European Federation of Allergy and Airways Diseases Patients Associations

EFA Briefing
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The EU Tobacco Products Directive is published

Briefing on the Directive 2014/40/EU[1] 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 and repealing Directive 2001/37/EC

1. Purpose

This briefing intends to inform about the newly adopted EU Directive on the manufacture, presentation and sale of tobacco and related products. Tobacco is a proven and classified carcinogen; it causes a great deal of respiratory diseases and is a major source of nuisance and exacerbation for people with asthma, allergy and COPD, leading to social and work exclusion and unnecessary illness (see the Annex for more information). As this directive is imposing more stringent rules for tobacco and related products, it is considered as a major achievement for tobacco control in the EU, as well as a great contribution to building a healthier society.

2. Background

The EU Directive 2001/37/EC was repeatedly called for review and update by the Council and the European Parliament in order to enable Member States to adapt to new developments in the tobacco sector and to diminish substantial differences between the Member States laws on the manufacture, presentation and sale of tobacco and related products. This step took place after the entry into force in all 28 EU Member States of the 2003 Framework Convention on Tobacco Control (FCTC), the world's first international health treaty, which established minimum standards for action on tobacco control.

3. General content

Tobacco is the most significant cause of premature death in the EU, responsible for almost 700,000 deaths every year. Given that 70% of the smokers start before the age of 18 and 94% before the age of 25 years, the directive targets the reduction of initiation of tobacco consumption at a young age.[2] It pursues the reduction by 2% of the number of youth smoking over the next five years, by approximating the laws, regulations and

[1] Available in all EU languages.
[2] European Commission Impact Assessment, available at: http://ec.europa.eu/health/tobacco/docs/com_2012_788_ia_en.pdf. The legal basis of the document is article 114 of the Treaty on the Functioning of the European Union (TFEU): the harmonisation of the national laws concerning the manufacture, presentation and sale of tobacco products will improve the functioning of the internal market (first paragraph), but at the same time the directive is aimed at ensuring a high level of health protection for European citizens (third paragraph).

administrative provisions of the Member States concerning:

- ingredients and emissions of tobacco products, including the maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;
- certain aspects of the labelling and packaging of tobacco products, including health warnings position, traceability and security features;
- prohibition of commercialisation of tobacco for oral use;
- cross-border distance sales of tobacco products;
- obligation to submit a notification of novel tobacco products;
- commercialisation and labelling of electronic cigarettes and refill containers, and herbal products for smoking.

4. Matters of interest relevant for EFA

Together with major non-governmental organisations (NGOs) in the field of tobacco control and smoking prevention, and in consultation with its members, EFA has advocated for the following priorities: **standardised cigarettes packs with combined text and pictorial health warnings covering 80% of the front and back of these packs, cessation information (e.g.: quit lines) as part of the health warnings, ban on slim cigarettes, full ban on all flavouring for all tobacco products, prohibition of cross-border distance sales of tobacco products, maintenance of the status quo on snus (banned in the EU but in Sweden), increased traceability of tobacco products and robust regulation of electronic cigarettes**.

Check EFA position paper for more information.

A. Ingredients/additives (articles 6 and 7)

The maximum yields of tar, nicotine and carbon monoxide as well as the measurement methods remain the same as in the previous directive. Manufacturers and importers of tobacco products continue to be required to report on the ingredients used in tobacco products. With the new directive, they should also submit a description of the additives used in cigarettes and roll-your-own tobacco products, and their properties.

Another important novelty is that cigarettes and roll-your-own tobacco products with a characterising flavour will be prohibited. However, the use of additives essential for the manufacture of tobacco products (such as sugar) can be allowed, provided that they do not result in a product with a characterising flavour and do not increase the addictiveness, toxicity or the CMR properties (properties of carcinogenicity, mutagenicity or reproductive toxicity) of the final tobacco product. What is more, the following additives will be prohibited:

- vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;
- caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
- additives having colouring properties for emissions;
- additives that have CMR properties in unburnt form;
- for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake.

In addition, no flavourings will be allowed in filters, papers or packages and those tobacco products with increased toxicity or addictiveness will not be commercialised.

