States in this area (Article 168 Para. 5 TFEU). In so far the competence arising from Article 168 TFEU is limited. However, the EU is entitled to adopt measures for the approximation of laws within the area of the internal market (Article 114 TFEU) – even when these touch upon matters of health. This is shown in the wording in Article 114 Para. 3 TFEU, according to which the Commission – in its proposals envisaged in Paragraph 1 concerning health ... will take as a base a high level of protection. Consequently, health protection is to be afforded high priority even in the case of measures to approximate laws within the internal market.

The tobacco industry has already questioned the competence of the EU with regard to the Tobacco Products Directive in earlier legal disputes. The ECJ however ruled that it is also possible to refer back to Article 114 TFEU (previously: Article 95 EG) if the planned measure serves to improve the functioning of the internal market and in addition the realisation of other objectives (e.g. health protection) are of "decisive" or "crucial" importance.[59]

Competence of the EU thus also exists with regard to the introduction of uniform packaging – including the printing of pictorial health warnings – since the regulation serves the purpose of unifying the diverging developments within the Member States in order thus to guarantee the functioning of the internal market. At the same time a high level of health protection is also taken into account in this manner.

The proposed regulation is also proportionate. This means that the instrument used (in this case: the introduction of standardised packaging along with pictorial health warnings) has to be appropriate for attaining the objective pursued and must not go beyond what is necessary to attain it.[60]

The ECJ has recognised the Community legislature must be allowed a broad discretion if it is to pass regulations in an area which entails political, economic and social choices on its part and in which it is called upon to undertake complex assessments.[61] Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which it is seeking to pursue.[62] However, this is not the case. In addition, it has to be taken into account that the EU Commission has opted not to include plain packaging in the proposal (which is also permissible). In the version now proposed, cigarette manufacturers are left with sufficient room to present their brands to the consumers. For this reason too, the regulation to standardise packaging with printing of pictorial health warnings does not give rise to any legal concerns.

2 No infringement of the Charter of Fundamental Rights of the European Union

The introduction of standardised packaging with large, pictorial health warnings does not represent an infringement of the Charter of Fundamental Rights of the European Union (CFR), in particular Article 11 CFR (Freedom of expression and information), Article 16 CFR (Freedom to conduct a business) and Article 17 CFR (Right to property).

It is debatable whether Article 11 CFR is at all relevant with regard to the interests of the tobacco industry. Admittedly Article 11 CFR protects both the freedom of expression and of information. However, the German Federal Constitutional Court determined that the scope of protection for freedom of expression in relation to health warnings for tobacco products is – in any case – not relevant according to the measures of German constitutional law. The same reasoning can be applied to the Charter of Fundamental Rights of the European Union. The Federal Constitutional Court says in this regard:

"The fundamental right to freedom of expression (Article 5 Para. 1, Basic Law/GG) can at best be used with regard to business advertising if the advertisement has judgmental, opinion-forming content or contains details that serve the purpose of shaping opinion (cf. BVerfGE 71, 162, 175 – Federal Constitutional Court). This is not fulfilled in this case: Insofar as manufacturers of tobacco products have to also circulate state warnings on their packaging, the state utilises this packaging without thereby otherwise compromising the advertising. In this respect it is not the formation or the expression of the opinion of the company that is affected, but exclusively its business practice. A different scenario would apply if the health warnings were not clearly recognisable as the expression of a foreign opinion, but could be attributed to the producer of the tobacco products. Were a subject of fundamental rights believed to have spread another's opinion as his own, the freedom of expression (Article 5, Para 1, s. 1 Basic Law) would have been affected. If the addressee of the advertising is given the im-

pression that the tobacco producer supports the dissemination of the health warnings of his own free will, i.e. distributes this message himself, then freedom of expression may offer the grounds for applying the legal test. If however it becomes clearly apparent that the opinion distributed on the tobacco product packets is attributable to another person, and if the distribution of this warning is a general condition of a commercial placing on the market of tobacco products, this labelling obligation regulates the business practice. Using this standard as a basis, the fundamental right of the complainant to freedom of expression is not affected by the contested regulation."[63]

Even if one were to believe the contrary opinion that the protective scope of Article 11 CFR was thematically relevant, Article 11 CFR can thus, in accordance with Article 52 CFR in conjunction with Article 10 Para. 2 of the European Convention of Human Rights (ECHR) be restricted to the protection of health.[64] The measure would also be proportionate, especially since the manufacturers of tobacco products still had enough space on the packaging for the presentation of their product. The respective brand remains readily discernible.

