EUROPEAN PARLIAMENT 2009 - 2014

Committee on the Environment, Public Health and Food Safety

08/05/2013

AMENDMENTS 1 - 24

Linda McAvan
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 1
Christian Engström, Christofer Fjellner, Rebecca Taylor

Proposal for a directive
Recital 34

Text proposed by the Commission	*Amendment*
(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[42] provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products***. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. Subjecting all*** nicotine-containing products***, whose nicotine content equals or exceeds the content of a nicotine containing product previously*** authorised under ***Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all*** nicotine containing products ***usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of*** Directive 2001/83/EC ***to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled***.	(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products ***which claim to have properties beneficial to human health. A significant number of*** nicotine-containing products ***presenting such claims have already been*** authorised under ***this regulatory regime. Member States are obliged to ensure*** nicotine containing products ***which do not fall under*** Directive 2001/83/EC ***and which are placed on the common market comply with the appropriate legislation listed in [new] Annex IV***.

Or. en

Justification

Clarifies that a 'two track' approach should be taken regarding nicotine containing products.Those which do not fall under Directive 2001/83/EC have to comply with the broad range of legislation listed in [new] Annex IV.

Amendment 2
Christian Engström, Christofer Fjellner, Rebecca Taylor

Proposal for a directive
Recital 35

Text proposed by the Commission	*Amendment*
(35) Labelling provisions should be introduced for nicotine containing products ***below the threshold set out in this*** Directive drawing the attention of consumers to potential health risks.	(35) Labelling provisions should be introduced for nicotine containing products ***falling outside of the scope of*** Directive ***2001/83/EC*** drawing the attention of consumers to potential health risks***, and Member States should be obliged to ensure that national age restrictions for buying nicotine containing products are kept in line with those for the sale of tobacco products***.

Or. en

Justification

A level playing field between age restrictions for the sale of nicotine-containing products and tobacco products should be maintained, so as to discourage minors from taking up either product for the first time.

Amendment 10
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

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 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 presenting

disease' is quoted from the first part of the medicines directive definition of a medicine 2001/83/EC Article 1.2(a)

Amendment 11
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

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

Text proposed by the Commission	*Amendment*
	1 a. 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 12
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

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

Text proposed by the Commission	*Amendment*
	1 b. 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 13
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

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

Text proposed by the Commission	*Amendment*
	1 c. 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 14
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

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

Text proposed by the Commission	*Amendment*
	1 d. 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 15
Christian Engström, Christofer Fjellner, Rebecca Taylor

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

Text proposed by the Commission	*Amendment*
	1 e. 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 16
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 17
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 18
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 19
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

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***.	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 20
Christian Engström, Christofer Fjellner, Rebecca Taylor, Chris Davies

Proposal for a directive
Article 18 – paragraph 3 – subparagraph 1 – 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 ***which do not fall under the scope of Directive 2001/83/EC*** shall carry the following health warning:

Or. en

Amendment 21
Christian Engström, Christofer Fjellner, Rebecca Taylor, Chris Davies

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

Text proposed by the Commission	*Amendment*
This product contains nicotine ***and can*** damage your health.	This product contains nicotine ***which is addictive and may*** damage your health.

Or. en

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.

Amendment 22
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive
Article 26 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) nicotine containing products ***below the threshold set out in Article 18(1)***;	(b) nicotine containing products;

Or. en

Amendment 24
Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive
Annex 2 b (new)

Text proposed by the Commission	*Amendment*
	ANNEX IV
	EU legislation applicable to nicotine-containing products:
	General safety:
	General Product Safety Directive 2001/95/EC
	The RAPEX system - notification and alerts of dangerous products
	Packaging and labelling:
	Dangerous Substances Directive 67/548/EEC
	Dangerous Preparations Directive 99/45/EC
	Classification, Labelling and Packaging of Substances and Mixtures - the CLP

Regulation 1272/2008 applies from 2015.

Chemical safety:

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) 1907/2006

Electrical safety:

Low Voltage Directive 2006/95/EC

Electro-Magnetic Compatibility Directive 2004/108/EC

Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU (where appropriate)

Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU

Batteries Directive 2006/66/EC

Weights and measures:

Making-up by weight or by volume of certain prepackaged products - Directive 76/211/EEC

Nominal Quantities for Prepacked Products Directive 2007/45/EC

Commercial practice

Distance Selling Directive 97/7/EC

Directive on Electronic Commerce 2000/31/EC

Misleading and Comparative Advertising Directive 2006/114/EC

Unfair Commercial Practices Directive 2005/29/EC

Or. en

Justification

Member states should apply the body of existing consumer and safety regulation to nicotine containing products. The requirement to report will mean a more systematic approach is taken, and will form the basis of a Commission review to be completed by April 2017