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Committee on the Environment, Public Health and Food Safety

2012/0366(COD)

14.5.2013

AMENDMENTS 1137 - 1233

Draft report
Linda McAvan
(PE508.085v03-00)

on the proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

Proposal for a directive
(COM(2012)0788 – C7-0420/2012 – 2012/0366(COD))

Amendment 1137
Sari Essayah

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment

deleted

Or. fi

Amendment 1138
Holger Krahrmer

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission

3. *Novel* tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment

3. **Lower-risk** tobacco products placed on the market shall respect the requirements set out in this Directive, **with the exception of Articles 4, 6, 7, 8, 9, 10, 12 and 13, which are to be adapted by the Member States to take into account lower-risk products.** The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Or. de

Amendment 1139
Erminia Mazzoni

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission

3. **Novel** tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment

3. **Reduced-risk** tobacco products **that are authorised and** placed on the market shall respect the requirements set out in this Directive, **except as provided for in paragraph 2**. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Or. it

Amendment 1140
Milan Cabrnoch

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2. ***The provisions of Article 12(1)(b) shall not apply to new tobacco products that have been scientifically proven to be less harmful than conventional tobacco products.***

Or. cs

Amendment 1141
Paolo Bartolozzi, Elisabetta Gardini, Sergio Berlato, Salvatore Tatarella, Giovanni La Via, Roberta Angelilli

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment

3. Novel ***and reduced-risk*** tobacco products placed on the market shall respect the requirements set out in this Directive. ***Reduced-risk tobacco products shall be covered by special provisions laid down by Member States under paragraph 2.*** The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Or. it

Justification

Reduced-risk products are tobacco-based products scientifically demonstrated to carry a lower risk than conventional tobacco products. A reference to this concept is required in order for consumers to be properly informed about the reduced risks.

Amendment 1142
Mario Pirillo

Proposal for a directive
Article 17 – paragraph 3 – point 1 (new)

Text proposed by the Commission

Amendment

(1) The Commission shall submit a study on the health effects of passive inhalation of emissions from novel tobacco products, including reduced-risk products.

Or. it

Amendment 1143
Milan Cabrnoch

Proposal for a directive
Article 17 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Member States may authorise the sale and define rules on the marketing and labelling of new categories of tobacco products that have been scientifically proven to be less harmful than conventional tobacco products, provided that it has been demonstrated, pursuant to paragraph 1, that their use could reduce risks, smoking-related diseases and harm to public health when compared with conventional tobacco products.

Or. cs

Amendment 1144
Bernadette Vergnaud

Proposal for a directive
Article 17 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. On the basis of independent, reliable and verifiable scientific and technical data, the Commission shall, within two years of the entry into force of this Directive, adopt delegated acts laying down rules governing evaluation, packaging, labelling, ingredients, placing on the market, presentation and sale of, and consumer information about, new tobacco products which are significantly less harmful than traditional tobacco products.

Or. fr

Amendment 1145
Erminia Mazzoni

Proposal for a directive
Article 17 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Article 12(b) shall not apply to reduced-risk tobacco products.

Or. it

Amendment 1146
Paolo Bartolozzi, Elisabetta Gardini, Sergio Berlato, Salvatore Tatarella, Giovanni La Via, Roberta Angelilli

Proposal for a directive
Article 18

Text proposed by the Commission

Amendment

Article 18

deleted

Nicotine-containing products

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

(a) products with a nicotine level exceeding 2 mg per unit, or

(b) products with a nicotine concentration exceeding 4 mg per ml or

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to

Directive 2001/83/EC.

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

4. The health warning referred to in paragraph 3 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.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.

Or. it

Justification

Nicotine-containing products should be regulated separately and only once appropriate scientific evidence has been produced as to their toxicity and potential addictiveness. What is more, Member States should be free to regulate the market in these products on their own territory.

**Amendment 1147
Linda McAvan**

Proposal for a directive
Article 18

Text proposed by the Commission

Amendment

Article 18

deleted

Nicotine-containing products

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

(a) products with a nicotine level exceeding 2 mg per unit, or

(b) products with a nicotine concentration exceeding 4 mg per ml or

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.

3.

Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

4. The health warning referred to in paragraph 3 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.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.

