
From: M. Calvetti [mc@ig-ed.org]
Sent: 08 February 2013 03:26
To: SCHLYTER Carl
Subject: Statement of the IG-ED concerning the Proposal for the EU Tobacco Directive 2001/37/EG

Statement of the IG-ED concerning the Proposal for the EU Tobacco Directive 2001/37/EG - "E-Cigarette/NCP"

Dear Mr SCHLYTER

we, the IG-ED, contact you with regard to the public expert hearing on February 25, 2013. We are the first independent, non-profit association of German-speaking longtime vapers, working voluntarily, non-paid and independent from manufacturers, retailers and discussion boards.

Let us start with an abstract of the statements arising from the following detailed submissions to clearly emphasize the key aspects:

* E-Cigarettes are consumer products, the product safety of devices and liquids is already ensured by the General Product Safety Directive 2001/95/EG and other pre-existing legislation.

* The addictiveness of nicotine without tobacco is not proven at all. There are scientific results of EU-institutions which rather imply the opposite.

* Nicotine is not a pharmaceutical agent as it does not cure anything.

* The proposed nicotine limit for e-cigarettes has no functional basis and was obviously set to protect the interests of the pharmaceutical industry with regard to smoking cessation products. No smoker will be able to change to e-vaping with such a low nicotine content of the over-the counter products.

* It is hard to escape the impression that the pharmaceutical industry was significantly involved in the proposal.

* With this proposal realised there will be no more less dangerous alternative for millions of e-cigarette consumers. Many of them will return to tobacco and thus be exposed to a much higher health risk.

* Our petition of the same tenor currently has about 17,000 signatures.

Nicotine containing products (NCP) are treated for the first time in the proposal for a revision of the directive 2001/37/EG covering the manufacture, presentation and sale of tobacco and similar products (TPD2).

This proposal does not involve a differentiation of the addictiveness of the different product groups. In the explanatory statement it is explicitly mentioned that the specific characteristics of the different tobacco products are taken into consideration [1]. But nevertheless without verification already existing measures are adopted for new, only similar product groups.

According to the latest findings, the high addictive potential of nicotine can only be proven in conjunction with tobacco. This is inter alia the result of scientific advisors of the EMCCDA (European Monitoring Centre for Drugs and Drugs Addiction) [2].

Some measures on which the expansion of the regulation in the tobacco directive are based can be found in the report about tobacco additives issued by the "Scientific Committee on Emerging and Newly Identified Health Risks" (SCENIHR) [3]). Tobacco additives amplify the addictiveness of nicotine and make tobacco consumption easier. In the

present proposal the Commission sees no necessity for measures to reduce the nicotine contents in tobacco products but focused on research of the tobacco additives beforehand. So the nicotine content in tobacco with additives stays unaltered. This is why there is a complete lack of understanding considering the proposed extremely low nicotine limits in e-cigarettes which contain no additives increasing the addictive potential.

There are national Medicines Laws which contain an exception for tobacco. In terms of the present proposal this exemption is not valid for all products mentioned there.

Furthermore the proposal contains the treatment of a substance (nicotine) as medicinal product even though there is no evidence that this substance has any curative or therapeutic characteristics (according to directive 2001/83/EG). Up to now, nicotine could only have an approval as medicinal product in case it was presented as smoking cessation product. Such a "nicotine replacement therapy" is the same as just continuing the addiction for nicotine dependants. Thus also the withdrawal syndromes are mitigated of course. But this therapy approach will only lead to success and relief from the dependence if a regular, controlled reduction of the substance is accomplished.

The determination of the maximum nicotine content in this proposal was done after a comparison with the nicotine content of pharmaceuticals for smoking cessation (Nicotine Replacement Therapy - NRT), which had an approval according to pharmaceutical regulations already due to their presentation.

In terms of nicotine replacement therapies (NRT) the nicotine content is indicated by consumption units unlike the e-cigarettes where the unit is millilitres. One millilitre is not one consumption unit, but more like about 10 "consumptions". The e-cigarette is supposed to be an enjoyable means of stimulation and savour. Setting the nicotine limit haphazardly at one tenth of the value of the over-the-counter-NRPs is a differentiation not justified by facts and is tantamount to a ban.

