

EUROPEAN SOCIETY OF CARDIOLOGY

POSITION PAPER ON THE

‘TOBACCO PRODUCTS DIRECTIVE’

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 THE MANUFACTURE, PRESENTATION AND SALE OF TOBACCO AND RELATED PRODUCTS

Introduction

The European Society of Cardiology (ESC)* welcomes 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 the manufacture, presentation and sale of tobacco and related products*’ [hereafter, Tobacco Products Directive (TPD)].

The ESC stresses that regulating tobacco products is crucial, alongside public health measures such as smoking bans, for the public’s perception of smoking as an important health hazard. This is notably the case for cardiovascular disease (CVD), the N°1 killer in Europe, responsible for the death of 1.9 million EU citizens yearly. Indeed, smoking causes 28% of CVD deaths in men aged 35 to 69 years and 13% of CVD deaths in women of the same age. Overall, CVD is estimated to cost the EU economy €195.5 billion a year.¹

The intention of the European Commission to promote the well-being of EU citizens through the revision of the TPD, is highly appreciated by the ESC. This position paper will provide the relevant scientific information on the impact of smoking on CVD and will outline recommendations for the pursuit of optimal public health protection measures within the proposed Directive.

* The European Society of Cardiology (ESC) represents over 80,000 cardiology professionals across Europe and the Mediterranean. Its mission is “to reduce the burden of cardiovascular disease in Europe”. The ESC provides an array of scientific and educational activities, such as the production and continuous updating of Clinical Practice Guidelines, the organisation of educational courses and initiatives, pan-European surveys on specific disease areas. It also organises the ESC Congress, the largest medical meeting in Europe, as well as subspecialty congresses, in conjunction with its constituent bodies. The ESC edits and publishes 9 of the world’s leading journals on cardiology.

¹ European Heart Network and European Society of Cardiology, European Cardiovascular Disease Statistics, 2012 edition

BACKGROUND

Tobacco & Cardiovascular Diseases (CVD)

Smoking is responsible for 25% of all avoidable deaths in smokers due to diseases of the heart and circulatory system or cardiovascular diseases (CVD). Indeed, smoking is associated with increased risk of all types of CVD, including coronary heart disease (CHD), ischemic stroke, peripheral artery disease (PAD) and abdominal aortic aneurysm. For example, the relative risk of myocardial infarction in smokers below 50 years of age is five-fold higher than in non-smokers.

The risk associated with smoking is primarily related to the amount of tobacco smoked daily and to the duration. Smoking is deleterious regardless the types of tobacco (e.g. low-tar - 'mild' or 'light' - cigarettes, filter cigarettes, cigars, pipes) and the way it is smoked (e.g. waterpipe). Smokeless tobacco (e.g. snus) is also associated with a small but statistically significant increased CVD risk.

Any reduction in smoking and second-hand smoke exposure will lead to reduced cardiovascular morbidity and mortality. Estimations indicate a 30% higher risk of CVD for a non-smoker exposed to passive smoking at home or in the work place. Several studies²³⁴ have reported that laws making indoor workplaces and public spaces smoke-free were associated with rapid, sizeable reductions in hospitalization for acute myocardial infarction (AMI). Alike, studies show that the risk of CVD is rapidly reduced after cessation, with significant morbidity reductions reported within the first 6 months and the risk approaching the risk of never-smokers within 10–15 years.⁵⁶⁷ **Smoking cessation is the most cost-effective treatment of CVD and the most cost-effective prevention strategy.**⁸⁹

ESC POSITION

INGREDIENTS & EMISSIONS

MEASUREMENT METHODS (ART.4)

The ESC welcomes the mandatory reporting system of ingredients used in tobacco products (Art. 5). However, it believes that independent testing laboratories, approved and monitored by the competent authorities in each Member State, should be carrying out or verifying the validity of data supplied by tobacco companies. Indeed,

² Barone-Adesi F, Vizzini L, Merletti F, Richiardi L. "Short-term effects of Italian smoking regulation on rates of hospital admission for acute myocardial infarction.", *European Heart Journal*, 2006

