From: Francis P. Crawley [fpc@gcpalliance.org]
Sent: 22 April 2013 21:33
To: SCHLYTER Carl
Subject: Amending Article 18, Proposed Tobacco Products Directive, COM(2012) 788 final
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Attachments: Proposed Consideration for a Revision to Article of the TPD 18 13-04-22,....pdf

Dear Mr. Schlyter,

Please find attached here a suggested consideration for revising Article 18 of the proposed Tobacco Products Directive (TPD) now under review by the European Parliament.

The attached consideration results from a wide discussion with experts in the field of medicine, addiction and health with an interest in the role of “e-cigarettes” and “vaping.”

Public health may benefit from clear regulatory procedures being established for non-tobacco nicotine containing products. It is suggested that a clear distinction should be made between:

(a) non-tobacco nicotine containing medicinal products: products authorised pursuant to Directive 2001/83/EC

(b) non-tobacco nicotine containing consumer products: products not authorised pursuant to Directive 2001/83/EC

The suggestion is that these two categories be established by the TPD and that the European Commission (together with Member States, the European Medicines Agency, and experts), be provided time to establish the scientific and health criteria clearly for regulating these categories. The principle interest is the reduction of tobacco products usage in the European Union by developing products that address the needs expressed by tobacco users, assisting them in reducing their usage of tobacco products and eventually quitting.

We appreciate that the time for you and your colleagues to submit amendments to improve the proposed TPD is limited. We hope that the attached consideration will assist you in your deliberations.

Should it be helpful, we would make ourselves available to discuss this with you or your staff at a time of your convenience.

Sincerely,

Francis

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Proposed Consideration for a Revision to Article 18

of the Proposal for a Directive of the European Parliament and Council on the approximation of the laws, regulations, and administrative provisions of the Member States concerning the manufacturing, presentation and sale of tobacco and related products

Brussels, 19.12.2012; COM(2012) 788 final

TITLE III – NON TOBACCO PRODUCTS

Article 18

Nicotine-containing products

1. The European Commission, in consultation the European Medicines Agency and Member States, as well as with scientific and health experts, shall adopt two categories for regulating non-tobacco nicotine containing products:

   (a) non-tobacco nicotine containing medicinal products: products authorised pursuant to Directive 2001/83/EC

   (b) non-tobacco nicotine containing consumer products: products not authorised pursuant to Directive 2001/83/EC

2. For 1(b) non-tobacco nicotine containing consumer products not authorised pursuant to Directive 2001/82/EC, each unit packet and any outside packaging shall carry the following health warning:

   This product contains nicotine, is addictive, and can damage your health.

3. The health warning referred to in paragraph 2 shall comply with the requirements specified in Article 10(4). In addition, it shall:

   (a) be printed on the two largest surfaces of the unit packet and any outside packaging;

   (b) cover 30% of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32% for Member States with two official languages and 35% for Member States with three official languages.

4. No later than two years from the date specified in Article 25, paragraph 1, the Commission shall submit to the European Parliament, the Council, and the Economic and Social Committee a report considering whether to propose further legislation on the placing on the market of non-tobacco nicotine containing consumer products not authorised pursuant to Directive 2001/83/EC.

5. In the report the Commission shall indicate, in particular, the features which should be considered in light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, paying special attention to

   (a) standards for the manufacture and supply of non-tobacco nicotine containing consumer products;

   (b) the appropriate minimum age of sale and purchase for non-tobacco nicotine containing consumer products;

   (c) consumer information requirements;

(d) advertising and communication requirements commensurate with the harm reduction potential of the products (in comparison with tobacco products), including the use of health claims;

(e) the role and acceptability of the availability of nicotine containing products for consumers of tobacco products.

6. With a view to drafting the report, the Commission shall track the usage and consumption patterns of non-tobacco nicotine containing consumer products, assisted by scientific and technical experts as well as the European Medicines Agency and Member States.

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 2 and 3 taking into account scientific and market developments and to adopt and adapt the content, position, format, layout, design and rotation of the health warnings.