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Amendment 130
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on behalf of the EFD Group

Report
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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

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

Amendment

Nicotine-containing products

1. Nicotine-containing products may only be placed on the market in accordance with the provisions for tobacco products as laid out in Articles 5, 17, 20, 21, 22, 23, 24, 25 and 26 of 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:
health warning:

This product contains nicotine and can 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 shall carry 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 shall be restricted in line with the legal age for sale of tobacco products in the relevant Member State;

(d) the products shall be available to be sold outside pharmacies;

(e) advertising and promotion shall be appropriately regulated;

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

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
adopt and adapt the position, format, layout, design and rotation of the health warnings.

people. Based on the evidence, the Commission shall report back to the European Parliament and the Council 5 years after the transposition date of this Directive. The report shall assess whether amendments to this Directive are necessary;

5a. 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 the 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.