



ЕКСПЕРТЕН КЛУБ ЗА  
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# Harm Reduction:

Differentiated Regulation in the Tobacco  
Debate in Bulgaria and in Brussels

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## 1. Context

An important moment for the tobacco users in the EU is approaching. In December this year the European Commission is expected to present a proposal for the revised Tobacco Excise Directive 2011/64/EU. In the coming months the European institutions, notably the Council where the Member States are represented, and the European Parliament will debate and will work with the Commission to establish the new rules and the minimum tax rates applied to tobacco products in the EU.

The two main objectives of the current Directive 2011/64/EU however will remain the same:

- (i) Improving public health, i.e., reducing smoking in the Member States,
- (ii) Proper functioning of the common market and harmonization of the taxation in the Member States.

There are three matters that will underpin the revision of the current framework with a view of making progress in achieving the two objectives.

- » **The first matter** is related to the minimum tax rates applied to traditional tobacco products for smoking given the differences in the economic development, purchasing power and inflation levels in the Member States. These differences are the reason for the growing difficulties in harmonizing the fiscal framework and hence the establishment of an index accounting for the financial and economic variations between the countries is expected to be discussed, as the nominal taxation level (laid down in the current version of the Directive) and the future higher or lower levels may turn out to be unreachable for some Member States and too low for others.
- » **The second matter** to be addressed in the revision of the Directive is related to incorporating the novel innovative tobacco products and nicotine substitutes introduced in the market after the current version of the Directive was adopted in 2011. The principle to be applied is that the revised European legislation should realistically reflect the changes in consumption and the market changes. Moreover, the novel products and definitions for them are included the main European Directive on Tobacco and Related Products 2014/40/EU, and the Member States have established own legislative and market

practices in response to the new trends, particularly in terms of these non-combustible products containing tobacco or containing only nicotine without tobacco. Amendments were also made to the EU Combined Nomenclature (CN) 2022 for customs purposes with the introduction of the following new position 2404 for the novel products which is based on their common features differentiating them from all the other tobacco products in Chapter 24 of CN<sup>1</sup>: **“Products containing tobacco, reconstituted tobacco, nicotine, or tobacco or nicotine substitutes, intended for inhalation without combustion; other nicotine containing products intended for the intake of nicotine into the human body”**; The new Excise Directive seems to be lagging behind the legislative developments and the consumption and market dynamics and therefore it is expected that the novel products will be included in its scope to be subject to excise duty. These are products such as heated tobacco products, e-liquids, nicotine pouches and other nicotine products gaining popularity in response to consumers’ needs and the market demand, which deliver nicotine to the human body in alternative ways without combustion and without having a therapeutic smoking cessation effect and therefore they are not medicinal products.

- » **Thirdly**, the revision of the Directive should contribute to implementing the good practices of proportionate and appropriate taxation and pricing measures which to result in reducing smoking prevalence and in tobacco harm reduction through the application of EU’s main principle of “better regulation”. The harm reduction concept is gradually and firmly finding its way into the policies of many Member States in addition to the traditional regulatory and fiscal measures and practices aimed exclusively at eradicating or restricting smoking. Harm reduction is a tested health strategy applied successfully in view of many types of risk behaviours and factors related to impaired health. When it comes to tobacco,

*...an understanding [is introduced] that positive health effects for the smokers are possible not only by means of cessation, but also by means of replacing the traditionally harmful tobacco products for smoking with less harmful products...*

1 <https://customs.bg/wps/portal/agency/media-center/on-focus/31-01-kh2022-vape>

tobacco harm reduction the approach does not substitute the main prevention and cessation strategies, but complements the to rather replaces the obsolete “either-or” mentality according to which the person is either a smoker, or a non-smoker. The harm reduction concept introduces an understanding that a positive health effects for the smokers are possible not only by means of cessation, but also by means of replacing the traditionally most harmful tobacco products for smoking with less harmful products through policies designed to influence consumption by regulatory and/or fiscal measures “nudging” the smokers towards the reduced risk alternatives.

## 2. Tobacco Harm Reduction

The harm reduction concept originated in the developed countries as an attempt to address the diseases and negative effects caused by drug use which became widespread after the 1960s<sup>2</sup> given the challenges and long-term efforts to overcome addiction. In this respect and in this specific context it is defined as *“policies, programmes and practices that aim to minimise the negative health, social and legal impacts associated with drug use, drug policies and drug laws.”*<sup>3</sup>

Starting as government programmes and activities of nongovernmental organizations focused on drug harm reduction the harm reduction strategy gradually expanded into a broader policy-making approach largely due to the failure of the ineffective prohibitionist strategies to manage the problem.

