

ERS position on the Revision of the Tobacco Products Directive

EXECUTIVE SUMMARY:

European Respiratory Society (ERS) supports the European Commission's Proposal for the Tobacco Products Directiveⁱ and Rapporteur Linda McAvan's efforts to improve it.

The main benefit of this proposal for European citizens and governments is the protection and improvement of health.ⁱⁱ Approximately 700 000 EU citizens die prematurely every year because of tobacco consumption.ⁱⁱⁱ A large proportion of these deaths is caused by respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) and lung cancer. 70% of smokers start before the age of 18 and 94% before the age of 25 years,^{iv} when lung damage already begins. Given this, we need to prevent children and young people from picking up their first cigarettes. Ensuring people stay healthy is particularly important in light of an ageing population and increasing healthcare costs in the EU. Keeping people healthy for longer has a positive impact on productivity and competitiveness^v and is an integral part of Europe 2020.^{vi}

ERS urges support for the following:

- Mandatory reporting system of ingredients used in tobacco products (Art. 5)
- Harmonised regulation of the ingredients of tobacco products (Art. 6)
- 80% pictorial health warnings, covering the front and back of packages. Based on evidence, the larger the pictorial health warnings are, the more effective they are. (Art. 9)
- Plain / standardised packaging of tobacco products.^{vii} Such a measure would be more effective in preventing young people from smoking than other options proposed. (Art. 13)
- Introduction of both visible and invisible security features on tobacco packaging and ensuring that the storage and access to such data is independent from tobacco companies (Art. 14)
- Prohibition on the cross-border distance sale of tobacco products (Art. 16)
- Strong regulatory framework and independent research for electronic cigarettes. The Article 14 guidelines of the UN – WHO Treaty state that countries should prioritise cessation treatments “strongly based on scientific evidence”. Any regulation of electronic nicotine delivery systems should be science based. (Art. 18)
- Ensuring the adoption of delegated acts is not exposed to the interests of the tobacco industry which would jeopardise the achievement of high level of health protection (Art. 22)

Above all, ERS calls for a speedy adoption of this Directive before the European Parliament elections in 2014.

INTRODUCTION:

As noted in the Proposal, **70% of European smokers have started before the age of 18 and 94% before the age of 25 years,^{viii} when lung damage already begins. Given this, we need to prevent children and young people from becoming smokers.** Ensuring people stay healthy is particularly important in light of an ageing population and increasing healthcare costs in the EU. Keeping people healthy and active for longer has a positive impact on productivity and competitiveness^{ix} and is an integral part of Europe 2020^x along with the target for inclusive growth against social exclusion.^{xi} Low socio-economic status is a preventable risk factor for respiratory diseases and therefore, it is important that we tackle together the great health inequalities in Europe revealed by the latest WHO Health Report.^{xii}

Approximately 700 000 EU citizens die prematurely every year because of tobacco consumption.^{xiii} A large portion of these deaths is caused by respiratory diseases. Close to 13 million people in the 27 countries of the EU suffer from one or more of the six main disease categories that are associated with smoking. These are: bronchitis and other lower respiratory infections; chronic obstructive pulmonary diseases; cardiovascular diseases: stroke, heart attacks and arterial obstructions; asthma; lung cancers; other cancers: pancreas, esophagus and stomach.^{xiv}

For ERS, the priority of the Revision of the Tobacco Products Directive is **to protect children and youth from becoming smokers** by preventing them from picking up their first cigarettes.

The most important measures in this proposal are the:

- introduction of **standard packs** with **increased health warnings**,
- prohibition of **characterising flavours**,
- strengthening of **traceability** and **security features** for combating illicit trade, and
- prohibiting **misleading features**, including slim cigarettes.

Furthermore, as a medical society, ERS pays particular attention to **electronic cigarettes**.^{xv}

Electronic cigarettes are designed for the purpose of direct nicotine delivery to the respiratory system and they fall into a regulatory gap in most countries, escaping regulation as medicinal products and avoiding the controls applicable to tobacco products.^{xvi}

There is no adequate scientific research available on the overall health risk or the long-term effects of electronic cigarette use on humans.^{xvii} Since electronic cigarettes have not been properly scientifically evaluated, their quality, safety, the extent of nicotine uptake or the amounts and kinds of other potentially harmful chemicals that these products deliver to the user have not been established.^{xviii}

The Article 14 guidelines of the UN – WHO Treaty state that countries should prioritise cessation treatments “strongly based on scientific evidence”. Any regulation of electronic nicotine delivery systems should be science-based. It is important to develop independent EU-supported research into these products and therefore, ERS is calling on the European Parliament to ask the European Commission to support such research. This should include medium- and long-term independent clinical trials and, behavioural studies.

