



EUROPEAN COMMISSION

## MEMO

Brussels, 26 February 2014

### Questions & Answers: New rules for tobacco products

Today the European Parliament approved a revised EU Tobacco Products Directive. This new law strengthens the rules on how tobacco products are manufactured, produced and presented in the EU, and introduces rules for certain tobacco-related products. This Memo seeks to answer questions on what exactly will change once the revised Directive enters into force.

#### Why did the Commission decide to revise the rules?

The new Directive aims to improve the functioning of the EU's internal market for tobacco products, whilst assuring a high level of public health. The Council and the European Parliament repeatedly called for a revision of the 2001 Directive, due to considerable developments in three main areas.

Firstly, new scientific evidence has emerged, for example on tobacco flavourings and on the effectiveness of health warnings.

Secondly, new products, such as electronic cigarettes and strongly flavoured tobacco products have emerged on the market.

Thirdly, there have been developments at international level over the past decade, to which EU Member States have responded with different regulatory approaches. The EU and all Member States are parties to the legally binding **WHO Framework Convention on Tobacco Control (FCTC)**, which entered into force in February 2005.

One of the most compelling reasons to strengthen the rules on tobacco products is the negative impact of tobacco consumption on people's health. Tobacco use is responsible for an estimated **700 000 avoidable deaths** in the EU every year. The vast majority of smokers start when they are very young – 70% before their 18<sup>th</sup> birthday and 94% before the age of 25. The new Directive aims to make tobacco products and tobacco consumption less attractive in the EU, in particular for young people.

## What will future cigarette packs look like?



As the picture shows, future packs will feature mandatory picture and text health warnings covering 65% of the front and the back of cigarette packs - to be placed on the top edge. 50% of the sides of packs will also be covered with health warnings (e.g. "smoking kills - quit now"; "tobacco smoke contains over 70 substances known to cause cancer"), replacing the

current printing of tar, nicotine and carbon monoxide (TNCO) levels.

Minimum dimensions for the health warnings will ensure visibility and slim; 'lipstick'-style cigarette packs, which are often targeted to young women, will no longer be allowed.

In order to ensure the visibility of health warnings, cigarette packs will be required to have a **cuboid shape** and each pack will contain a **minimum of 20 cigarettes**.

**No promotional or misleading features or elements** will be allowed on packs. This includes, for example, references to lifestyle benefits, to taste or flavourings or their absence (e.g. "free of additives"), special offers or suggestions that a particular product is less harmful than another.

Similar rules will apply to **roll-your-own tobacco** (RYO) packs, which will also have to carry 65% combined health warnings on the front and back as well as the additional text warnings. RYO products can have a cuboid or cylindrical shape, or be in the form of a pouch, and each pack will contain a minimum of 30g of tobacco.

## How about the labelling of less common tobacco products?

Whereas the EU Directive covers all tobacco products, Member States have some discretion when it comes to labelling rules for products not currently used in significant quantities such as **pipe tobacco, cigars, cigarillos** and **smokeless products**.

While Member States may choose to exempt these products from stringent labelling rules e.g. combined picture and text health warnings, they will be obliged to ensure that these products carry a general warning and an additional text warning. Smokeless tobacco products will have to display health warnings on the two largest surfaces of the pack. As in the former Directive, specific rules apply for the placement and size of all warnings.

## **Can Member States introduce plain packaging?**

While the new rules mean that health warnings will cover a substantial part of the total surface of cigarette packages, a certain space will remain available for branding. The new Directive specifically allows Member States to introduce further measures relating to standardisation of packaging – or plain packaging – where they are justified on grounds of public health, are proportionate and do not lead to hidden barriers to trade between Member States.

## **Will flavourings be banned? How about additives, etc.?**

Flavourings in cigarettes and RYO tobacco must not be used in quantities that give the product a distinguishable ('characterising') flavour *other* than tobacco. The Directive prohibits cigarettes and RYO tobacco with any such characterising flavour. Member States and the Commission may consult an independent European advisory panel before taking decisions in this regard. **Menthol** is considered a characterising flavour and will be banned after a phase-out period of four years – a period which applies to all products with more than a 3% market share in the EU.

Other tobacco products, such as cigars, cigarillos and smokeless products are exempted from the ban on characterising flavours. This exemption will be removed if there is a substantial change in circumstances (in terms of sales volumes or prevalence levels among young people). Tobacco for oral use (*Snus*) is exempted from this ban, as well as from certain other provisions regulating ingredients.

Additives necessary for the manufacture of tobacco products, including sugar lost during the curing process, can continue to be used. The Directive does not discriminate between tobacco varieties such as Virginia, Burley or Oriental tobacco.

## **What information will makers of tobacco products have to provide?**

Mandatory reporting on **ingredients** is foreseen for all tobacco products through a standardised electronic format. Enhanced reporting obligations will be in place for certain frequently used substances found in cigarettes and RYO tobacco (priority list). This will enable regulators to gain more information on the ingredients contained in tobacco products and their effects on health and addiction.

As in the previous Directive, there will be mandatory reporting of emissions of tar, nicotine and carbon monoxide for cigarettes, as well as other emissions where such information is available. Member States may also require manufacturers to carry out further studies on the effect of additives on health.

## Will electronic cigarettes still be available to buy/smoke?

Yes. However new rules will be put in place so that the product's safety and quality can be assured. The new rules are designed to ensure equal treatment across the EU for nicotine containing e-cigarettes (products that do not contain nicotine are not covered by the Directive).

### Disposable



### Rechargeable



### Refillable



E-cigarettes can be disposable (i.e. single use), rechargeable (with a single use cartridge) or refillable (by means of a refill container).