Nowadays, harm reduction as a policy-making framework can be defined as *“actions directed to reducing the damage resulting from harmful behaviour by both individuals and society”*.<sup>4</sup> The term is now applied in many areas such as alcohol consumption, road safety, pollution, physical inactivity, diet, sexual activity, etc.<sup>5</sup>

The harm reduction policies as means for addressing multiple public health issues stemming from harmful addictive behaviour come as a result of the gradual reduction of the effectiveness of the other possible policies (often

2 Lenton S, Single E. 1998. The definition of harm reduction. *Drug and Alcohol Review* 17(2):213.

3 Harm Reduction International (2022) *Global State of Harm Reduction 2022*. London: Harm Reduction International

4 Levesque, R. J. R. (2018). ‘Harm Reduction’. In R. J. R. Levesque (ed.), *Encyclopedia of Adolescence*, 1716–1718. New York: Springer.

5 Institute of Medicine (US) Committee to Assess the Science Base for Tobacco Harm Reduction; Stratton K, Shetty P, Wallace R, et al., editors. *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*. Washington (DC): National Academies Press (US); 2001. 2, Principles of Harm Reduction

restrictive or prohibitive policies). This is fully applicable to Bulgaria where a review of the implemented measures has shown no significant impact from the accumulation of one or more restrictive measures.<sup>6</sup>

Tobacco harm in Bulgaria can be demonstrated using health and financial measures. According to a study conducted by our team in 2021 of four smoking-related diseases 10 000 deaths, 250 000 sick leave days and almost 450 000 health insured persons affected annually can be attributed to tobacco use. The economic indicators are even more salient: smoking accounts for 3-7% or BGN 4.4 billion of the annual economic losses<sup>7</sup>.

According to a recent report on the most common risk factors<sup>8</sup> by a team of researchers and health experts the possible strategies to address the risk associated with smoking are as follows:

- Education on the harms of smoking and increasing health literacy;
- Pharmacological treatment with cytisine, varenicline, or bupropion (they however are associated with limited long-term efficacy and significant side effects);
- Individual counselling, group therapy and programmes specifically aimed at groups such as pregnant women, young people or people living with health conditions such as chronic obstructive pulmonary disease, cardiovascular disease, etc;
- Substituting cigarettes or other smoking products with other types of nicotine or tobacco use without combustion that entail lower exposure to toxicants, carcinogens and other harmful constituents;
- Substituting smoking with smoke-free/non-combusting products will eliminate second-hand smoke. Second-hand smoke, like mainstream smoke, contains thousands of chemicals many of which are toxic;
- Regulation of product marketing and labelling, including fiscal measures targeting types of products based on the level of risk they pose.<sup>9</sup>

6 Шарков (2020), „Намаляване на вредите от тютюна: Преглед на регулаторните рамки и иновациите“, ЕКИП

7 Panchev S., Sharkov. A, Measuring the public-health and economic effects of the switch in consumption habits from traditional tobacco products from smoking to new non-combustible nicotine alternatives, author, EJPP Vol. 12, No 3 (2021), Sofia University

8 „(Не)победими пандемии“, Георгиева М., Момеков Г., и др., ПанЕвропа, 2022

9 Подходи за намаляване на вредата от тютюнопушенето

One of the recommended approaches has already been tested in terms of its impact in the aforementioned study measuring tobacco harm in Bulgaria<sup>10</sup>. The approach in question is risk reduction by replacing cigarettes and other tobacco products for smoking with the new non-combustible alternatives. If only 15% of the smokers switch

*...these findings should encourage the medical professionals to apply this smoking cessation approach more proactively.*

to less harmful alternatives the average disease incidence for the four groups of smoking-related diseases will be reduced by about 56 000 health insured persons (or 12%) affected by smoking-related diseases. The full potential impact from changing consumer habits (switching to less harmful alternatives) amounts to a reduction of the negative effects in the amount of BGN 1.8 billion or a 41% reduction in financial terms. Moreover, a recent clinical trial by the St. Mary University in London of one of the non-combustible products, e-cigarettes, shows that they are almost twice as effective a smoking cessation aid as nicotine patches and gums.

The subjects abstaining from smoking are much more likely to use e-cigarettes as an alternative to the traditional cigarettes compared to the other nicotine products (79.8% vs 9.1%). The conclusion is that these findings should encourage the medical professionals to apply this smoking cessation approach more proactively<sup>11</sup>. It is important to note that the change in consumer behaviour is a natural process that currently takes place without any incentives and is driven by the growing health awareness and lifestyle and health choices of the consumers. In this respect there is an opportunity to achieve a natural balance between the desired health effects, the natural consumer needs and last but not least the interests of the companies that develop and manufacture alternative products. This means that instead of implementing passive policies or policies for restrictions that go against the consumers' wishes and needs a positive outcome can be achieved more rapidly by enhancing the existing autonomous system of incentives.

