Amendment 135
Frédérique Ries, Rebecca Taylor and Chris Davies,
on behalf of the ALDE Group
Martin Callanan
on behalf of the ECR Group

Report

Linda McAvan
Manufacture, presentation and sale of tobacco and related products
COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)

Proposal for a directive

Article 18

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

Amendment

1. Nicotine-containing products may only be placed on the market in accordance with the provisions for tobacco products as laid out in this Directive. Member States shall ensure that nicotine containing products comply with all relevant EU legislation.

2. Nicotine-containing products that are presented as having properties for treating or preventing disease may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.

3. For all nicotine-containing products notified in accordance with the procedure set out in article 18(1), Member States shall ensure that:
damage your health.

(a) the product is clearly labelled with the nicotine content, instructions for use, instructions for reporting adverse reactions, and details of the manufacturer;

(b) each unit packet and any outside packaging carries the following health warning:
"This product is intended for use by existing smokers above the legal smoking age as an alternative to tobacco products. It contains nicotine which is a highly addictive substance. Consult your doctor if you are pregnant, breast feeding, allergic to nicotine or propylene glycol, or have high blood pressure."

(c) the sale of the product is restricted in line with the legal age for sale of tobacco products in the relevant Member State; in any case it should not be allowed under the age of 18;

(d) the products are available to be sold outside pharmacies.

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.

4a. Nicotine-containing products may not be placed on the market unless Member States have appropriate regulation on advertising and promotion including a provision that excludes advertising and promotion for people below the age of 18.
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.

5. Member States shall monitor the development of the nicotine-containing products market, including any progress made in harm reduction, as well as any evidence of gateway use amongst young people. Based on the evidence, the Commission shall report back to the European Parliament and the Council five years after the date of transposition of this Directive. The report shall assess whether amendments to this Directive are necessary.

6. The Commission shall request an opinion from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) within 24 months of the entry into force of this directive in order to obtain reliable scientific and toxicological data to determine the health effects of the main ingredients of electronic cigarettes as well as suggestions for potential measures to regulate this tobacco-related product.

Or. en

Justification

A notification procedure will ensure a better control of E-cigarettes at EU level and as the same time it will maintain the availability of this nicotine-containing product which help people stop smoking and is much less harmful than any tobacco products.
### Recital 33

**Text proposed by the Commission**

| 33) Nicotine-containing products are sold on the Union market. The different regulatory approaches taken by Member States to address health and safety concerns associated with these products have a negative impact on the functioning of the internal market, in particular considering that these products are subject to significant cross-border distance sales including via the internet. |

**Amendment**

| 33) Nicotine-containing products - including e-cigarettes - are sold on the Union market. However Member States have taken different regulatory approaches to address health and safety concerns associated with these products. There is a need for harmonized rules, and all nicotine containing products should be regulated under this directive as a related tobacco product taking account the well-established use of nicotine. Given the potential of these products to aid smoking cessation, Recognising the health imperative of reducing smoking, Member States should ensure that they can be made available at least as widely as tobacco products. |

Or. en

### Justification

In line with the changes put at the article 18 related to nicotine-containing products.
Amendment 137
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Proposal for a directive
Recital 34

Text proposed by the Commission
(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. 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.

Amendment
deleted
Justification

Medicines regime for Electronic-cigarettes is not appropriate as these nicotine-containing products are not sold for therapeutic aims but as an efficient alternative to conventional tobacco products, helping many smokers to steer away from smoking harmful tobacco products.