No contravention of Article 16 CFR (freedom to conduct a business) can be found either. It may well be that "the protection of human health may justify considerable negative consequences of an economic nature for certain business operators and takes precedence over economic considerations".[65] Furthermore there exists for the legislator a "broad scope of discretion if he – as is the case here – has to pass judgement with regard to complex economic issues," so that from this point of view, the measure is to be assessed as proportionate.[66]

Sufficient consideration has also been given in the proposal to the fundamental right arising from Article 17 CFR (Right to property). From the presentation given by the EU-Commission on the occasion of the introducing the Directive[67] it is easy to see that the branding – which is anyway very easily remembered in the field of tobacco products – remains easily recognisable on the remaining percentage part of the packaging. The fact that – "the protection of human health may justify considerable negative consequences of an economic nature for certain business operators and takes precedence over economic considerations" – is also valid here.[68]

3 On the admissibility of the delegation of legislative powers in the proposal

The delegation of legislative powers in the proposal for the Tobacco Products Directive does not violate Article 290 TFEU.

A legislative act (in this case the proposal) may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act. (Article 290 TFEU). The conditions, under which this delegation may occur, are specified further in in Article 290 TFEU.

In the proposal, a delegation of this kind is foreseen, for example in Article 9 Para. 3 – with regard to the combined, health-related warnings for smoking tobacco. The fact remains, however, that the fundamental decision, which is of relevance to fundamental rights, either in favour of or against the introduction of combined textual and pictorial health warnings will be made within the realms of the "normal" European legislative process involving the European Parliament and the Member States. Only after the Tobacco Products Directive has been accepted in its proposed form as part of the ordinary legislative procedure, does the possibility exist of adopting delegated acts regarding questions of more minor importance [for example the adaptation of textual health warnings, the establishment of picture libraries (for the health warnings) or even the determination of positioning, format, layout, design, rotation and proportions of the health warnings]. Furthermore, the power to adopt delegated acts may be revoked at any time by the European Parliament or the Council (Article 22 Para. 3 of the proposal). A delegated act shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. (Article 22 Para. 5 of the proposal). This process thus meets the guidelines arising from Article 290 TFEU. There is no breach of the principle of democracy.

4 The introduction of plain packaging does not contravene international law

Admittedly the cigarette brand falls within the scope of the TRIPS-Agreement since a "brand" is a "symbol or combination of symbols through which a company's product or service can be differentiated from similar products from another company".[69] However, the TRIPS-Agreement only contains minimum standards that are to be met by all WTO-Members thus bringing about a harmonisation of the immaterial property protection/rights.[70] The WTO-Members are, for example, obligated to ensure the registrability of trademarks (Article 15 TRIPS "Protectable Subject matter").

The tobacco industry claims that the introduction of plain packaging will prevent the trademark owner from actually using the brand trademark and thus contravenes the TRIPS-Agreement. However, the TRIPS-Agreement only grants the trademark owner a so-called "negative right", i.e. he shall have the exclusive right to prevent all third parties not having the owner's consent from using the trademark ... (cf. Article 16 Para. 1, TRIPS).[71] He is still able to do this, even after the introduction of plain packaging. A so-called "positive right", i.e. of actually using the trademark, cannot be assumed from the TRIPS-Agreement or the Paris Agreement on the Protection of Intellectual Property, which is referred to in the TRIPS-Agreement.[72] This is actually conceded in an expert opinion commissioned by Japan Tobacco International.[73] Nevertheless, in the expert opinion a positive right is derived from the "spirit of the Paris Agreement": In 1956 at the Lisbon Conference for the Revision of the Paris Convention a text proposal was submitted by AIPPI (Association Internationale pour la Protection de la Propriété Intellectuelle), in which an exclusive right to use a mark was granted. This proposed text was, however, not accepted by the Member States.[74] The historical interpretation of the text of the agreement therefore shows that a positive right to the use of a