### Why are new rules needed for e-cigarettes?

E-cigarettes are a relatively new product category and their market share is growing. While they may have a role to play in smoking cessation or reduction, their long-term effects on public health are not yet known. As nicotine is an addictive and toxic substance, safety and quality requirements for nicotine-containing e-cigarettes are necessary. Reporting obligations are also needed so that public authorities can monitor and learn more about these products. A number of decisions on e-cigarettes will be left to the Member States, e.g. the regulation of flavours, advertising without cross border effects, and age limits.

The new rules will not apply to medicinal e-cigarettes (as set out in Directive 2001/83/EC) or medical devices (Directive 93/42/EEC), but will cover all consumer electronic cigarettes placed on the EU market.

## What will change for e-cigarette consumers and manufacturers?

### Consumers of eCigarettes:

- **will benefit from improved safety and quality requirements** for products: taking into account nicotine's classification as a toxic substance, there will be a maximum nicotine concentration level for e-cigarettes and maximum volumes for cartridges, tanks and containers of nicotine liquids. These will have to be child and tamper-proof and protected against leakage to limit the risk of exposing consumers – in particular children – to the risks of handling or ingestion. Only ingredients of high purity may be used in the nicotine-containing liquid, and e-cigarettes will be required to deliver the nicotine doses at consistent levels under normal conditions of use. This means that a similar level of nicotine should be delivered each time an e-cigarette is puffed for the same amount of time and with the same strength.
- **will be better informed through new packaging and labelling requirements:** health warnings on e-cigarette packs will be mandatory, as will instructions for their use, information on addictiveness and toxicity, a list of all substances contained in the product and information on the product's nicotine content. No promotional elements will be allowed on packs.
- **will be better protected:** Member State authorities and the Commission will be able to act in cases of justified safety concerns relating to these products. Authorities will monitor the market for any evidence that e-cigarettes lead to nicotine addiction or to traditional tobacco consumption, especially in young people and non-smokers, and the Commission will report on safety concerns and market developments.

**E-cigarette manufacturers** (in addition to manufacturing their products in line with the above rules on safety, quality and packaging) will be required to:

- **notify Member States before placing new products on the market:** notification will include information on the manufacturer, the ingredients used and emissions, nicotine dose and uptake, product and production process and a declaration that the manufacturer takes full responsibility for the quality and safety of the product under normal use.
- **report annually to Member States:** on the sales volumes of the products, types of users and their preferences and trends.
- **comply with specific rules on advertising:** existing rules for cross-border advertising and promotion of tobacco products will also apply to e-cigarettes.

### Can the rules on e-cigarettes be revisited at a later date?

Monitoring and reporting on all developments relating to e-cigarettes – including market and health related developments – has been built into the new Directive. The information collected will provide a good overview of what additional legislative action, if any, is required, and the Commission will revisit the issue if necessary.

## **Is the ban on *snus* (oral tobacco) maintained?**

Yes. In the EU, oral tobacco (such as *snus*) – which is not chewed – has been banned since 1992. Sweden has an exemption under its Accession Treaty, provided it ensures that the product is not sold outside Sweden. *Snus* is addictive and has adverse health effects. Already before 1992, a number of Member States had banned the product, taking into account its significant growth potential and attractiveness for young people.

## **What is being done to combat illicit trade of tobacco products?**

The new Directive includes strong measures against illicit trade of tobacco products to ensure that only products complying with the Directive are sold in the EU. It introduces an EU-wide tracking and tracing system for the legal supply chain and visible and invisible security features (e.g. holograms) which should facilitate law enforcement and help authorities and consumers detect illicit products. The measures foreseen in the new Directive will help to redirect tobacco trade to legal channels, and may also help Member States restore lost revenue. Tracking and tracing of tobacco products will be phased in, with cigarettes and RYO the first required to comply, followed by all other tobacco products.

## **Will cross-border distance sales be banned?**

Cross-border distance sales will not be banned at EU-level, but individual Member States may choose to ban such sales. If they do, retailers may not supply consumers located in that Member State. If they do not choose to ban these sales, retailers that wish to sell tobacco products cross-border must notify their activity prior to the first sale in the Member State in which they are located and in those Member States to which they sell tobacco products. They also must also put in place an age-verification system to ensure that tobacco products are not sold to children and adolescents.

## **What are the expected health and economic benefits of the new rules?**

Strict rules on packages and attractive flavours should help to deter young people from experimenting with, and becoming addicted to, tobacco. The revision is expected to lead to a **2% drop in consumption of tobacco over a period of 5 years**. This is roughly equivalent to **2.4 million fewer smokers in the EU**.

Governments and society as a whole will benefit from improved public health, namely longer healthy lives. Health is a value in its own right, and a healthy population is a key factor for economic growth. The reduction in tobacco consumption resulting from the new measures is calculated to translate into **annual healthcare saving to the amount of €506 million**.

Clearer and more accurate information on tobacco products will enable people to take informed decisions. Moreover, manufacturers of tobacco products will benefit from clearer rules, an improved functioning of the internal market and a level playing field. The new rules also take account of the specific needs of small and medium-sized companies.

### **When will the new rules apply?**

The new Directive should enter into force in May 2014. A transposition period of two years for Member States to bring national legislation into line with the revised Directive means that most of the new rules will apply in the first half of 2016. However, the Directive also foresees a transitional period for all product categories to give manufacturers and retailers time to sell off their existing stock insofar as it complies with the old Directive or other relevant legislation. As mentioned above, a phase-out period of four years is foreseen for all products with more than a 3% market share in the EU, for example menthol cigarettes.

### **For more information:**

[http://ec.europa.eu/health/tobacco/products/index\\_en.htm](http://ec.europa.eu/health/tobacco/products/index_en.htm)

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