Or. en

Amendment 1148
Renate Sommer

Proposal for a directive
Article 18 – paragraph 1

Text proposed by the Commission

Amendment

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

deleted

a) products with a nicotine level exceeding 2 mg per unit, or

b) products with a nicotine concentration exceeding 4 mg per ml or

c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.

Or. de

Amendment 1149
Frédérique Ries

Proposal for a directive
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

Amendment

1. *Products which do not contain nicotine or which contain it in quantities smaller than those referred to in paragraph 1(a) may be placed on the market in accordance with the provisions of Directive 2001/95/EC on general product safety.*

1a. Member States shall ensure that nicotine-containing products are not sold to persons below the age required for purchasing tobacco products or related products;

The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

Or. fr

Justification

Electronic cigarettes, which fall into a legal grey area in the EU, are novel products and should be treated as such under the law.

Amendment 1150
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. *The following nicotine-containing products* may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

Amendment

1. *Nicotine-containing products that are presented as having properties for treating or preventing disease in human beings, other than through any message specified in paragraph 3, may only be placed on the*

market if they were authorised pursuant to Directive 2001/83/EC

Or. en

Justification

This makes a medicines marketing authorisation mandatory if a health claim is made using strictly the definition in the medicines directive: ‘presented as having properties for treating or preventing disease’ is quoted from the first part of the medicines directive definition of a medicine 2001/83/EC Article 1.2(a)

Amendment 1151

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti

Proposal for a directive

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. *The following* nicotine-containing products *may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:*

Amendment

1. *Articles 6(1) to (9), 10, 12(1) and (2) and 16 shall apply, mutatis mutandis, to nicotine-containing products other than tobacco products.*

Or. it

Amendment 1152

Martin Callanan

Proposal for a directive

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. *The following nicotine-containing* products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

Amendment

1. *If nicotine containing* products *are presented as having properties for treating or preventing disease they* may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.

Justification

Nicotine containing products such as electronic cigarettes make no claims to improve human health and should not be classified as medicinal products. Such a classification would limit their availability on the market, while more harmful tobacco products remain freely available.

Amendment 1153**Christel Schaldemose, Judith A. Merkies****Proposal for a directive****Article 18 – paragraph 1 – introductory part***Text proposed by the Commission*

1. **The following** nicotine-containing products may only be placed on the market if they **were** authorised pursuant to Directive 2001/83/EC:

Amendment

1. Nicotine-containing products may only be placed on the market if they **are** authorised pursuant to Directive 2001/83/EC, **taking into account the well-established use of nicotine.**

Justification

There is a wide spectrum of medicines authorisation. Given the well-established use of nicotine in nicotine replacement therapies, e-cigarettes should be able to be authorised under a permissive, "light" medicines regime, which does not require clinical trials - as long as the product can prove that it is similar to other products already on the market - such as nicotine replacement therapies.

Amendment 1154**Erik Bánki****Proposal for a directive****Article 18 – paragraph 1 – introductory part***Text proposed by the Commission*

1. **The following** nicotine-containing products may only be placed on the market

Amendment

1. Nicotine-containing products may only be placed on the market if they were

if they were authorised pursuant to
Directive 2001/83/EC:

authorised pursuant to Directive
2001/83/EC.

Or. en

Justification

The regulatory concept of this article is not supported. With the exception of tobacco products – nicotine-containing products – regardless of nicotine quantity – should be classified as pharmaceuticals. Article 18 of the draft does not promote ensuring high level health protection and violates Article 168, Paragraph (7) of the Treaty on the Functioning of the European Union. Article 18 represents a step back when compared to the Hungarian regulations in force, therefore it is unacceptable in the current form.

Amendment 1155

Sari Essayah

Proposal for a directive

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. **The following** nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

Amendment

1. Nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

Or. fi

Amendment 1156

Glenis Willmott, Andrés Perelló Rodríguez, Kartika Tamara Liotard, Carl Schlyter, Catherine Stihler, Antonyia Parvanova

Proposal for a directive

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. **The following** nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

Amendment

1. Nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.

(If adopted, paragraphs 1(a) - (c), 2 to 5 of

this Article should be deemed to be deleted.)