The ERS position on nicotine containing products (NCPs) / electronic cigarettes is presented in further detail within “Article 18” in this Position Paper.

ERS urges for support on:

- **INGREDIENTS & EMISSIONS:**
 - Reporting of ingredients and emissions (Article 5);
 - Regulation of ingredients (Article 6);

- **LABELLING & PACKAGING:**
 - General provisions (Article 7);
 - Combined health warnings for tobacco smoking (Article 9) with:
 - Amendment 677 (Willmott),
 - Amendment 678 (Anderson);
 - Product description (Article 12);
 - Appearance and content of unit packets (Article 13) with:
 - Amendment 897 (Willmott);
 - Traceability and security features (Article 14) with:
 - Amendment 40 (Rapporteur McAvan),
 - Amendment 41 (Rapporteur McAvan),
 - Amendment 987 (Childers),
 - Amendment 991 (Childers),
 - Amendment 993 (Hibner);

- **TOBACCO FOR ORAL USE:**
 - Tobacco for oral use (Article 15);

- **CROSS-BORDER DISTANCE SALES OF TOBACCO PRODUCTS:**
 - Cross-border distance sales of tobacco products (Article 16) with:
 - Amendment 42 (Rapporteur McAvan);

- **NON-TOBACCO PRODUCTS:**
 - Nicotine-containing products (Article 18) with:
 - Amendment 1250 (Rapporteur McAvan);

- **FINAL PROVISIONS:**
 - Exercise of the delegation (Article 22).

The following recommendations on the revision of the Tobacco Products Directive are presented in the order of the European Commission's Proposal.

INGREDIENTS & EMISSIONS:

- **Reporting of ingredients and emissions (Article 5):**

ERS supports the proposed reporting system of ingredients. It is important that the data on ingredients supplied by tobacco companies is verified independently by competent authorities.

- **Regulation of ingredients (Article 6):**

ERS welcomes Article 6 on the ingredients of tobacco products.

With a view to preventing the uptake of smoking among children, ERS also supports the prohibition of placing tobacco products with a characterising flavour on the market. Furthermore, the prohibition of additives which increase toxicity, addictiveness or imply health benefits, is crucial.

LABELLING & PACKAGING:

- **General provisions (Article 7):**

ERS supports Article 7.

- **Combined health warnings for tobacco smoking (Article 9):**

ERS supports Article 9 but suggests a modification regarding the size of the pictorial health warnings on tobacco product packages.

Based on evidence, bigger and pictorial health warnings are more effective.^{xix} Therefore, citizens should have the pictorial and textual warnings rather than tobacco advertisements. Hence, **ERS supports 80% health warnings covering tobacco product packages (front and back)** as proposed in Amendments: 677 (Willmott) and 678 (Anderson). Furthermore, Thailand, Australia, Uruguay, Sri Lanka and New Zealand have / are going to introduce pictorial health warnings between 80 and 85%.

- **Product description (Article 12):**

ERS supports Article 12.

- **Appearance and content of unit packets (Article 13):**

ERS urges support for Amendment 897 (Willmott) on plain packaging in Article 13.

ERS notes that the EC proposal introduces more elements of pack standardisation. This is welcome, however it does not go far enough.

ERS proposes the EU to mandate **plain packaging** on tobacco products and to adopt similar regulations on tobacco packaging and labelling that Australia did in 2012. According to the European Commission Impact Assessment, **plain packaging is expected to achieve the policy objectives e.g. “preventing young people from smoking” more effectively than other options proposed.**

Contrary to the claims of the tobacco industry,^{xx} research shows that children find plain packs (with large graphic health warnings) less appealing and are less likely to be misled by the sophisticated marketing techniques designed to make smoking attractive to them.^{xxi} In addition, the tobacco industry denies the power of branding regarding packaging design but at the same time, is using marketing techniques designed to tempt youth and is tenaciously holding on to package branding.^{xxii}

ERS maintains the position that the tobacco packages must not be appealing but instead, be “drab dark brown” with large graphic health warnings, made of cardboard, rectangular in shape, with no recognisable branding on the outer or inner surface of the package.^{xxiii} Plain standardised packaging of tobacco products would put all the tobacco manufacturers on a level playing field and with the space on the packs left for trademarks, the manufacturers would still be able to compete for a market share.