³ Twose J, Schiaffino A, García M, Borrás JM, Fernández E. "Correlates of exposure to second-hand smoke in an urban Mediterranean population", *BMC Public Health*, 2007

⁴ Villalbí JR, Sánchez E, Benet J, Cabezas C, Castillo A, Guarga A, Saltó E, Tresserras R; Barcelona Group for Smoking Regulation Policies Evaluation. "The extension of smoke-free areas and acute myocardial infarction mortality: before and after study", *BMJ Open*, 2011

⁵ European Society of Cardiology, *European Guidelines on cardiovascular disease prevention in clinical practice (version 2012)*, *European Heart Journal* (2012) 33, 1635–1701

⁶ European Heart Network and European Society of Cardiology, *European Cardiovascular Disease Statistics, 2012 edition*

⁷ T. Jørgensen et al., "Population-level changes to promote cardiovascular health", *European Journal of Preventive Cardiology*, 02/2012

⁸ Critchley JA, Capewell S. Mortality risk reduction associated with smoking cessation in patients with coronary heart disease: a systematic review. *JAMA* 2003; 290(1):86-97.

⁹ Kahn et al. The impact of prevention on reducing the burden of cardiovascular disease. *Circulation* 2008 Aug; 31(8):1686-96

there is overwhelming evidence that the tobacco industry will not admit use of products with increased toxicity or addictiveness.¹⁰

REGULATION OF INGREDIENTS (ART. 6)

The ESC strongly agrees that products with a characterising flavour should be banned from the market. Flavours improve the taste and make it easier to inhale, particularly for young people just starting to smoke.¹¹ All tobacco products with additives (e.g. caffeine, vitamins, etc), which convey false security to consumers with regard to their impact on health or which increase the toxic or addictive effect of a tobacco product, should also be banned.

These rules should apply to all tobacco products - including cigars, cigarillos and pipe tobacco - due to their negative impact on health and regardless of the fact that these products are mostly consumed by older people.

LABELLING & PACKAGING

GENERAL PROVISIONS (ART. 7)

The display of trademarks or promotional elements must be avoided, with the rapid introduction of plain packaging in all member countries. Indeed, studies suggest that this will have a large impact on preventing young adults from trying smoking and will lead to a reduction in smoking prevalence in older consumers.^{12,13}

TEXT WARNINGS FOR TOBACCO SMOKING (ART. 8)

Given the burden represented by cardiovascular diseases (CVD), each unit packet and any outside packaging of tobacco for smoking should carry information on the increased risk of CVD: *"Tobacco smoke increases up to 5 times the relative risk of heart disease & stroke"*.

COMBINED HEALTH WARNINGS FOR TOBACCO SMOKING (ART. 9)

Combined health warnings are primordial and should cover 75% of the front and the back surfaces of packages. Evidence shows that warnings of 75% and above are significantly more effective than those of 50% and below and are particularly effective with young adults.¹⁴ For example, in Canada smoking rates amongst 15 to 19 year olds fell from 25% to 17% between the introduction of pictorial warnings and 2011.¹⁵

Also, it is crucial to have rotating combined health warnings as evidence shows that they otherwise become 'invisible' for the smokers, who get too used to them.¹⁶

¹⁰ Golden Holocaust. Origins of the cigarette catastrophe and the case for abolition. R.N. Procter. University of California Press, 2012.

¹¹ EAHC, Economic analysis of the EU market of tobacco, nicotine and related products, http://ec.europa.eu/health/tobacco/docs/tobacco_matrix_report_eu_market_en.pdf

¹² Hammond D, Daniel S, White CM. The effect of cigarette branding and plain packaging on female youth in the United Kingdom. *J Adolesc Health* 2013 Feb;52(2):151-7.

¹³ White CM, Hammond D, Thrasher JF, Fong GT. The potential impact of plain packaging of cigarette products among Brazilian young women: an experimental study. *BMC Public Health* 2012;12:737.