Or. en

Justification

The only justification for allowing the marketing of nicotine containing products (NCPs) is for cessation purposes. It is very difficult to assess the nicotine delivery of NCPs. An intensive use of NCPs with a low level of nicotine could still lead to significant nicotine intake. It is thus appropriate to subject all NCPs to pharmaceutical legislation. This would ensure the quality, safety and efficacy of NCPs, as well as a level playing field for all nicotine containing products.

Amendment 1157

Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. **The following** nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

Amendment

1. Nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.

Or. pl

Justification

All nicotine-containing products should be subject to controls.

Amendment 1158

Hannu Takkula

Proposal for a directive

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. **The following** nicotine-containing products may only be placed on the market

Amendment

1. Nicotine-containing products may only be placed on the market if they were

if they were authorised pursuant to
Directive 2001/83/EC:

authorised pursuant to Directive
2001/83/EC.

Or. fi

Amendment 1159
Françoise Grossetête

Proposal for a directive
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. **The following nicotine-containing** products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

1. **Nicotine-containing** products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.

Or. fr

Justification

Electronic cigarettes are not currently covered by any legislation. Several tests have shown that some e-cigarettes contain toxic products, such as diethylene glycol, and many carcinogens. Classifying e-cigarettes as a medicinal product (in the same way as methadone in the context of the treatment of heroin addiction) would appear to be the best solution. E-cigarettes could then be used to help people cut down on or stop smoking.

Amendment 1160
Holger Krahmer

Proposal for a directive
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to **the simplified registration procedure under Articles 14 and 15 of** Directive 2001/83/EC:

Justification

The requirement that certain nicotine-containing, lower-risk products must be authorised under the same conditions as medicinal products for human use is disproportionate compared to tobacco products. The simplified registration procedure as provided for in the case of homeopathic medicines appears reasonable.

Amendment 1161

Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive

Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Member States shall introduce a ban on the use of nicotine-containing products in public places.

Or. pl

Amendment 1162

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. This Directive shall not apply to nicotine containing products authorised pursuant to Directive 2001/83/EC.

Or. en

Justification

Makes it clear that provisions of the directive do not also apply to NCPs regulated as medicines.

Amendment 1163
Rebecca Taylor

Proposal for a directive
Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Where appropriate, Member States may impose marketing restrictions on nicotine-containing products similar to those which apply to the marketing of tobacco products.

Or. en

Justification

Member States should be able to apply certain restrictions to the marketing of nicotine containing products, so as to prevent for example manufacturers from using marketing techniques aimed at minors such as advertising near schools, or promoting their products in a way which glamorises them, thus indirectly appealing to minors.

Amendment 1164
Françoise Grossetête

Proposal for a directive
Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Member States shall ensure that nicotine-containing products are not sold to persons below the age required for purchasing tobacco products.

Or. fr

Amendment 1165
Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive
Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Nicotine-containing products other than tobacco products in respect of which marketing authorisations are granted under Directive 2011/83/EC shall not be covered by this Directive.

Or. it

Amendment 1166
Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive
Article 18 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. Member States shall introduce a minimum age for purchasing nicotine-containing products.

Or. pl

Justification

Introducing a minimum age for purchasing products containing tobacco and nicotine is in keeping with the objective of this directive.

Amendment 1167
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive
Article 18 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. For nicotine-containing products where paragraph 1 does not apply, the products may be placed on the market if

they comply with this Directive

Or. en

Justification

Ensures that the TPD applies to all other NCPs, and limits the application of medicines regulation to those vendors making health claims consistent with the medicines regulation definition. It rules out member states classifying NCPs as medicines under Article 1.2(b) of 2001/83/EC – the ‘functional’ definition based on changes to physiology – an approach that has been repeatedly struck down in courts in Europe and clearly does not apply to the dominant nicotine product, cigarettes.

Amendment 1168

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

1c. Member States shall ensure that nicotine containing products comply with European Union consumer protection, safety and other relevant legislation in force.

Or. en

Justification

Member states should apply the body of existing consumer and safety regulation to nicotine containing products.

Amendment 1169

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 d (new)

Text proposed by the Commission

Amendment

1d. No later than 12 months from entry into force of this Directive, each Member State shall provide the Commission with a report on the measures it has taken to implement and enforce the legislation set out in [new] Annex IV as it applies to nicotine containing products and the effectiveness of those measures.

