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analysis

A NEW APPROACH TOWARDS TOBACCO LEGISLATION

THE CASE FOR HARM REDUCTION IN CEE AND THE EU

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CENTER FOR ECONOMIC AND MARKET ANALYSES

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EXECUTIVE SUMMARY

The new study on ‘A New Approach Towards Tobacco Legislation: The Case for Harm Reduction in CEE and the EU’ examines the fundamental principles of tobacco policy and their applications. With the political support for the policy of reduced risks in the Czech Republic, as well as discussions on cancer prevention ongoing at the EU level, we analyse whether the objective of the European Commission to achieve a tobacco-free generation by 2040, where less than 5 % of people use tobacco, is achievable. What we find is that the current trajectory of the international debate on the topic, including abstinence and prohibitionism, is a route that is not realistic. For this reason, we firmly believe that what is needed at the EU level is the more achievable target of smoke-free generation, and that the way to achieve it is through evidence-based policy which incorporates the harm reduction approach.

With the program statement of the new Czech government, it became clear that the topic of public health is going to be given a high political priority. This has been undoubtedly caused not only by the COVID-19 pandemic, but also by the increased focus on health policies at the EU level. Some of the recent European initiatives which are addressed in the plans of the Czech government are *inter alia* Europe's Beating Cancer Plan and its section on addictions management.

The manifesto informs that in dealing with the problem of addictions, the Czech government will apply a policy based on a scientifically proven and balanced approach to risk prevention and harm reduction. Further support for the policy has been given by a new Czech national anti-drug coordinator, Jindřich Vobořil, who said that in relation to addictions management, for years decision-makers have focused on abstinence-only policies, but that the available scientific data shows that a rational policy based on harm reduction principles should be implemented instead. The same has been recognized by the Minister of Health, Vlastimil Válek, who said that he also supports the risk reduction policy, and that he would like to see the discussions around it to become a priority of the upcoming Czech Presidency of the Council of the EU.

It is against this background that we analyze the tobacco control policy at the Member State and at the EU levels, and we investigate the extent of the implementation of the harm reduction policy. Based on the analysis as well as on the results of the Harm Reduction Index, which for the first time ever aims to measure the implementation of harm reduction practices, the study shows that the goal of a tobacco-free generation by 2040 will not be achieved. Average smoking prevalence in the EU27 countries is expected to decrease to 11 % by 2040. A change in the approach to policy toward tobacco and nicotine products is therefore necessary.

The study concludes that a target of smoke-free generation by 2040 should be set instead. The objective will be achievable through the adoption of harm reduction policy which promotes a shift from traditional cigarettes to less harmful products, and which provides European citizens with the right tools to quit and to reduce smoking.

At the European level, tobacco policy is currently under review, and discussions amongst the Member States on the future direction of this policy will be taking place shortly. It is certain that these discussions will feature some Member States who support the end-game approach based on abstinence. It is therefore very encouraging to see that the Czech government has set upon a different path. The Czech government has the opportunity to pave the way for a different approach, one where

a more pragmatic, evidence- and reality-based understanding of addictions and mental health serves as its foundation.

Based on the report, we call upon the government of the Czech Republic to initiate an ambitious and comprehensive policy review in the area of tobacco addiction, where science is put first. To achieve that, the Czech model towards tobacco addiction should be based on the following overarching pillars:

1. Promotion of the Czech model in the EU, for instance as a part of the upcoming Czech and subsequently Swedish Presidency of the Council of the EU,
2. Discussions on the establishment of a smoke-free generation target by 2040,
3. More extensive involvement of harm reduction experts in policy design, incorporation of latest scientific findings and reactivity of latest market developments,
4. Assessment of and preparation for the impact of new regulation on SMEs and local economies as a consequence of changes in consumer behaviour,
5. Launch of a public information campaign on harm reduction practices, and on lower risks alternative tobacco products,
6. Support for policies that recognize the inherent differences in harm levels between different tobacco and nicotine products, in particular when compared to traditional cigarettes,
7. Support for policies which allow for differentiated rules on advertising, flavours, packaging, health warnings and other relevant fields, depending on the relative harmfulness of a product.