trademark was obviously not wanted by the Member States.[75] Against this backdrop there also cannot be any inadmissible restriction of a – non-existent – positive right of usage by plain packaging. In the expert opinion for the tobacco industry it is astonishingly stated in clarification that "no one doubts that WTO Members can ban the sale of certain products (e.g. pharmaceuticals, fireworks, alcohol and tobacco.)"[76] Therefore it is not comprehensible why a less radical measure (plain packaging) should not be consistent with the TRIPS-Agreement, when the farther-reaching measure of a sales ban is permissible.

Finally, it should be emphasised that in accordance with Article 8 of the TRIPS-Agreement the Members may adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of the Agreement. This is, as explained in the above, clearly the case. Thus there is no violation of the TRIPS-Agreement.

ABNR Demands

The ABNR requests the political decision-makers to advocate the implementation of a modern, European health policy and to do all they can to actually improve the prevention of tobacco consumption through the aforementioned proposed amendments to the Tobacco Products Directive. Support of the current proposal by the Federal Republic of Germany would in itself be of particular significance in the European legislative process due the weighting of votes in the Council of the European Union. In view of the proven health risks through both active and passive consumption of tobacco products, under no circumstances should greater value be placed on economic interests than on the health of human beings.

In summary, the ABNR assesses the proposal as follows:

We agree to the following points:

1. The introduction of product unit packets – preferably standardised – with large textual and pictorial health warnings on both front and back.
2. The introduction of information on smoking cessation on the packaging.
3. Strict specifications regarding product description.
4. A ban on all smokeless tobacco products. Labelling of smokeless tobacco products with health warnings.
5. A ban on cross-border distances sales, alternatively a multi-level age-verification system.

The ABNR rejects the following points, and/or calls for improvements in this regard:

1. The ABNR does not agree with the regulation regarding tobacco products with a "characterising flavour" in Article 6 of the proposal.
2. The ABNR does not agree with the regulation in Article 6 regarding a "significant" increase of a toxic or addictive effect of additives in tobacco products.
3. The ABNR does not endorse the determination of maximum amounts in Article 6 of the proposal.
4. There must be a uniform, Europe-wide regulation regarding which additives are banned and which are permitted in tobacco products. Additives are to be banned if they are themselves toxic, carcinogenic or addictive or if they contribute to a toxic or addictive effect. Additives may be permitted if they are harmless to health.
5. We endorse the extension of the scope to include other Nicotine Containing Products. However, E-Cigarettes should be classified as medicines (regardless of their nicotine content).
6. There should be no exceptions for cigars, cigarillos, pipe tobacco and water-pipe tobacco.
7. A display ban should be introduced.

[1] For the whole paragraph cf.: European Commission: http://ec.europa.eu/health-eu/my_lifestyle/tobacco/index_en.htm, downloaded on 04.07.2012

[2] European Commission: Press Release for World No Tobacco Day 2012, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/511&format=HTML&aged=0&language=DE&guiLanguage=en, downloaded on 04.07.2012

[3] The Tobacco Products Directive was transposed into German Law via the "Tabakprodukt-Verordnung" (Tobacco Products Regulation).

[4] European Commission Press Release 19.12.2012

[5] Commission, Proposed Tobacco Products Directive, COM(2012) 788 final, English version, p. 6

[6] Eriksen, Mackay, Ross. The Tobacco Atlas: Forewords by John R. Seffrin (CEO, American Cancer Society US), Peter Baldini (Executive Director, World Lung Foundation, US), "Tobacco is the only legal product that when used as directed, is lethal", p. 9, 4th edition

[7] Proposed Tobacco Products Directive , COM(2012) 788 final, Engl. p. 6

[8] German Cancer Research Center (Ed.): Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product", p. 1, Heidelberg, 2012