¹⁴ Health Warning Messages on Tobacco Products: A Review (Hammond 2011, Tobacco Control) <http://www.tobaccolabels.ca/health/resources/2011hwmreviewhammondpdf>
European Commission, A review of the science base to support the development of health warnings for tobacco packages http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf

¹⁵ Canadian Tobacco Use Monitoring Survey (CTUMS) 2011 http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/ctums-esutc_2011-eng.php

¹⁶ Cigarette packet warning labels can prevent relapse: findings from the International Tobacco Control 4-Country policy evaluation cohort study. Partos TR et al. *Tob Control*. 2012 Apr 25

PRODUCT DESCRIPTION (ART. 12)

The labelling of a unit packet and any outside packaging and the tobacco product itself should not include information about tar, nicotine and carbon monoxide yields, because such labelling has made it possible to sell false security to consumers concerned about their health. Indeed, yield labels seriously mislead the consumers and provide a false basis for decision makers.¹⁷

It is therefore strongly suggested that yield labels are replaced with general information on the dangers of tobacco smoking and consumption.

CROSS-BORDER DISTANCE SALES OF TOBACCO PRODUCTS

CROSS-BORDER DISTANCE SALES OF TOBACCO PRODUCTS (ART. 16)

Age verification mechanisms must be implemented in all Member States, not only for retail outlets engaged in distance sales, but also at the point of sale. Large economic penalties must be foreseen for retailers in case of violation.

Indeed, the protection of children/adolescents from taking up smoking is essential to the future health of Europeans. Finland and most US states have already implemented strict regulation in this field and evidence shows that low violation rates cannot be reached without penalising violators.^{18,19,20}

NON-TOBACCO PRODUCTS

NICOTINE-CONTAINING PRODUCTS (ART. 18)

Nicotine containing products must be tightly regulated by national authorities. In particular, all non-tobacco nicotine containing products must require medicine authorisation, namely in order to guarantee that only safe products are sold and to prevent promotion to young adults who are non-smokers.

Nicotine-containing products requiring medical authorisation should be associated to nicotine replacement therapy: as such, they should not carry health warnings, since these could mislead users attempting to quit smoking.

ADDITIONAL RECOMMENDATIONS

E-CIGARETTES

A conference of the Parties to the WHO Framework Convention on Tobacco Control (FCTC) concluded that if electronic cigarettes are not banned, a two-pronged strategy – regulating them by the competent authorities in

¹⁷ D. Hammond*, C.M. White, Improper disclosure: Tobacco packaging and emission labelling regulations, <http://davidhammond.ca/Old%20Website/Publication%20new/2012%20Constituent%20Labels%20-%20Public%20Health%20%28Hammond%20&%20White%29.pdf>
K. Gallopel et al., Consumer understanding of cigarette emission labelling, <http://eurpub.oxfordjournals.org/content/early/2010/07/01/eurpub.ckq087.full>

¹⁸ The Tobacco Act of Finland. <http://www.stm.fi/tiedotteet/tiedote/-/view/1522179#en>, (2010).

¹⁹ DiFranza JR, Dussault GF. The federal initiative to halt the sale of tobacco to children--the Synar Amendment, 1992-2000: lessons learned. *Tob Control* 2005 Apr;14(2):93-8.

²⁰ Stead LF, Lancaster T. Interventions for preventing tobacco sales to minors. *Cochrane Database Syst Rev* 2005;(1):CD001497.

each Member State as both a tobacco and a medical product – could close potential loopholes in their regulation.²¹

Scientific evidence shows that:

- › even cartridges labelled as containing 'no nicotine' may contain nicotine (as well as other carcinogens and other toxic substances)²²
- › the emitted amount of nicotine may be markedly different in the same batch
- › brands containing flavours such as vanilla or chocolate, will attract children, with subsequent increased risk of experimenting with cigarettes or other nicotine containing products.

