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

Amendment 137/REV
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Report
Linda McAvan
Manufacture, presentation and sale of tobacco and related products
COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)
Directive 2001/83/EC are fulfilled.

**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.