The main benefit of this Proposal for European citizens and governments is the improvement of health.^{xxiv} According to the WHO European Health Report 2012, mortality rates by main types of cancer indicate that lung cancer (mainly caused by tobacco smoking) is responsible for the greatest number of cancer deaths in Europe.^{xxv} The expected result of a 2% drop in consumption within a five year period corresponds to 2.4 million smokers. Therefore, the expected socio-economic benefits represent an annual amount of 9.4 bEUR to the EU, even with reduced tax revenues deducted.^{xxvi} Moreover, we would be able to save the health services vast sums of money.^{xxvii}

As a further benefit, the estimated 2% reduction of tobacco consumption would lead to a net gain in employment of 2,235 employees in the EU^{xxviii} by jobs gained in other sectors than tobacco.

Currently, five Member States (Ireland, Finland, France, Belgium and United Kingdom) are at varying stages in considering standard packs.^{xxix} Plain packaging is the best option as there is no less stringent measure available to reach the goal of improving the Internal Market while protecting public health.^{xxx}

- **Traceability and security features (Article 14):**

ERS welcomes the provisions delegating powers to the European Commission to adopt technical measures related to the traceability, identification and security features of tobacco packs.

Strengthening the traceability and identification features is one of the most effective measures the EU countries can use for combating illicit trade. **ERS supports the Rapporteur’s introduction of both visible and invisible security features (Am. 41) and ensuring the storage and access to data to be independent (Am. 40).** ERS welcomes: Am. 987 (Childers), Am. 991 (Childers) and Am. 993 (Hibner).

TOBACCO FOR ORAL USE:

- **Tobacco for oral use (Article 15):**

ERS supports Article 15.

CROSS-BORDER DISTANCE SALES OF TOBACCO PRODUCTS:

- **Cross-border distance sales of tobacco products (Article 16):**

ERS supports the Rapporteur's call for a prohibition on the cross-border distance sales (Am. 42). The enforcement of the requirements of the Directive for sales through internet or postal delivery services e.g. relating to age verification, cannot be implemented ensuring a high level of health protection.

NON-TOBACCO PRODUCTS:

- **Nicotine-containing products (Article 18):**

ERS welcomes the Rapporteur's recommendations on Article 18, Amendment 1250 (Rapporteur McAvan) and calls for a strong regulatory framework for nicotine containing products / electronic cigarettes. ERS supports efforts for finding a balanced solution considering Member States' different approaches.

ERS supports the option that electronic cigarettes should be authorised and regulated under Directive 2001/83/EC and recommends Member States to adopt this approach. For the countries that do not take this approach, ERS supports greater quality controls and monitoring proposed by the Rapporteur.

ERS urges the Member States and MEPs to:

- **ensure that nicotine containing products / electronic cigarettes are safe and quality assured;**
- **restrict their marketing, sale and promotion** so that they are only targeted at smokers for cessation purposes, and do not appeal to non-smokers, in particular children and youth;
- **prohibit their use in workplaces and public places** in order to limit second hand exposure to the vapour, and also to ensure that their use does not undermine smoking prevention and cessation by reinforcing the normalcy of cigarette use.

Most importantly, ERS calls on the European Parliament to call for independent EU-supported research into these products. This should include medium and long term independent clinical trials and, behavioural studies.

FINAL PROVISIONS:

- **Exercise of the delegation (Article 22):**

ERS underlines the need to ensure that the adoption of delegated acts is not exposed to the interests of the tobacco industry which are incompatible with achieving a high level of health protection.

European Respiratory Society (ERS) is the leading professional organisation in its field in Europe. It is broad-based, with some 11,000 members and counting in over 100 countries. Its scope covers both basic science and clinical medicine. ERS seeks to alleviate suffering from respiratory disease and promote lung health through research, sharing of knowledge and through medical and public education. The annual congress attracts over 20,000 professionals from Europe and beyond.