ANNEX I – SUGGESTED AMENDMENTS

Proposal for a Directive Recital 18

<i>Text proposed by the Commission</i>	<i>Amendment</i>
(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco which are mainly consumed by older consumers, should be granted an exemption from certain ingredients requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people.	DELETE
<i>Justification</i>	
<p><i>All tobacco products, including cigars, cigarillos and pipes, should be addressed by the Directive due to their negative impact on health and regardless of the fact that these products are mostly consumed by older people. It should be considered that the ageing population in the EU is increasing rapidly. This means that a growing number of older Europeans are and will be suffering from serious disorders which are prevalent at an older age, including those linked to smoking. The severe burden represented by an unhealthy population for the EU society and economy are an obvious call for measures aimed at preventing diseases. This is in line with the European Commission objective to increase the average number of healthy life years by 2 by 2020.</i></p>	

Proposal for a Directive Recital 22

<i>Text proposed by the Commission</i>	<i>Amendment</i>
(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings are more effective than text-only	(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined and rotating health warnings are more effective than

²¹ Electronic nicotine delivery systems, including electronic cigarettes. Report by the Convention Secretariat. Conference of the Parties to the WHO Framework Convention on Tobacco Control. 18 June 2012, Seoul <http://www.who.int/mediacentre/news/releases/2008/pr34/en/index.html>

²² U.S. Food and Drug Administration (FDA) <http://www.fda.gov/forconsumers/consumerupdates/ucm225210.htm>.

<p>warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.</p>	<p>text-only warnings. In this light rotating combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.</p>
<p><i>Justification</i></p>	
<p><i>Evidence clearly shows that health warnings should be changing as they otherwise become 'invisible' for the smokers, who get too used to them.</i></p>	

Proposal for a Directive
Recital 38

<i>Text proposed by the Commission</i>	<i>Amendment</i>
<p>(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, , the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.</p>	<p>(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, , the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.</p>
<p><i>Justification</i></p>	
<p><i>There should be no exemptions: all tobacco products, including cigars, cigarillos and pipes, should be addressed by the Directive due to their negative impact on health and regardless of the fact that these products are consumed above all by older people. It should be considered that the ageing population in the EU is increasing rapidly. This means that a growing number of older Europeans are and will be suffering from serious disorders which are prevalent at an older age, including those linked to smoking. The severe burden represented by an unhealthy population for the EU society and economy represent an obvious call for measures aimed at preventing diseases. This is in line with the European Commission objective to increase the average number of healthy life years by 2 by 2020.</i></p>	

Proposal for a Directive
Article 4 – Paragraph 1 (new)

<i>Text proposed by the Commission</i>	<i>Amendment</i>
	1 (new) The quantities of all ingredients used in the manufacture of tobacco products by brand and name type, as well as their emissions and the tar, nicotine and carbon monoxide yields will be measured.
<i>Justification</i>	
<i>The measurement of the quantities of all ingredients used in the manufacture of tobacco products, as well as their emissions and the tar, nicotine and carbon monoxide yields should be mandatory.</i>	

Proposal for a Directive
Article 4 – Paragraph 2

<i>Text proposed by the Commission</i>	<i>Amendment</i>
<p>2. The measurement referred to in paragraph 1 shall be carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States.</p> <p>Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available.</p>	<p>2. The measurement referred to in paragraph 1 (new) and 1 shall be carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States.</p> <p>Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available.</p>
<i>Justification</i>	
<i>The measurement of the quantities of all ingredients used in the manufacture of tobacco products, as well as their emissions and the tar, nicotine and carbon monoxide yields should be mandatory. In order to guarantee the accuracy of data, measurements should be carried out or verified by independent national or European testing laboratories, approved and monitored by the competent authorities in each Member State.</i>	

Proposal for a Directive
Article 6 – Paragraph 10

<i>Text proposed by the Commission</i>	<i>Amendment</i>
<p>10. Tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products shall be exempted from the prohibitions laid down in paragraphs 1 and 5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is a substantial change of circumstances as established in a Commission report.</p>	DELETE

Justification

Products with a characterising flavour should be banned from the market. The same goes for products with additives which convey false security to consumers with regard to their impact on health or which increase the toxic or addictive effect of a tobacco product. These rules should apply to all tobacco products, including cigars, cigarillos and pipes due to their negative impact on health and regardless of the fact that these products are mostly consumed by older people. It should be considered that the ageing population in the EU is increasing rapidly. This means that a growing number of older Europeans are and will be suffering from serious disorders which are prevalent at an older age, including those linked to smoking. The severe burden represented by an unhealthy population for the EU society and economy represent an obvious call for measures aimed at preventing diseases. This is in line with the European Commission objective to increase the average number of healthy life years by 2 by 2020.

