

ON EU TOBACCO PRODUCTS REGULATIONS

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Abstract: *The objective of the paper is to present the expected impacts of the new EU Tobacco Products regulation on the sector and on human health. To achieve this objective, the most important new moments in the newly adopted Tobacco Products Directive have been outlined and the positions of the main interested parties on the new tobacco excise duties regulations have been presented. As a result of the research important conclusions have been drawn up, paving the road for future evidence based policy recommendations.*

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1. Expected impacts of the new EU tobacco products directive

The new Tobacco Products Directive has a high influence on the development of the tobacco sector in the EU. More than ten years have passed since the adoption of the previous Tobacco Products Directive (2001/37/EC). During this time, there have been several market, scientific and international developments in the tobacco sector and the existing rules have a number of weaknesses and gaps. Therefore it has become necessary to update and complete the current Directive. A revision was repeatedly called for by the Council and the European Parliament. While the overall objective of the revision is to improve the functioning of the internal market, it is expected that citizens in all Member States will benefit from improved public health. Practically, the aim of the directive is to make tobacco products less attractive by strengthening the rules on how such products can be manufactured, presented and sold. Each year, 700 000 people across the EU die from tobacco-related illnesses. Many more suffer with chronic illnesses brought on by tobacco consumption. Smoking is one of the greatest preventable threats to people's health. That's why the revision as proposed by the European Commission addresses the following main issues:

- how to regulate products which do not contain tobacco, but which are closely linked to smoking or tobacco consumption, for example electronic and herbal cigarettes,
- labelling and packaging of tobacco products
- additives, such as flavourings, used in tobacco products,
- internet sales of tobacco products, and
- tracking and tracing of these products.

Later on two important steps have been made in the legislative process: firstly, on [19 December 2012 the European Commission has adopted the proposal of the directive;](#) and secondly, on [21 June 2013 the Council has agreed on the revision of](#) the draft EU

tobacco directive. This agreement (a so-called general approach) will serve as the basis for negotiations with the European Parliament.

The new [Tobacco Products Directive \(2014/40/EU\)](#) has entered into force on 19 May 2014. It is expected to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens. The [Tobacco Products Directive \(2014/40/EU\)](#), replacing [Directive \(2001/37/EC\)](#), lays down *rules governing the manufacture, presentation and sale of tobacco and related products*. These include cigarettes, roll your own tobacco, pipe tobacco, cigars, cigarillos, smokeless tobacco, electronic cigarettes and herbal products for smoking.

Tobacco business representatives, non-governmental organizations and analysts have been included in the debate on the impacts of the directive on the European Union Economy and its citizens' health. Roland Berger Strategy Consultants have been commissioned by the tobacco giant Philip Morris International to assess the potential economic impact of the new TPD. In their study, they analyze the impact of the new directive on the entire tobacco sector and on the EU Member States' economies in two key aspects: 1.) Employment; and 2.) Tax revenue.

Their result have shown that the cigarette and fine-cut tobacco sector in the EU Member States, including suppliers and retailers, account for more than 600,000 jobs (employees on full-time and part-time schedules, excluding seasonal workers). This is a conservative estimate. Others, including the European Commission, have calculated much higher figures, some of them exceeding one million jobs. The sector generated tax revenues (from tobacco taxes and VAT) of more than EUR 100 bn in 2012.

The new tobacco products directive's standardization of packaging and labeling of tobacco products will most probably reduce consumers' value perception, influenced by strong brands and high degree of product differentiation. This will shift the demand towards lower-priced products sourced from either the legal or the illicit (black) market. Price competition will reduce the prices in all tobacco market segments. Demand for cigarettes and fine-cut tobacco is expected to increase by up to 2% – an unintended consequence of standardizing the appearance of cigarette packs. Following the prohibition of slim and menthol cigarettes, their consumers will potentially turn to the illicit market. In total, the black market is expected to grow by 25-55%, from 68 bn cigarettes to 84-106 bn cigarettes¹.

As a result, between 70,000 and 175,000 jobs could be lost in the EU, not counting seasonal workers. These numbers include direct employment effects in the tobacco sector – mainly due to the shrinking legal cigarette and fine-cut market – as well as indirect employment effects brought on by the tax losses. The drop in tax revenue from excise taxes and VAT on tobacco products ranges from

a conservative estimate of EUR 2.2 bn to an elevated estimate of EUR 5.0 bn across the EU. Of the EUR 5.0 bn loss in tax revenue, approximately EUR 3.6 bn result from an increase in illicit trade.