[9] German Cancer Research Center "Improvement of youth and consumer protection by revision of the EU Tobacco Products Directive", p.33; Carpenter CM, Wayne GF, Pauly JL, Koh HK, Connolly GN (2005): New cigarette brands with flavours that appeal to youth: tobacco marketing strategies. Health Aff (Millwood), 24, 1601-1610; Conolly GN (2004): Sweet and spicy flavours: new brands for minorities and youth. Tob. Control, 13, 211-212; Manning KC, Kelly KJ, Comello ML (2009) Flavoured cigarettes, sensation seeking and adolescents' perceptions of cigarette brands. Tob Control, 18, 459-465

[10] German Cancer Research Center "Improvement of youth and consumer protection by revision of the EU Tobacco Product Directive 2001/37/EC", p.29

[11] For the paragraph, cf.: German Cancer Research Center (Ed.): Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product", p. 2, 25, Heidelberg, 2012

[12] European Commission: Memo/12/1005: "Questions and answers: Towards a new EU law on Tobacco Products", p. 4

[13] Proposal, Recital No. 16

[14] http://ec.europa.eu/health/scientific_committees/opinions_layman/tobacco/de/about.htm, downloaded on 16.07.2012

[15] For the whole paragraph, cf.: http://ec.europa.eu/health/scientific_committees/opinions_layman/tobacco/en, downloaded on 16.07.2012

[16] German Cancer Research Center "Improvement of youth and consumer protection by revision of the EU Tobacco Product Directive 2001/37/EC", Heidelberg, 2010, p. 18 with further references.

[17] Ibidem.

[18] Mark Hulit (Affiliate Employee, BAT Holdings Limited): "Marketing issues, corporate affairs conference, May 27, 1994 – Manila", http://legacy.library.ucsf.edu/tid/jga42e00/pdf, downloaded on 05.07.2012;

[19] Cf. http://www.euro.who.int/de/what-we-do/health-topics/disease-prevention/tobacco/news/news/2011/04/ukraine-adopts-pictorial-health-warnings-on-tobacco-products, downloaded on 05.07.2012; http://www.fctc.org/index.php?option=com_content&view=article&id=398:spain-to-have-pictorial-warnings&catid=239:packaging-and-labelling&Itemid=243, downloaded on 26.07.2012

[20] http://ec.europa.eu/health/tobacco/docs/ebs332_en.pdf, p. 96, downloaded on 05.07.2012

[21] For the paragraph cf.: WHO/Region Office for Europe: "Ukraine adopts pictorial health warnings for tobacco products", 14.04.2011, http://www.euro.who.int/de/what-we-do/health-topics/disease-prevention/tobacco/news/news/2011/04/ukraine-adopts-pictorial-health-warnings-on-tobacco-products, downloaded on 05.07.2012

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[26] ITC Project (March 2012), ibidem.: "The Netherlands and Germany (both of which have only small text warnings) tended to show the lowest rates of health warning effectiveness across the measures".

[27] German Cancer Research Center (Ed.): Effectiveness of Pictorial Health Warnings on Cigarette Packages, Heidelberg, 2013

[28] German Cancer Research Center (Ed.): Improvement of youth and consumer protection by revision of the EU Tobacco Product Directive 2001/37/EC, p. 19

[29] ibidem.

[30] ibidem.

[31] German Cancer Research Center (Ed.): Zigarettenwerbung in Deutschland – Marketing für ein gesundheitsgefährdendes Produkt, p. 43 [No English version available- excerpt translated]

[32] ibidem, p. 43 with further references.

[33] German Cancer Research Center (Ed.): Improvement of youth and consumer protection by revision of the EU Tobacco Product Directive 2001/37/EC, p. 22, with further references.

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[47] European Commission, MEMO/12/1005 "Questions and answers: Towards a new EU law on Tobacco Products" 19.12.2012, , p. 8

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[62] ECJ Judgement of 10.12.2002, Recital 123

[63] Federal Constitutional Court - BVerfGE 95, 173 = Ruling of 02.01.1997 – 2 BvR 1915/91

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[70] Krajewski: "Wirtschaftsvölkerrecht", p.158, Heidelberg, 2009

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