**Proposal for a Directive
Article 8 – Paragraph 2 (new)**

<i>Text proposed by the Commission</i>	<i>Amendment</i>
	<p>2 (new) Each unit packet and any outside packaging of tobacco for smoking shall carry the following information message:</p> <p><i>Tobacco smoke increases up to 5 times the relative risk of heart disease & stroke</i></p>
<i>Justification</i>	
<p><i>Text warnings may not disregard the risk of cardiovascular disease (CVD). Indeed, CVD is the N°1 killer in Europe, responsible for the death of 1.9 million EU citizens yearly and killing more than all cancers combined. Smoking causes 28% of CVD deaths in men aged 35 to 69 years and 13% of CVD deaths in women of the same age. Overall, CVD is estimated to cost the EU economy €195.5 billion a year.</i></p>	

**Proposal for a Directive
Article 12 – Paragraph 1**

<i>Text proposed by the Commission</i>	<i>Amendment</i>
<p>1. The labelling of a unit packet and any outside packaging and the tobacco product itself shall not include any element or feature that:</p>	<p>1. The labelling of a unit packet and any outside packaging and the tobacco product itself shall not include information about tar, nicotine and carbon monoxide yields nor any element or feature that:</p>
<i>Justification</i>	
<p><i>The labelling of a unit packet and any outside packaging and the tobacco product itself should not include information about tar, nicotine and carbon monoxide yields, because such labelling has made it possible to sell false security to consumers concerned about their health. Indeed, yield labels seriously mislead the consumers and provide a false basis for decision makers.</i></p>	

Proposal for a Directive
Article 16 – Paragraph 4

<i>Text proposed by the Commission</i>	<i>Amendment</i>
4. Retail outlets engaged in distance sales shall be equipped with an age verification system, which verifies at the time of sale, that the purchasing consumer respects the minimum age foreseen under the national legislation of the Member State of destination. The retailer or nominated natural person shall report to the competent authorities a description of the details and functioning of the age verification system.	4. Retail outlets engaged in distance sales and local points of sale shall be equipped with an age verification system, which verifies at the time of sale, that the purchasing consumer respects the minimum age foreseen under the national legislation of the Member State of destination. The retailer or nominated natural person shall report to the competent authorities a description of the details and functioning of the age verification system. Member States shall enforce economic penalties to non-compliant retailers and points of sale.
<i>Justification</i>	
<i>Age verification mechanisms must be implemented in all Member States, not only for retail outlets engaged in distance sales, but also at the point of sale. Large economic penalties must be foreseen for retailers in case of violation. The protection of children/adolescents from taking up smoking is essential to the future health of Europeans.</i>	

Proposal for a Directive
Article 18 – Paragraph 1

<i>Text proposed by the Commission</i>	<i>Amendment</i>
1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC: (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.	1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC and may only be sold to consumers holding a medical prescription: (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.
<i>Justification</i>	
<i>All non-tobacco nicotine containing products must require medicine authorisation, namely in order to guarantee that only safe products are sold and to prevent promotion to young adults who are non-smokers.</i>	

Proposal for a Directive
Article 18 – Paragraph 3

<i>Text proposed by the Commission</i>	<i>Amendment</i>
<p>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:</p> <p><i>This product contains nicotine and can damage your health.</i></p>	<p>DELETE</p>
<p><i>Justification</i></p>	
<p><i>Nicotine-containing products must require medical authorisation and should be associated to nicotine replacement therapy. As such, they should not carry health warnings, since these could mislead users attempting to quit smoking.</i></p>	