- ⁱ The European Commission Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning manufacture, presentation and sale of tobacco and related products – COM(2012)788 final
- ⁱⁱ European Commission: Impact Assessment: http://ec.europa.eu/governance/impact/index_en.htm
- ⁱⁱⁱ The European Commission Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning manufacture, presentation and sale of tobacco and related products – COM(2012)788 final
- ^{iv} The European Commission Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning manufacture, presentation and sale of tobacco and related products – COM(2012)788 final
- ^v European Commission: Impact Assessment: http://ec.europa.eu/governance/impact/index_en.htm
- ^{vi} See: European Commission, Europe 2020, Europe 2020 targets: http://ec.europa.eu/europe2020/europe-2020-in-a-nutshell/targets/index_en.htm
- ^{vii} “Plain packaging is the term used to refer to the standardisation of pack colour and removal of all branding from packaging, with the exception of brand name which appears in a standardised font and position on the package.” Plain Packaging of Cigarettes, Leading education and social research, Institute of Education, University of London, <http://www.ioe.ac.uk/research/53750.html>
- ^{viii} The European Commission Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning manufacture, presentation and sale of tobacco and related products – COM(2012)788 final
- ^{ix} European Commission: Impact Assessment: http://ec.europa.eu/governance/impact/index_en.htm
- ^x See: European Commission, Europe 2020, Europe 2020 targets: http://ec.europa.eu/europe2020/europe-2020-in-a-nutshell/targets/index_en.htm
- ^{xi} European Commission, Europe 2020, Inclusive growth – a high-employment economy delivering economic, social and territorial cohesion: http://ec.europa.eu/europe2020/europe-2020-in-a-nutshell/priorities/inclusive-growth/index_en.htm#
- ^{xii} See: World Health Organisation, The European Health Report: http://www.euro.who.int/__data/assets/pdf_file/0003/184161/The-European-Health-Report-2012,-FULL-REPORT-w-cover.pdf
- ^{xiii} The European Commission Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning manufacture, presentation and sale of tobacco and related products – COM(2012)788 final
- ^{xiv} Europa, Press releases RAPID, Q&A: The Fight Against Tobacco in the EU, http://europa.eu/rapid/press-release_MEMO-11-349_en.htm?locale=en#footnote-1footnote-1
- ^{xv} “Electronic cigarettes”, also referred to as “e-cigarettes” or “electronic nicotine delivery systems (ENDS)” by the WHO, are categorised as ‘nicotine containing products’ together with other products such as nicotine containing chewing gum. Electronic cigarettes look like cigarettes, but are actually nicotine inhalators. They contain pure nicotine to be inhaled by vaporizing nicotine liquid and consist of a battery, a charger, a replaceable cartridge and an atomizer which heats the cartridge ingredients to create a vapour that is inhaled by the consumer, ‘vaper’. Nicotine is delivered through cartridges containing ‘e-liquid’ that typically consists of propylene glycol, nicotine and flavourings. E-liquids contain nicotine concentrations between 0 and 48 mg/ml, typically 18 mg/ml. Thus, the devices can be adjusted to various levels of nicotine as per the needs of the user. They normally do not contain tobacco and there is no combustion, smoke or odour. Electronic cigarettes are used like cigarettes: when the user draws on an electronic cigarette, visible vapour is produced and a LED may light up to mimic the glow of a real cigarette. Vapers report that the sensation, ‘nicotine hit’, is similar to that of using tobacco cigarettes. More than 200 flavours are available. European Commission, Health & Consumer Protection Directorate-General, Orientation Note, Electronic Cigarettes and the EC Legislation, 2008; European Parliament, Library of the European Parliament, Library Briefing, Electronic cigarettes, 27/03/2013
- ^{xvi} WHO Framework Convention on Tobacco Control (FCTC), Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP/4/12, Provisional agenda item 5.8, Control and prevention of smokeless tobacco products and electronic cigarettes, Report by the Convention Secretariat, 2010