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10 See 6

11 'A randomised trial of e-cigarettes versus nicotine replacement therapy'. Peter Hajek, PhD, Anna Phillips-Waller, BSc, Dunja Przulj, PhD, Francesca Pesola, PhD, Katie Myers Smith, DPsych, Natalie Bisal, MSc, Jinshuo Li, MPhil, Steve Parrott, MSc, Peter Sasieni, PhD, Lynne Dawkins, PhD, Louise Ross, Maciej Goniewicz, PhD, PharmD, Qi Wu, MSc, Hayden James McRobbie, PhD. [New England Journal of Medicine](https://doi.org/10.1056/NEJMoa1808779). DOI: 10.1056/NEJMoa1808779

### 3. Different Harm – Different Regulation

Excises are a key regulation tool for tobacco and tobacco products. If however a tax increase is absorbed by the manufacturers and affects the retail prices this can shift the consumer channels towards finding the same product at a lower price which oftent means that the product is not taxed, is illegal or counterfeit. The scope of change in consumer behaviour

is measured by the price elasticity of demand.

*When the tax burden and the prices go up significantly the smokers shift to illicit products feeding into illegal and criminal activities.*

A global review of the available literature on this issue from 2019 shows that the price elasticity of tobacco products varies between -0.2 and -0.8 and in developed countries it is -0.4<sup>12</sup>. When the price elasticity is -0.4 a 10% increase in prices will result in a 4% decline in consumption.

The multiple increases of the excise

rates and the prices in Bulgaria in the past years did not however lead to reducing smoking prevalence because of the price elasticity in the country. When the tax burden and the prices go up significantly the smokers shift to illicit products feeding into illegal and criminal activities. In this respect a tax differential between the traditional and the less harmful products may serve as an incentive to switch from the more harmful to the less harmful products in addition to contributing to harm reduction.

Another study of the demand in the retail stores also confirms the relatively high price elasticity in the e-cigarette demand<sup>13</sup>. The study shows that a 10% price increase reduces the demand for reusable e-cigarettes by 14% and of disposable e-cigarettes by 16%. This data highlights the importance of excise policy and outlines the options for implementing innovative harm reduction policies involving differentiated regulation of the less harmful nicotine alternatives.

Moreover, the excise differentiation with lower rates for the less harmful nicotine products may not produce a significant negative fiscal effect. i.e. if the calculations are right and if consistent health, economic and fiscal policies are carried out, the net fiscal effect may be neutral or even positive in terms

12 Chaloupka, F. J., Powell, L. M., & Warner, K. E. (2019). 'The use of excise taxes to reduce tobacco, alcohol, and sugary beverage consumption'. Annual Review of Public Health, 40, 187–201

13 Huang, J., Gwarnicki, C., Xu, X., Caraballo, R. S., Wada, R., & Chaloupka, F. J. (2018). 'A comprehensive examination of own- and cross-price elasticities of tobacco and nicotine replacement products in the U.S'. Preventive Medicine, 117, 107–114.

of healthcare and social assistance savings. Our calculations show that if 50% of the smokers switch to less harmful alternatives, the impact on the public finances will be a decrease in expenditures by an average of BGN51 million annually<sup>14</sup>.

It is key to not impose reactive restrictions or restrictions equivalent to those for the traditional tobacco products when formulating the fiscal and regulatory policies. The innovative less harmful alternatives to

smoking have their specific characteristics which require a different regulatory approach. The effects of usage of innovative less harmful alternatives to smoking and the alternatives as such have own different characteristics, hence require a different regulatory approach. Instead, the often-abused precautionary principle can be replaced by the innovative principle defined as: ***“New or innovative technologies should not be held to a higher standard of safety than existing ones where the level of risk is comparable, other than to the extent that they can be shown plausibly to exacerbate the risks from the existing technologies, otherwise their potential to deliver benefits will be lost.”***<sup>15</sup>

*It is key to not impose reactive restrictions or restrictions equivalent to those for the traditional tobacco products in when formulating the fiscal and regulatory policies*

14 See 6

15 Hewson, V. and Snowdon, C. (2022) Vaper Trails: New nicotine products and the innovation principle. London: Institute of Economic Affairs.

## 4. Policy Recommendations

Adopting the harm reduction principle as a leading principle in the policies against tobacco smoke involves adopting and implementing specific health, taxation, and consumer regulation policies. Here are several proposals in this respect which it would be a good idea to include in the revised Excise Directive 2011/64/EU, and in the next revision of the Tobacco and Related Products Directive 2014/40/EU:

- Establishing the harm reduction principle as both a complementary and a key principle of tobacco policy;
- Promoting a policy that stimulates the use of smoke-free products with lower risk profile;
- Replacing the precautionary principle with the innovation principle where relevant;
- Differentiated treatment of non-combustible alternatives and all innovative less harmful products that is different from the treatment of traditional tobacco products;
- Revising the rules for the minimum excise rates to reflect the different risk profiles of the different products;
- Referring to the estimated possible savings in terms of lower mortality and morbidity when calculating the excise rates for excisable goods.

Overall, our recommendation is to adopt the harm reduction paradigm to replace the obsolete and no longer useful prohibitive and restrictive concepts and policies. Such an approach entails a differential regulatory treatment of the innovative less harmful products, more specifically differential tax treatment.





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