Or. en

Justification

The requirement to report will mean a more systematic approach is taken, and will provide data for a future a Commission review

Amendment 1170

Christian Engström, Christofer Fjellner, Rebecca Taylor, Chris Davies

Proposal for a directive

Article 18 – paragraph 1 e (new)

Text proposed by the Commission

Amendment

1e. Member States shall ensure that nicotine-containing products are not sold to persons below the national legal age for purchasing tobacco products.

Or. en

Justification

A level playing field in the age sale requirements between nicotine-containing products and tobacco products should be maintained, so as to prevent young people from buying NCPs.

Amendment 1171

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

***(a) products with a nicotine level
exceeding 2 mg per unit, or*** ***deleted***

Or. en

Justification

Thresholds make no sense as the products above and below still need to be regulated appropriately – the distinction between whether medicines regulation or consumer regulation is applied rests on whether a therapeutic health claim is made, not on an arbitrary threshold.

Amendment 1172
Martin Callanan

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

***(a) products with a nicotine level
exceeding 2 mg per unit, or*** ***deleted***

Or. en

Amendment 1173
**Glenis Willmott, Andrés Perelló Rodríguez, Kartika Tamara Liotard, Carl Schlyter,
Catherine Stihler, Antonyia Parvanova**

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

***(a) products with a nicotine level
exceeding 2 mg per unit, or*** ***deleted***

Or. en

Justification

Consequential amendment to the proposal by the same authors to subject all NCPs to pharmaceutical legislation.

Amendment 1174
Françoise Grossetête

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

*(a) products with a nicotine level
exceeding 2 mg per unit, or* *deleted*

Or. fr

Amendment 1175
Renate Sommer

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

*a) products with a nicotine level
exceeding 2 mg per unit, or* *deleted*

Or. de

Amendment 1176
Jolanta Emilia Hibner, Malgorzata Handzlik, Boguslaw Sonik

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

*(a) products with a nicotine level
exceeding 2 mg per unit, or* *deleted*

Or. pl

Amendment 1177
Hannu Takkula

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

*(a) products with a nicotine level
exceeding 2 mg per unit, or* *deleted*

Or. fi

Amendment 1178
Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

*(a) products with a nicotine level
exceeding 2 mg per unit, or* *deleted*

Or. it

Amendment 1179
Sari Essayah

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

*(a) products with a nicotine level
exceeding 2 mg per unit, or* *deleted*

Or. fi

Amendment 1180
Frédérique Ries

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

a) *products with a nicotine level exceeding 2 mg per unit, or*

a) **Products which are presented as having properties beneficial to human health, or as having therapeutic qualities in terms of being a smoking cessation;**

b) the amount of nicotine in the cartridge is greater than 10 mg, or if the charging solution "e-liquid" has a higher concentration of nicotine than or equal to 20 mg / ml.

Or. xm

Justification

E-cigs are by definition "borderline" products that have to be regulated as such. This is why appropriate thresholds of nicotine are needed in order to avoid a majority of E-cigs to be regulated as medicinal products, even when cessation is not claimed and the cartridge does not contain any substance which may be described as medicine.

Amendment 1181
Holger Krahmer

Proposal for a directive
Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

a) products with a nicotine level exceeding 2 mg per unit, or

a) products **for absorption** with a nicotine level exceeding 2 mg per unit, or

Or. de

Justification

Lower-risk products, such as the so-called e-cigarette, can replace conventional tobacco

products and help to reduce the negative health effects of tobacco consumption as a whole. A statutory regulation is necessary, but the demand for authorisation in accordance with the Directive on medicines intended for human use is not in keeping the current state of scientific knowledge and should re-examined.

Amendment 1182

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or deleted

Or. en

Amendment 1183

Martin Callanan

Proposal for a directive

Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or deleted

Or. en

Amendment 1184

Erik Bánki

Proposal for a directive

Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or deleted

Justification

The regulatory concept of this article is not supported. With the exception of tobacco products – nicotine-containing products – regardless of nicotine quantity – should be classified as pharmaceuticals. Article 18 of the draft does not promote ensuring high level health protection and violates Article 168, Paragraph (7) of the Treaty on the Functioning of the European Union. Article 18 represents a step back when compared to the Hungarian regulations in force, therefore it is unacceptable in the current form.

