

Article 18 Compromise Amendment Proposal - Maximising Public Health Benefits and Tobacco Harm Reduction?

Introduction

This proposal is an attempt to find common ground for an proportionate approach to regulation of e-cigarettes or nicotine containing products (NCPs). The aim is to ensure the products are safe, properly labelled and packaged, accurately described and marketed fairly, but without imposing disproportionate burdens, costs and restrictions that would make it less likely that smokers will switch and so protects the cigarette category from competition from much less harmful products.

The points below set out what the amendment aims to achieve. It is based as closely as possible on the amendment (1250) proposed by the ENVI rapporteur, Linda McAvan MEP, and EPP shadow rapporteur, Karl Heinz Florenz.

1. NCPs where a health claim is made would be subject to regulation under the medicines directive;
2. A 'simplified procedure' would apply for all other NCPs;
3. The simplified procedure requires each manufacturer or importer to submit an 'independently audited compliance report'. This has some similarities with the regulatory approach taken to cosmetics in Regulation 1223/2009, which requires each product to undergo a safety assessment, creation of a product information file and notification of a competent authority.
4. The audited compliance report would provide evidence that:
 - a. they meet all applicable safety, packaging and labelling, consumer protection and marketing legislation;
 - b. full disclosure of product detail, with safeguards for commercial confidentiality;
 - c. they have a complaint handling and risk management regime.

This goes considerably beyond what is required of consumer product vendors, as it requires them to provide proactive evidence of compliance.

5. The simplified procedure also requires warnings and appropriate information are placed on the packaging, and that members states address other aspects of the regulation of e-cigarettes;
6. Products would be removed from the market if:
 - a. Regulators considered there was evidence from the compliance reporting that the products did not comply with the general safety requirement of other law
 - b. The compliance reports were not produced or were incomplete;
 - c. The products did not meet the requirements laid down for warnings etc
7. After five years, a Commission review, informed by scientific advice, of the working of the directive would take place to examine its effectiveness and propose amendments if necessary;
8. A suitable lead in time would be needed for compliance reporting, but not as long as envisaged for an authorisation process. This could give faster results and produce results sooner while the industry is still in a rapid growth phase.

The proposed amendment

Article 18 a (new, replacing COM Article 18 Proposal)

*Text proposed by McCavan / Florenz –
amendment 1250*

Article 18 a

Nicotine-containing products

Amendment

Article 18a

Nicotine-containing products

1. (a) 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.

(b) This Directive shall not apply to nicotine containing products authorised pursuant to paragraph 1a.

Justification

Establishes that any health claims made for NCPs must be made subject to medicines regulation – the language ‘treating and preventing disease’ is from the definition of a medicine in 2001/83/EC, so this is legally watertight. Where a product is medicinally licenced, then this Directive does not apply to avoid overlaps.

1. Nicotine-containing products may only be placed on the market if they are authorised pursuant to:

(a) Directive 2001/83/EC, or

(b) The **simplified** procedure as set out in paragraph 2 and 3.

(c) Nicotine containing products **which are not authorised pursuant to paragraph 1a** may be placed on the market if they **comply with applicable European Union safety and consumer protection legislation and with the **simplified** procedure as set out in paragraphs 2 and 3**

Justification

All other NCPs are to be regulated under this directive – thus providing clarity and proper approximation of laws. It asserts the applicability of directives and regulations covering: general product safety; electrical safety; classification labelling & packaging of hazardous preparations; weights and measures; fair commercial practices; and data protection – and the use of the simplified procedure to show that they are compliant.

Simplified procedure

2. Under the **simplified** procedure, Member States shall require manufacturers and importers of nicotine-containing products to submit **an application for a marketing authorisation**, which shall contain the following:

Simplified procedure

2. Under the **simplified** procedure, Member States shall require manufacturers and importers of nicotine-containing products to submit **an independently audited compliance report**, which shall contain the following:

Justification

This places a requirement on the manufacturers and importers to demonstrate they meet legislation in force. This is a non-trivial undertaking involving an audit and detailed assessment of products and processes.

a) Evidence that the product **is manufactured in accordance with the principles and guidelines of Good Manufacturing Practice;**

a) Evidence that the product **meets the general safety requirement and other applicable legislation in force;**

Justification

This establishes a broader obligation to demonstrate safety and consumer protection compliance that goes beyond the narrow specification of the manufacturing process.