Not only evidence of the participation of the pharmaceutical industry as stakeholders in the public consultation of a tobacco directive [4] but also the inclusion of their statement in the commission staff working document under 7.1 [5] for us - the consumers of a legal product - create the suspicion of the pharmaceutical industry exerting influence.

Nicotine is a neurotoxin but the commercially available nicotine liquids are of low concentration. The normal nicotine concentration consumers use is in the range of 12 - 36 mg/ml corresponding to 1.3 - 3.6 per cent. Product safety of this mixture of substances is provided by the Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures and Directive 1999/45/EG (which will be valid for mixtures until June 2015).

Our opinion is that the countries' different treatment of e-cigarettes occurs only due to a broader interpretation as a presentation pharmaceutical of some member countries [6]. Thus there is no need for a harmonisation. We strongly believe that existing law must be applied and enforced instead.

Furthermore we demand the regulation of e-cigarettes as an enjoyable means of stimulation and savour - consumer products - apart the measures of tobacco control. A future regulation of e-cigarettes in a tobacco directive which has to comply with the binding WHO Framework Convention on Tobacco Control (FCTC) would be a disproportional and unreasonable restriction for the consumers.

You can read another detailed statement in our petition "e-cigarette in danger ("E-Zigarette in Gefahr") directing your browser to <http://www.change.org/de/Petitionen/e-zigarette-in-gefahr>. The English translation of the petition text is on our website: http://ig-ed.org/presse/petition/PT_EN.pdf. The petition was started in January this year and mobilised more than 17,000 signees up to now.

This open letter addressed to the committee members of the EU Parliament will also be published on our website.

Sincerely

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References:

[1] 1. CONTEXT OF THE PROPOSAL

In line with Article 114 TFEU a high level of health protection has been taken as a basis when choosing between different policy options identified in the review of the TPD. In this context, the proposal seeks to regulate tobacco products in a way that reflects their specific characteristics (nicotine has addictive properties) and the negative consequences of their consumption (mouth, throat and lung cancer, cardiovascular problems including heart attacks, strokes, clogged arteries, increased risk of blindness, impotence, lower fertility, impact on the unborn child etc).

(Proposal for Directive 2001/37/EG, Explanatory Memorandum, 1. Context of the proposal, page 3)

http://ec.europa.eu/health/tobacco/docs/com_2012_788_en.pdf

[2] Monoamine Oxidase Inhibitors Allow Locomotor and Rewarding Responses to Nicotine

<http://www.nature.com/npp/journal/v31/n8/full/1300987a.html>

Uncoupling between noradrenergic and serotonergic neurons as a molecular basis of stable changes in behavior induced by repeated drugs of abuse

<http://www.ncbi.nlm.nih.gov/pubmed/17686465>

Inhibition of Monoamine Oxidases Desensitizes 5-HT_{1A} Autoreceptors and Allows Nicotine to Induce a Neurochemical and Behavioral Sensitization

<http://www.jneurosci.org/content/29/4/987.short>

[3] SCENIHR. Addictiveness and attractiveness of Tobacco Additives. 12. November 2010;

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_031.pdf

[4] 2. RESULTS OF CONSULTATIONS WITH INTERESTED PARTIES AND IMPACT ASSESSMENT

A first exchange of views with health NGOs, tobacco- and pharmaceutical industries

took place on 3 and 4 December 2009 and on 19 and 20 October 2010

(Proposal for Directive 2001/37/EG, Explanatory Memorandum, 2. Results of Consultations with interested parties and impact assessment, page 3)

http://ec.europa.eu/health/tobacco/docs/com_2012_788_en.pdf

[5] COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0453:FIN:>

EN:PDF

[6] German: Kommentar zum Arzneimittelgesetz (AMG) herausgegeben von
Erwin Deutsch, Hans-Dieter Lippert, Verlag Springer, ISBN:
9783642014550,
§2 Arzneimittelbegriff Seite 26;
http://books.google.at/books?id=e10TTssGmUkC&printsec=frontcover&hl=de&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false