Amendment 1185

Glenis Willmott, Andrés Perelló Rodríguez, Kartika Tamara Liotard, Carl Schlyter, Catherine Stihler, Antonia Parvanova

Proposal for a directive**Article 18 – paragraph 1 – point b**

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or deleted

Justification

Consequential amendment to the proposal by the same authors to subject all NCPs to pharmaceutical legislation.

Amendment 1186

Françoise Grossetête

Proposal for a directive**Article 18 – paragraph 1 – point b**

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or deleted

Amendment 1187
Renate Sommer

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

b) products with a nicotine concentration exceeding 4 mg per ml or *deleted*

Or. de

Amendment 1188
Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or *deleted*

Or. pl

Amendment 1189
Hannu Takkula

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or *deleted*

Or. fi

Amendment 1190
Frédérique Ries

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or ***deleted***

Or. fr

Justification

This ceiling has no scientific basis and no relevance to the products available on the market.

Amendment 1191
Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or ***deleted***

Or. it

Amendment 1192
Sari Essayah

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or ***deleted***

Or. fi

Amendment 1193
Christofer Fjellner, Jarosław Leszek Wałęsa

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

(b) products with a nicotine concentration exceeding **4** mg per ml or

Amendment

(b) products with a nicotine concentration exceeding **50** mg per ml or

Or. en

Amendment 1194
Holger Krahmer

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

b) products with a nicotine concentration exceeding **4** mg per ml or

Amendment

b) products **for inhalation** with a nicotine concentration exceeding 4 mg per ml or

Or. de

Justification

Lower-risk products, such as the so-called e-cigarette, can replace conventional tobacco products and help to reduce the negative health effects of tobacco consumption as a whole. A statutory regulation is necessary, but the demand for authorisation in accordance with the Directive on medicines intended for human use is not in keeping the current state of scientific knowledge and should re-examined.

Amendment 1195
Ewald Stadler

Proposal for a directive
Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

b) products with a nicotine concentration exceeding 4 mg per ml or

b) products with a nicotine concentration exceeding 24 mg per ml or

Or. de

Justification

When switching from regular cigarettes to so-called e-cigarettes, smokers initially need 24mg /ml. The Commission proposal would therefore increase the number of smokers again.

Amendment 1196

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.

deleted

Or. en

Amendment 1197

Martin Callanan

Proposal for a directive

Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.

deleted

Or. en

Amendment 1198

Erik Bánki

Proposal for a directive

Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Or. en

Justification

The regulatory concept of this article is not supported. With the exception of tobacco products – nicotine-containing products – regardless of nicotine quantity – should be classified as pharmaceuticals. Article 18 of the draft does not promote ensuring high level health protection and violates Article 168, Paragraph (7) of the Treaty on the Functioning of the European Union. Article 18 represents a step back when compared to the Hungarian regulations in force, therefore it is unacceptable in the current form.

Amendment 1199

Glenis Willmott, Andrés Perelló Rodríguez, Kartika Tamara Liotard, Carl Schlyter, Catherine Stihler, Antonia Parvanova

Proposal for a directive

Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Or. en

Justification

Consequential amendment to the proposal by the same authors to subject all NCPs to pharmaceutical legislation.

Amendment 1200
Françoise Grossetête

Proposal for a directive
Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Or. fr

Amendment 1201
Renate Sommer

Proposal for a directive
Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Or. de

Amendment 1202
Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive
Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Amendment 1203

Hannu Takkula

Proposal for a directive

Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Or. fi

Amendment 1204

Frédérique Ries

Proposal for a directive

Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Or. fr

Justification

This ceiling has no scientific basis and no relevance to the products available on the market.

Amendment 1205

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive

Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Or. it

Amendment 1206
Sari Essayah

Proposal for a directive
Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. *deleted*

Or. fi

Amendment 1207
Holger Krahrmer

Proposal for a directive
Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml. c) products whose intended use results in a mean maximum peak plasma concentration exceeding 25 ng of nicotine per ml.

Or. de

Justification

Lower-risk products, such as the so-called e-cigarette, can replace conventional tobacco products and help to reduce the negative health effects of tobacco consumption as a whole. A

statutory regulation is necessary, but the demand for authorisation in accordance with the Directive on medicines intended for human use is not in keeping the current state of scientific knowledge and should re-examined.

