Amendment 170
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Report **A7-0276/2013**
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Manufacture, presentation and sale of tobacco and related products
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Proposal for a directive
Article 18

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 ***in accordance with the notification procedure set out in Article 17 of this Directive.*** ***Member States shall ensure that nicotine-containing products comply with all relevant Union legislation, and in particular with Directive 2001/95/EC on general product safety.***
(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***	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.

nicotine- containing products pursuant to Directive 2001/83/EC.

3***. As regards nicotine-containing products to be placed on the market in accordance with paragraph 1, Member States shall ensure that:***

(a) nicotine-containing products with a nicotine level exceeding 30 mg/ml are not placed on the market;

(b) manufacturers and importers of nicotine-containing products submit to the competent authorities a list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof, as well as any changes. Member States shall then ensure the dissemination of this information on a website with due regard to the protection of trade secrets. Manufacturers and importers shall also report to the authorities about national sales volumes by brand name and type;

(c) nicotine-containing products with additives listed in Article 6(4) are not placed on the market;

(d) the unit packet of nicotine-containing products includes a leaflet with instructions for use, including that the reference that the product is not recommended for use by non-smokers, contra-indications, warnings for specific risk groups, reporting of adverse reactions, place of manufacture and contact details of the manufacturer or importer;

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:

(e) each unit packet and any outside packaging of nicotine-containing products carry the following health warning:

"This product contains nicotine ***and can damage your health***".	"This product ***is intended for use by existing smokers. It*** contains nicotine ***which is a highly addictive substance***"***;***
	(f) 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;
	(g) the products are available to be sold outside pharmacies;
	(h) flavourings are allowed in the products;
	(i) the limitations on advertising, sponsorship, audiovisual commercial communication and product placement for tobacco products as set out in Directive 2003/33/EC and Directive 2010/13/EC shall apply to nicotine-containing products;
	(j) cross-border distance sales of nicotine-containing products are regulated in accordance with Article 16;
	(k) tobacco trademarks, brand names and symbols are not used on nicotine-containing products.
4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10***(4). In addition, it shall:***	4. The health warning referred to in paragraph ***3(e)*** shall comply with the requirements specified in ***Article 10.***
(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***	5. ***Member States shall monitor the development of the nicotine-containing products market, including any evidence of gateway use among young people and report their findings to the Commission. Based on the evidence submitted as well as scientific studies the Commission shall submit a report to the European Parliament and the Council on nicotine-containing products five years after entry into force of this Directive. The report shall assess if amendments to this Directive or any further legislation are necessary.***

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Justification

A notification procedure will ensure a better control of E-cigarettes at EU level and at 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.