Amendment 58
ALDE-ECR - EFD
Consolidated amendment replacing Amendments 1146 to 1248, JURI 65, IMCO 59, INTA 55, AGRI 69, ITRE 65
Proposal for a directive
Article 18

Text proposed by the Commission	*Amendment*
	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:
	(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. 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 more than two official languages.

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 5 years after the transposition date 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 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.

Or. en