¹ The new Tobacco products directive – potential economic impact, Roland Berger Strategy Consultants, 2013 p.3

All EU Member States will be affected by the new tobacco products directive. However, some countries will be particularly hard-hit. Strong effects will occur in Germany, Greece, France, Poland and Romania. Countries with high demand for slim or menthol cigarettes, such as Bulgaria or Poland, will experience disproportionate losses.

In particular, the new [Tobacco Products Directive \(2014/40/EU\)](#):

- prohibits cigarettes and roll-your-own tobacco with *characterising flavours*,
- requires the tobacco industry to submit detailed *reports to the Member States on the ingredients used in tobacco products*, in particular cigarettes and roll-your-own tobacco,
- requires that *health warnings* appear on packages of tobacco and related products. Combined (picture and text) health warnings must cover *65% of the front and back of cigarette and roll-your-own tobacco packages*,
- sets *minimum dimensions* for warnings and eliminates *small packages* for certain tobacco products,
- bans all *promotional and misleading elements* on tobacco products,
- introduces *EU-wide tracking and tracing* to combat illicit trade of tobacco products,
- allows Member States to *prohibit internet sales* of tobacco and related products,
- sets out safety and quality requirements for *consumer electronic cigarettes*,
- obliges manufacturers to *notify novel tobacco products* before placing them on the EU market.

The revision of tobacco products rules had become necessary 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.

Undoubtedly, the most compelling reasons to strengthen the rules on tobacco products is the negative impact of tobacco consumption on people's health. According to EU health statistics, tobacco use is responsible for 700 000 avoidable deaths in the EU every year. The vast majority of smokers start when they are very young – 70% before their 18th 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.

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.



Fig. 1. Cigarettes packaging according the new Tobacco Products Directive

Source: <http://ec.europa.eu/health/tobacco/products/revision/>

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.

The EU Tobacco products Directive covers all tobacco products, but 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.

According to the new rules health warnings will cover a substantial part of cigarette packages, but a certain space will remain available for branding. The new Directive specifically allows Member States to introduce further standardisation of packaging – the so called “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.

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.

Mandatory reporting on ingredients is foreseen for all tobacco products in a standardised electronic format. Enhanced reporting obligations will be in place for certain frequently used substances found in tobacco products (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.



Fig. 2. Electronic cigarettes available to buy according to the new Tobacco Products Directive
Source: <http://ec.europa.eu/health/tobacco/products/revision/>

Electronic cigarettes will be available to buy and smoke. 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). E-cigarettes can be disposable (i.e. single use), rechargeable (with a single use cartridge) or refillable (by means of a refill container).

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.

Consumers of e - cigarettes:

- 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. E - cigarettes will be child and tamper-proof protected as well as protected against leakage in order to limit the risk of exposing consumers or 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) are *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.

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.

In the EU, “oral tobacco” (or *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.

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.

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 must also put in place an age-verification system to ensure that tobacco products are not sold to children and adolescents.

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.

The new Directive has entered 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. The Directive also foresees a transitional period for all product categories to give manufacturers and retailers

time to sell off their existing stock 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.

2. Positions of the main players in tobacco regulation sector on tobacco excise duties

Fiscal policy is used to achieve both revenue generation and public health goals. How Multinational Companies in tobacco sector accept the excise and other taxes levied on tobacco? They have given their own position in many events, they lobby for keeping the excise duties low as long as possible. On the other hand various health organisations insist for increase in the excise duties, because they find increase of cigarettes final prices is the best way for smokers to quit their habits. International organisations also give their positions on the topic. Here are some statements representing the positions of the the main players in the tobacco regulation sector:

- The Multinational Companies: “We do not support excessive tax increases. In our view, governments must strike a balance between maintaining taxes at levels that achieve their policy objectives and not making tobacco products unaffordable for adult smokers.”¹

- The World Health Organisation: “The most effective approach to controlling the spread of tobacco use is through policies that directly reduce the demand for it. There are many valuable ways of going about this, from advertising bans to public smoking prohibitions, but the most potent and cost-effective option for governments everywhere is the simple elevation of tobacco prices by use of consumption taxes. ... On average, a 10% price increase on a pack of cigarettes would be expected to reduce demand for cigarettes by about 4% in high-income countries and by 4% to 8% in low- and middle-income countries, where lower incomes tend to make people more sensitive to price changes.”²