Amendment 1208
Françoise Grossetête

Proposal for a directive
Article 18 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. *deleted*

Or. fr

Amendment 1209
Renate Sommer

Proposal for a directive
Article 18 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. *deleted*

Or. de

Amendment 1210
Gaston Franco

Proposal for a directive
Article 18 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. **deleted**

Or. en

Justification

All decisions in this directive are highly political decisions. Any changes have to made with ordinary legislative procedure.

Amendment 1211
Milan Cabrnoch

Proposal for a directive
Article 18 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. **deleted**

Or. cs

Amendment 1212

Holger Krahrmer

Proposal for a directive

Article 18 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. **deleted**

Or. de

Justification

The delegation of powers is at odds not only with the principle of subsidiarity and any legal basis, but also with the implementing guidelines for ‘delegated acts’ (Article 290 TFEU) and ‘implementing acts’ (Article 291 TFEU) set out in the Treaty.

Amendment 1213

Jolanta Emilia Hibner, Malgorzata Handzlik, Bogusław Sonik

Proposal for a directive

Article 18 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. **deleted**

Or. pl

Amendment 1214
Martin Callanan

Proposal for a directive
Article 18 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. **deleted**

Or. en

Amendment 1215
Erik Bánki

Proposal for a directive
Article 18 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. **deleted**

Or. en

Justification

The regulatory concept of this article is not supported. With the exception of tobacco products – nicotine-containing products – regardless of nicotine quantity – should be classified as pharmaceuticals. Article 18 of the draft does not promote ensuring high level health protection and violates Article 168, Paragraph (7) of the Treaty on the Functioning of the European Union. Article 18 represents a step back when compared to the Hungarian

regulations in force, therefore it is unacceptable in the current form.

Amendment 1216

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

**Proposal for a directive
Article 18 – paragraph 2**

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. *deleted*

Or. it

Amendment 1217

Sari Essayah

**Proposal for a directive
Article 18 – paragraph 2**

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC. *deleted*

Or. fi

Amendment 1218

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 2

Text proposed by the Commission

2. The Commission shall *be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC.*

Amendment

2. The Commission shall, *by 1 April 2017, carry out a study on nicotine-containing products in consultation with relevant stakeholders and the Member States. This study will consider whether there is a need for specific legislation in regard to nicotine-containing products.*

Or. en

Justification

Nicotine containing products are potentially a huge market and vital for public health as an alternative to cigarettes. It is important that regulation is designed with care and is legally robust – not to be excessively burdensome or too general to capture any specific risks arising from the products.

Amendment 1219

Hannu Takkula

Proposal for a directive

Article 18 – paragraph 2

Text proposed by the Commission

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update *the nicotine quantities set out in paragraph 1* taking into account scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update *any need for regulation of the threshold nicotine quantity which may subsequently manifest itself* taking into account scientific *and research* developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.

Amendment 1220
Theodoros Skylakakis

Proposal for a directive
Article 18 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Paragraphs 1 and 2 shall not apply to products whose entry onto the market is likely to lead to a significant improvement in the overall health of the population, taking into account both the degree to which they replace more harmful tobacco products, and the extent to which they are adopted by non-users of tobacco products. The decision shall be taken by Member States.

Or. el

Justification

The percentage of smokers differs between Member States, and Member States are therefore best placed to decide whether to allow the marketing of products which, taking into account all the putative consequences, are likely to lead to an improvement in the overall health of the population.

Amendment 1221
Erik Bánki

Proposal for a directive
Article 18 – paragraph 3

Text proposed by the Commission

Amendment

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

deleted

This product contains nicotine and can damage your health.

Or. en

Justification

The regulatory concept of this article is not supported. With the exception of tobacco products – nicotine-containing products – regardless of nicotine quantity – should be classified as pharmaceuticals. Article 18 of the draft does not promote ensuring high level health protection and violates Article 168, Paragraph (7) of the Treaty on the Functioning of the European Union. Article 18 represents a step back when compared to the Hungarian regulations in force, therefore it is unacceptable in the current form.

Amendment 1222
Françoise Grossetête

Proposal for a directive
Article 18 – paragraph 3

Text proposed by the Commission

Amendment

Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning: ***deleted***

This product contains nicotine and can damage your health.