From Commission web site: *A safe product is one which poses no threat or only a reduced threat in accordance with the nature of its use and which is acceptable in view of maintaining a high level of protection for the health and safety of persons. A product is deemed safe once it conforms to the safety provisions provided in European legislation, or, in the absence of such rules, if it complies with the specific national regulations of the Member State in which it is being marketed or sold. [more]*

Applicable legislation includes directives covering general safety, electrical safety, labelling and packaging of hazardous preparations, weight and measures, fair marketing practices, on-line marketing and data protection. These could also be listed in an annex and member states required to report on implementation and enforcement.

b) A detailed description of the product in question, including all ingredients and quantities thereof, **as well as information on emissions;**

b) A detailed description of the product in question, including all ingredients and quantities thereof, **with appropriate protection for proprietary information**

Justification

The requirement for measuring emissions is impractical given the different designs of e-cigarettes and NCPs and the absence of standardised 'smoking' regimes. An emissions testing regime could be developed in future. Some safeguards are needed to protect manufacturers' proprietary information, recipes etc so this disclosure will need commercial confidentiality protection

c) A Risk-Management Plan, including a system for monitoring and recording any adverse reactions;

c) A Risk-Management Plan, including a system for **reporting** and recording **faulty or unsafe products**, any adverse reactions **or other complaints;**

Problems will only come to light if there is a system for reporting, and the system should cover a broader range of concerns

Member States shall be entitled to charge a fee for **processing the application**. They

Member States shall be entitled to charge a fee for **assessing compliance reports**.

may also require manufacturers or importers to **carry out additional tests or** submit additional information. Each Member State shall take due account of **authorisations previously granted by** another Member State.

Where necessary to establish compliance with paragraph 1, they may also require manufacturers or importers to submit additional information. Member State shall take due account of **compliance reports submitted in another** Member State.

Justification

This allows member states to demand certain standards of evidence, but limits it to establishing compliance with the regulation in force – ie. demonstrating they meet existing standards. Manufacturers would be responsible for compiling reports.

3. For products **authorised** under the **simplified** procedure, Member States shall ensure that the following conditions are fulfilled:

3. For products **compliant** under **paragraph 1(c) and the compliance** procedure, Member States shall ensure that the following conditions are fulfilled:

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

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:

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This product is intended for use by existing smokers **aged 18 or over** as an alternative to tobacco cigarettes. 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.**

This product is intended for use by existing **adult** smokers as an alternative to tobacco cigarettes. It contains nicotine, which is **an** addictive substance.

Justification

Provides appropriate warnings. These may need further refinement, and technical committee to amend or specify in more detail. Note that 3c below reflects the different ages are specified in member states, so rather than specify 'aged 18 or over' this uses 'adult'. Note that other warnings may be required under other directives or regulations (eg. CLP regulation) – for example the presence of allergens, nuts residues etc. E-cigarettes are less addictive than cigarettes, and no addictiveness warning is included in the Commission's proposal. The addiction warning for smokeless tobacco just uses 'addictive'. The warning should avoid giving partial medical advice and needs to leave space for other mandatory warnings arising from packaging and labelling legislation.

c) flavourings shall not be allowed;

Deleted

Justification

NCPs without flavourings would not be viable – all use some sort of flavouring, and a ban on flavourings would be a de fact ban on e-cigarettes. Flavourings are important in making e-cigarettes appeal to smokers and persuading them to switch and in retaining smokers as NCP users rather than relapsing. If there were concerns about certain flavours having harmful effects they could be considered under safety legislation or as part of the review proposed in paragraph 4 when more information was available. Options for later review include: restriction to a positive list; prohibition of a negative list; prohibition of a category of flavours (eg. confectionary); prohibition of flavours aimed a target group (like young people. But some care is needed – users can always mix their own liquids using whatever flavours they choose, so banning commercial flavoured products may simply stimulate mixing, which has risks too.

d) the sale of the product shall be restricted in line with the legal age for sale of tobacco products in the relevant Member State;

*e) the products shall be available **to be sold outside pharmacies**;*

f) advertising and promotion shall be appropriately regulated;

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 **for general sale, subject to paragraph c***

e) advertising and promotion shall be appropriately regulated

Justification

Clarifies scope and ensures that e-cigs are not competitively disadvantaged relative to cigarettes. There is no case for restricting e-cigarette sales to pharmacies or any other class only. Available for general sale is consistent with internal market principle of free movement of goods, with the only qualification (para c) related to age.

[new] 3a. Nicotine containing products that do not comply with paragraph 1, 2 and 3 may not be placed on the market.

Justification

This gives the directive some force. It requires manufacturers and importers to meet existing law, and to prove that they do, and to prove it in a way that satisfies the authorities. If the authorities believe they are non-compliant based on the information received, then they should remove the products from the market using the powers in the existing directives. It also means that vendors that do not provide audited compliance reports of an acceptable standard (ie. like the ISE) would have their products removed from the market. However, the default is the products are allowed onto the market until a case against them is made. An authorisation process bars them from the market until a case for them is made.

4. 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

4. 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 **and**

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.

independent scientific advice, 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.

Justification

This requires the Commission to assess development take appropriate scientific advice (for example from SCENIHR) and return with amendments if necessary. These could include broader applicability of medicines regulation; a bespoke regulatory framework for NCPs (as has been devised for cosmetics); specific standards for e-liquids or e-cigarettes; or no change.