These measures do not apply to other tobacco products, such as cigars, cigarillos and pipe tobacco. This choice has been justified by the fact that these products are mainly consumed by older consumers, while the focus of this piece of legislation is to discourage young people to start using tobacco. The exemption could be nonetheless removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people). Finally, tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category (e.g.: menthol cigarettes) can still be allowed until 2020.

EFA supports the ban of certain additives. However, we maintain our opinion that the same provisions should apply to all tobacco products without exception. It is regrettable that menthol will only be progressively phased-out and that the ban will only take effect from 2020. In addition, we welcome the provision that requires the Commission to study the use of flavoured water-pipe by young people to check whether characterised flavours have to be prohibited for these products too.

B. Packaging and labelling (articles 8-14)

Labelling

A tobacco product package should carry a health warning covering 65% of the bottom part of the package's surface. With the new directive, health warnings will be irremovably printed, indelible and in no way hidden or interrupted. Health warnings should contain one of the text warnings and a corresponding coloured photograph listed in the directive's Annexes. This will be accompanied by smoking cessation information with telephone numbers, e-mail addresses or Internet sites informing consumers about the support available to persons who want to stop smoking.

Tar, nicotine and carbon monoxide levels on the packages will be replaced by a message referring to harmful substances of tobacco that will appear on the bottom part of one of the lateral surfaces. The remaining lateral surface will present a general warning on the effects of tobacco on health.

However, it should be possible to continue to grant an exemption from certain labelling requirements to those tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, as long as there is no substantial change in terms of sales volumes or consumption patterns of young people. The labelling of these other tobacco products should follow rules that are specific to them (warnings covering 30% of the back and 40% of the tobacco products packages' front).

Packaging

Certain packaging could mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. As a consequence, the new directive harmonises certain aspects of the packages: no packaging should include images or text (for instance, discount offers or reference to free distribution) that could suggest economic advantages to consumers inciting to buy those tobacco products or any elements that that promote tobacco products or mislead consumers to believe that the product is less harmful than others (for example, words as "low-tar", "light", "mild", "natural", "organic", "without additives", "slim").

Despite the European Parliament Rapporteur Mrs McAvan's proposal to include a provision on compulsory plain packaging in the directive, plain packaging remains a voluntary option for the Member States.

In addition, as a measure to limit purchase capacity of young people, cigarette packs will be in a cuboid shape and contain at least 20 cigarettes, and on roll-your-own tobacco packages must contain at least 30g of tobacco. Some flexibility is foreseen as bevelled and rounded edges are allowed for cigarettes packages and cylinders and stand-up pouches are allowed for roll-your-own tobacco ones. Slim cigarettes will continue to be allowed on the market, but slim or fancy packages will not.

Although EFA supports the restricted conditions on packaging and labelling, we believe that larger graphic warnings should be obligatory in the future as they are more effective than text-only messages. The new provisions represent an important step forward for European tobacco control policy as currently health warnings are much smaller, placed on the bottom and, in some Member States, there is no obligation to use pictures (only ten Member States use graphic warnings). However, we encourage Member States to adopt national legislations requiring plain package for tobacco and related products in order to emphasise the danger and harm of these products. Packaging is the main marketing channel for tobacco producers to attract and retain users and plain standardised packaging has been proven to reduce the appeal of tobacco to children and young people and to reinforce health warning messages. We welcome the proposals of Ireland and the United Kingdom for plain packaging as those measures could start a virtuous circle throughout the European Union with the objective of improving citizen's health.

C. Traceability and security features (articles 15 and 16)

Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier that includes the following features:

- → date, place and manufacturing facility;
- → machine used, production shift or time of manufacturing;
- → product description;
- → intended market of retail sale, shipment route and importer into the European Union;
- → identity of all purchasers from manufacturing to the first retail outlet; and
- → invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

What is more, Member States shall ensure that all relevant stakeholders engaged in the supply of tobacco and related products maintain complete and accurate records of all relevant transactions. In addition, all operators involved in the trade of tobacco products should be provided with the necessary equipment for the recording of tobacco products purchased, sold, stored, transported or otherwise handled.