Or. fr

Amendment 1223
Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive
Article 18 – paragraph 3

Text proposed by the Commission

Amendment

Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in ***deleted***

paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

Or. pl

Amendment 1224

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

**Proposal for a directive
Article 18 – paragraph 3**

Text proposed by the Commission

Amendment

Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

deleted

This product contains nicotine and can damage your health.

Or. it

Amendment 1225

Renate Sommer

**Proposal for a directive
Article 18 – paragraph 3 – introductory part**

Text proposed by the Commission

Amendment

Each unit packet and any outside packaging of nicotine-containing products ***below the thresholds set out in paragraph 1*** shall carry the following health warning:

: Each unit packet and any outside packaging of nicotine-containing products ***not authorised in accordance with Directive 2001/83/EC*** shall carry the following health warning:

Or. de

Amendment 1226
Georgios Koumoutsakos

Proposal for a directive
Article 18 – paragraph 3 – introductory part

Text proposed by the Commission

Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

Amendment

Under Articles 5, 6 and 12, each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

Or. el

Justification

Consumers of nicotine-containing products must enjoy the same level of protection under the provisions of Articles 5, 6 and 12, as these are addictive products and are widely sold on the internet.

Amendment 1227
Holger Krahrmer

Proposal for a directive
Article 18 – paragraph 3 – introductory part

Text proposed by the Commission

Each unit packet and any outside packaging of nicotine-containing products ***below the thresholds set out in paragraph 1*** shall carry the following health warning:

Amendment

Each unit packet and any outside packaging of nicotine-containing products shall carry the following health warning:

Or. de

Justification

Lower-risk products, such as the so-called e-cigarette, can replace conventional tobacco products and help to reduce the negative health effects of tobacco consumption as a whole. A statutory regulation is necessary, but the demand for authorisation in accordance with the Directive on medicines intended for human use is not in keeping the current state of scientific knowledge and should re-examined.

Amendment 1228
Hannu Takkula

Proposal for a directive
Article 18 – paragraph 3 – introductory part

Text proposed by the Commission

Each unit *packet* and any outside packaging of nicotine-containing products *below the thresholds set out in paragraph 1* shall carry the following health warning:

Amendment

All unit *packets* and any outside packaging of nicotine-containing products shall carry the following health warning:

Or. fi

Amendment 1229
Christian Engström, Christofer Fjellner, Rebecca Taylor, Chris Davies

Proposal for a directive
Article 18 – paragraph 3 – introductory part

Text proposed by the Commission

Each unit packet and any outside packaging of nicotine-containing products *below the thresholds set out in paragraph 1* shall carry the following health warning:

Amendment

Each unit packet and any outside packaging of nicotine-containing products *which do not fall under the scope of Directive 2001/83/EC* shall carry the following health warning:

Or. en

Amendment 1230
Sari Essayah

Proposal for a directive
Article 18 – paragraph 3 – introductory part

Text proposed by the Commission

Each unit packet and any outside packaging of nicotine-containing products *below the thresholds set out in paragraph 1* shall carry the following health warning:

Amendment

Each unit packet and any outside packaging of nicotine-containing products shall carry the following health warning:

Or. fi

Amendment 1231
Georgios Koumoutsakos

Proposal for a directive
Article 18 – paragraph 3 – subparagraph 1

Text proposed by the Commission

This product contains nicotine and **can damage** your health.

Amendment

This product contains nicotine and **damages** your health.

Or. el

Amendment 1232
Frédérique Ries

Proposal for a directive
Article 18 – paragraph 3 – subparagraph 1

Text proposed by the Commission

This product contains nicotine and can damage your health.

Amendment

This product contains nicotine, **but not tobacco or tar**, and can damage your health.

Or. fr

Justification

Health warnings should reflect the true nature of the product in question and describe it as fully as possible.

Amendment 1233
Christian Engström, Christofer Fjellner, Rebecca Taylor, Chris Davies

Proposal for a directive
Article 18 – paragraph 3 – subparagraph 1

Text proposed by the Commission

This product contains nicotine **and can** damage your health.

Amendment

This product contains nicotine **which is addictive and may** damage your health.

Justification

Consumers should be informed of the addictive characteristics of nicotine, and that such an addiction may be detrimental to health. While the effects of nicotine on the human body are well established, and for the most part do not pose serious risks to health, the effect of long-term use of nicotine-containing products cannot currently be confirmed, so caution is needed.