- The International Monetary Fund: “Ultimately, tobacco excise tax rates must reflect the purchasing power of the local consumers, rates in neighboring countries, and, above all, the ability and willingness of the tax authority to enforce compliance.”³

As recognized by all parties in the argument, fiscal measures are a key component of a comprehensive tobacco policy. And a key factor in deciding on the right tax rate is the potential impact that tax increases have on the development of illicit trade. Illicit trade is driven by a large number of factors including excessive taxation. Although it is possible to maintain high tax levels without a corresponding high level of smuggling, tax remains a key incentive for illicit trade in tobacco products. Moreover, governments must have the capacity, willingness, and ability to enforce the laws and control their borders. Notwithstanding researching illicit trade is not an objective of this paper, it is worth to mention that there are many interesting researches on the government policy towards illicit trade in the cigarette business. In Bulgaria for example (Skafida, Silver, Rechel and Gilmore, 2012): “Transnational Tobacco Companies (TTC) have been involved in cigarette smuggling to and through Bulgaria since at least 1975 and used smuggling as a market-

¹ statement of: Philip Morris International Inc., available at:

http://www.pmi.com/eng/tobacco_regulation/tobacco_taxation/pages/tobacco_taxation

² source: Tobacco Free Initiative, <http://www.who.int/tobacco/economics/taxation/en/index.html>

³ in: Curbing the Epidemic, 1999, the World Bank. Appendix A, A view from the International Monetary Fund, <http://siteresources.worldbank.org/INTETC/Resources/375990-1113853423731/Appendix.asp>

entry strategy. National tobacco company Bulgartabac appears to have been involved in smuggling its own cigarettes from and reimporting them to Bulgaria. Since Bulgaria's accession to the EU opened the market to the TTCs, TTCs have exaggerated the scale of the illicit trade to successfully convince politicians and public health experts that tax increases lead to cigarette smuggling. Yet, sources point to TTCs' continued complicity in cigarette smuggling to and through Bulgaria between 2000 and 2010. TTCs aimed to influence the Bulgarian tobacco excise tax regime, import duties and pricing mechanism, but appear to have been less successful than in other former communist countries in part due to the co-existence of a state-owned tobacco company. Undisclosed meetings between the tobacco industry and government ministers and officials are ongoing despite Bulgaria being a party to the Framework Convention on Tobacco Control (FCTC)."

As a whole, experience shows that adopting a policy of gradual tax increases, combined with effective measures to counter illicit trade is the optimal way for governments to meet both revenue and health objectives, while reducing the risk of stimulating and fostering the illegal market. Governments should not only consider the optimal tax level - it is even more important to adopt the right tax structure. Ill-conceived tax structures will encourage a shift in demand to lower-taxed cigarettes or other tobacco products.

In order to provide the functioning of the Internal market of the EU and in the same time to provide a high level of protection of human health, the Council of the EU adopted changes in the fiscal legislation of the EU relating the tobacco products. The Council of the EU has undertaken an extensive review of the rates and structures of the excise duties levied on tobacco products in the EU. Directive 2010/12/EC of the Council introduces changes to the previous directives 92/79/EEC, 92/80/EEC, 95/95/EC and Directive 2008/118/EC of the Council from 16 December 2008 concerning the general arrangement for excise duty. According to the new directive, the minimal excise duty on cigarettes in the EU set by the EU legislation has been 57% of the weighted average retail selling price of the cigarettes released for consumption and at least 64 Euro for 1000 pieces of cigarettes.

Conclusion

EU regulation (both the directive concerning the excises on tobacco products and the new tobacco product directive) has a huge impact on the tobacco sector. Cigarettes are the most heavily taxed consumer goods in the EU and taxes will increase even more in the period 2014 – 2017 as required by directive 2010/12/EC. In the same time the new tobacco products directive that has entered into force in 2014 has standardized the appearance of cigarette packs and gives smokers alarming information on the product. The final objective of both measures is to improve EU citizens health, to provide more resources for the income part of the EU member states budgets and to reduce annual health care expenditures of EU member states.

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