In addition to the unique identifier, Member States shall require that all unit packets of tobacco products commercialised carry a tamper proof security feature, composed of visible and invisible elements, and that is irremovable, indelible and not hidden or interrupted.

EFA is glad to see that invisible security features were added to visible ones. However, all tobacco products should be treated in the same way and no different provisions in terms of implementing dates should apply to cigarettes and roll-your-own tobacco and to other tobacco products.

D. Smokeless tobacco products and extension of the product scope (article 17)

Smokeless tobacco product means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use.

According to the directive, all packaging of smokeless tobacco products shall carry the following health warning: *"This tobacco product damages your health and is addictive"*. In addition, the text of the health warnings shall appear on the two largest surfaces of the package (although the size is reduced compared to that of cigarettes and roll-your-own tobacco).

The ban on oral tobacco is maintained, except for Sweden which has an exemption. As a consequence, as there is no cross-border element in regulating this product, the provisions of the directive (namely in terms of warnings and characterising flavours) do not apply to oral tobacco.

EFA welcomes the maintenance of the ban on oral tobacco due to its harmful and addictive effects that have been confirmed by the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and other studies, but regrets that Sweden continues to be an exception.

E. Notification of novel tobacco products (article 19)

Member States will require manufacturers and importers of novel tobacco products to submit a notification of any new product they intend to place on the national market. The notification shall contain a description of the product, instructions for its use and information on ingredients and emissions. Manufacturers and importers shall also present:

- → available scientific studies on toxicity, addictiveness and attractiveness, in particular as regards its ingredients and emissions;
- → available studies, executive summaries and market research on the preferences of various consumer groups, including young people and current smokers;
- → other available and relevant information, including a risk/benefit analysis of the product, expected effects on cessation of tobacco consumption, expected effects on initiation of tobacco consumption and predicted consumer perception.

EFA is glad to see that all new products entering the EU market will have to be notified to the competent authorities and that the burden of proving the safety of these products for consumers is on manufacturers and importers. However, we believe that there should be no novel tobacco products introduced.

F. Electronic cigarettes and herbal products for smoking (articles 21-23)

Electronic cigarettes

Member States shall ensure that electronic cigarettes and refill containers commercialised comply with the new directive and with all other relevant Union legislations. They can be marketed either as a medicine (when they claim to have health benefits, and consequently they will be regulated by the medicinal products legislation) or as a consumer product (subject to the provisions of this directive as regards warnings, maximum nicotine strength, pre-market notification system in line with novel products and maximum size for cartridges, refillable tanks and e-liquid bottles, and the same EU advertising bans as for tobacco).

In particular, manufacturers and importers shall submit a notification to the national competent authorities. Member States shall ensure that:

- → nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml;
- → the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml;
- → the nicotine-containing liquid does not contain additives;
- → only ingredients of high purity are used in the manufacture of the nicotine-containing liquid;
- → except for nicotine, only ingredients that do not pose a risk to human health in heated or unheated form are used in the nicotine-containing liquid;
- → electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;
- → electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

In addition, unit packets of electronic cigarettes and refill containers should include a leaflet with the instructions for use and storage of the product, with a reference that the product is not recommended for use by young people and non-smokers, as well as information on contra-indications, warnings for specific risk groups, possible adverse effects, addictiveness and toxicity, and contact details of the manufacturer or importer.

Manufacturers and importers of electronic cigarettes and refill containers should submit, annually, to the competent authorities:

- → comprehensive data on sales volumes, by brand name and type of the product;
- → information on the preferences of various consumer groups, including young people, non-smokers and other users;
- → executive summaries of any market surveys carried out in the respect of the above.

In case of any concerns related to suspected adverse effects on human health, the economic operator shall immediately take a corrective action, withdraw or recall the product from the market.

With the new directive, promotion of electronic cigarettes and refill containers is prohibited, with exception of publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers. Flavourings are permitted and will be subject to national and not EU law. If three or more Member States decide to ban electronic cigarettes, the European Commission may consider an EU-wide action.

Herbal products for smoking

Herbal product for smoking means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process.

According to the directive, each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning: *"Smoking this product damages your health"*. It shall cover 30% of the area of the corresponding surface of the unit packet and of any outside packaging.