- ^{xvii} European Parliament, Library of the European Parliament, Library Briefing, Electronic cigarettes, 27/03/2013; The BMA Occupational Medicine Committee and the Board of Science, A briefing: E-cigarettes in public places and workplaces, 2012; AMA – American Medical Association, Electronic Cigarettes are Drug Delivery Devices and Should Be Subject to FDA Regulations, <http://www.prnewswire.com/news-releases/ama-electronic-cigarettes-are-drug-delivery-devices-and-should-be-subject-to-fda-regulations-96337279.html>
- ^{xviii} WHO Framework Convention on Tobacco Control (FCTC), Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP/4/12, Provisional agenda item 5.8, Control and prevention of smokeless tobacco products and electronic cigarettes, Report by the Convention Secretariat, 2010; European Parliament, Library of the European Parliament, Library Briefing, Electronic cigarettes, 27/03/2013; Tobacco Free Utah, The Truth About E-Cigarettes, 2010, <http://www.tobaccofreeutah.org/pdfs/Ecigarettes.pdf>; ATTUD – Association for the Treatment of Tobacco Use and Dependence, 2009, <http://www.ereleases.com/pr/2009-ATTUD.pdf>; FDA – U.S. Food and Drug Administration, U.S. Department of Health & Human Services, News & Events, Public Health Focus, Electronic Cigarettes (e-Cigarettes) <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm#>; Tobacco Free Utah, The Truth About E-Cigarettes, 2010, <http://www.tobaccofreeutah.org/pdfs/Ecigarettes.pdf>; The BMA Occupational Medicine Committee and the Board of Science, A briefing: E-cigarettes in public places and workplaces, 2012; AMA – American Medical Association, Electronic Cigarettes are Drug Delivery Devices and Should Be Subject to FDA Regulations, <http://www.prnewswire.com/news-releases/ama-electronic-cigarettes-are-drug-delivery-devices-and-should-be-subject-to-fda-regulations-96337279.html>; See: American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids; Policy Guidance Document Regarding E-Cigarettes, 2010, http://www.ttac.org/tcn/tfp/2010/may-2010/pdfs/Policy_Guidance_E-Cigarettes.pdf
- ^{xix} Tobacco Control, Health Warning Messages on Tobacco Products: A Review, David Hammond 2011 <http://tobaccocontrol.bmj.com/content/early/2011/05/23/tc.2010.037630.abstract>
- ^{xx} See: Philip Morris (New Zealand) Limited, A response to the Ministry of Health Consultation on Plain Packaging of Tobacco Products, 5 October 2012
- ^{xxi} Cancer Research UK, Press Release: “More than 200,000 UK children start smoking every year”: <http://www.cancerresearchuk.org/cancer-info/news/archive/pressrelease/2013-03-22-more-than-200000-uk-children-start-smoking-every-year>
- ^{xxii} See: Philip Morris (New Zealand) Limited, A response to the Ministry of Health Consultation on Plain Packaging of Tobacco Products, 5 October 2012
- ^{xxiii} Tobacco Control Laws: <http://www.tobaccocontrolaws.org/legislation/country/australia/summary>
- ^{xxiv} European Commission: Impact Assessment: http://ec.europa.eu/governance/impact/index_en.htm
- ^{xxv} World Health Organisation, The European Health Report: http://www.euro.who.int/__data/assets/pdf_file/0003/184161/The-European-Health-Report-2012,-FULL-REPORT-w-cover.pdf
- ^{xxvi} European Commission: Impact Assessment: http://ec.europa.eu/governance/impact/index_en.htm

^{xxvii} Cancer Research UK, Cancer News: "MOs dismiss tobacco industry claims about cigarette packs": <http://www.cancerresearchuk.org/cancer-info/news/archive/cancernews/2013-03-27-MPs-dismiss-tobacco-industry-claims-about-cigarette-packs?rss=true>

^{xxviii} European Commission: Impact Assessment: http://ec.europa.eu/governance/impact/index_en.htm

^{xxix} See: European Parliament, Committee on the Environment, Public Health and Food Safety, Rapporteur Linda McAvan, Draft Report on the Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning manufacture, presentation and sale of tobacco and related products (COM(2012)0788 – C7-0420/2012 – 2012/0366(COD))

^{xxx} European Commission: Impact Assessment: http://ec.europa.eu/governance/impact/index_en.htm