Manufacturers and importers of herbal products for smoking are required to inform the competent authorities about all ingredients and quantities used in the manufacture of such products. In addition, the Member States shall ensure that the information is publicly available on a website.

EFA believes that if nicotine is used as a medical treatment to quit smoking, it is necessary that patients understand the consequences it may have on their health, and especially its addictiveness, and get it either

through prescription or from pharmacy – depending on national regulations, and therefore that the products are regulated under the medicinal products legislation. However, we welcome the measure that electronic cigarettes entering the EU market as general products will be controlled and have to be proved to be safe for consumers. The provision that applies the same advertising ban as on tobacco is particularly welcome, as well as the one that leaves Member States free to decide and gives the Commission the power to adopt an EU-wide legislation in case of three similar Member States' decisions. We are concerned to see that the ban on characterising flavours do not apply to these products and that is up to Member States to decide on this topic.

5. Conclusions and next steps

Tobacco remains the main cause of preventable deaths and diseases, causing 700,000 deaths every year in the European Union. This fundamental piece of legislation has the potential for making a meaningful difference for the next generation of European citizens, by protecting the majority of Europe's children from taking up the deadly habit of smoking. **The long-term objective, as reiterated several times by the World Health Organisation, should be to create a future free of tobacco-caused deaths and diseases**. EFA will follow up and work with our members so that any national measures will take into consideration the patient perspective.

Annex: tobacco smoke, allergy, asthma and COPD

COPD: the World Health Organisation (WHO) estimates that tobacco smoke is the primary cause of COPD in developed countries, a preventable but progressive chronic disease that, in contrast with other smoking related disease, is the only cause of death that is still increasing and is expected to become the third leading cause in 2030 worldwide.[3] Lifelong smokers have a 50% probability of developing COPD during their lifetime; along the same line, there is also evidence that the risk of developing COPD falls by about half with smoking cessation.[4] Smokers have six times greater risk of developing COPD than non-smokers and 80-90% of COPD death are due to tobacco smoking.[5]

Allergy: research shows that smoking and exposure to second hand smoke is a major factor in provoking allergic responses by babies and young children.[6]

Asthma: smoking in asthma is associated with a higher degree of asthma severity, worsening of symptoms, increased hospital admissions, accelerated decline in lung function, limited short-term responses to medicines and poorer asthma control.[7]

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is a non-profit network of allergy, asthma and chronic obstructive pulmonary disease (COPD) patients' organisations, representing 35 national associations in 22 countries and over 400,000 patients in Europe. EFA is dedicated to making Europe a place where people with allergies, asthma and COPD have the right to best quality of care and safe environment, live uncompromised lives and are actively involved in all decisions influencing their health.

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[3] WHO, *COPD factsheet*, November 2012, available at: http://www.who.int/mediacentre/factsheets/fs315/en/. European Respiratory Society (ERS), *The European Lung White Book – Respiratory health and disease in Europe*, November 2013.

[4] Laniado-Laborín L., *Smoking and Chronic Obstructive Pulmonary Disease (COPD). Parallel Epidemics of the 21st Century*, in International Journal of Environmental Research and Public Health, 2009.

[5] Presentation from Sixth European Conference on Tobacco or Health, March 2014.

[6] Kulig M., Luck W., Lau S., Niggemann B., Bergmann R., Klettke U., Guggenmoos-Holzmann I., Wahn U., *Effect of pre- and post-natal tobacco smoke exposure on specific sensitisation to food and inhalant allergens during the first years of life*, in Allergy, March 1999. Halken S., *Prevention of allergic disease in childhood: clinical and epidemiological aspects of primary and secondary prevention*, in Pediatric Allergy Immunology, June 2004.

[7] Thomson N. C., Chaudhuri R., Livingston E., *Asthma and cigarettes smoking*, in European Respiratory Journal, November 2004. Fattahi F., Hylkema M. N., Melgert B. N., Timens W., Postma D. S., ten Hacken N.H., *Smoking and nonsmoking asthma: differences in clinical outcome and pathogenesis*, in Expert Review of Respiratory Medicine, February 2011. Polosa R., Thomson N. C., *Smoking and asthma: dangerous liaison*, in European Respiratory Journal, August 2012.