By creating a Czech model towards tobacco addiction, and by building it on the above key recommendations, the Czech Republic will be able to pioneer a new way of addressing nicotine addiction policy, moving from the outdated and harmful idea of prohibition, to the one which is based on science, and which puts the health of European citizens first.

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1 INTRODUCTION

It has been an undisputed fact for many years that cancer is among the leading causes of death in European countries. Despite the inhabitants of the European Union being only 10 % of the global population, they suffer a quarter of global cancer cases (Special Committee on Beating Cancer, 2022). Naturally, this is a consequence of high life expectancy in the region, and as life expectancy continues to grow, it can be expected that so will the focus on cancer.

Furthermore, 27 % of all cancer cases can be attributed to tobacco smoking, making it the single largest avoidable health risk and the most significant cause of premature death in the EU, responsible for nearly 700 000 deaths every year. Around 50 % of smokers, states the European Commission, die prematurely - on average 14 years earlier (Europe's Beating Cancer Plan, 2021).

In view of these facts, the European Commission in its new Europe's Beating Cancer Plan announced its goal of building towards a tobacco-free generation by bringing smoking down to 5 % by 2040. According to the Plan, this goal will be reached by:

"...reviewing the Tobacco Products Directive (TPD) and the Tobacco Taxation Directive (TTD). This includes working in full transparency towards plain packaging and a full ban on flavours, ..., extending taxation to novel tobacco products, and tackling tobacco advertising, promotion, and sponsorship on the internet and social media..., extending coverage to emerging products, such as e-cigarettes and heated tobacco products, and expanding smoke-free environments, including outdoor spaces." (Europe's Beating Cancer Plan, 2021)



27 % of all cancer cases can be attributed to tobacco smoking, making it the single largest avoidable health risk.

While we share the European Commission's goal of curbing cancer and other health risks and harm to both smokers and non-smokers, we are going to show over the course of this study that the methods chosen by the European policymakers to achieve the goal of reduced cancer incidence are not optimal.

Namely, we establish that:

1. **The goal of a tobacco-free generation by 2040 is unrealistic and may in fact cause harm**
2. **The methods proposed by the European Commission are based on disputed scientific claims**
3. **Better alternatives to the steps proposed in the Beating Cancer Plan exist and are already practised in some countries**

We are also going to suggest alternative steps that the European decision-makers could take, based on expert opinions and experience from the different Member States.

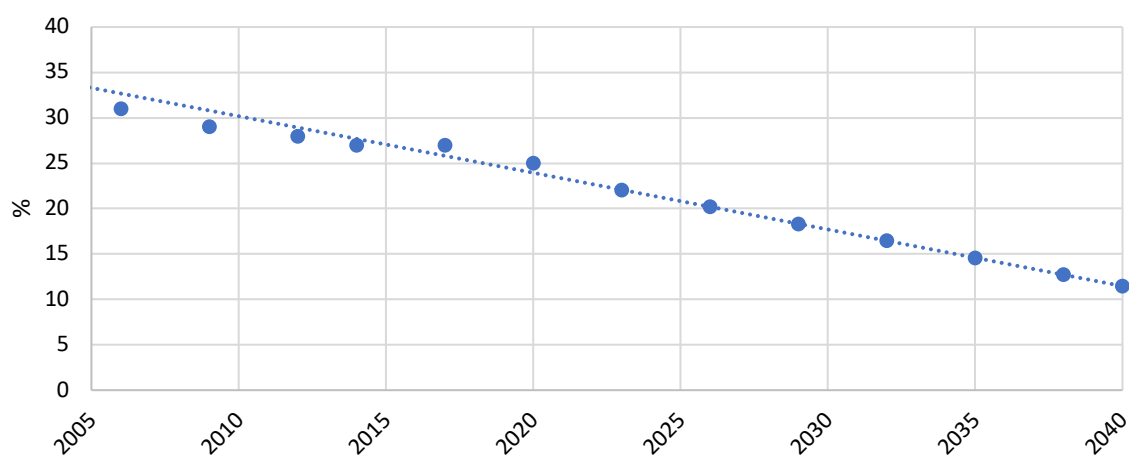
The goal of a tobacco-free generation by 2040 is unrealistic

One of the major steps in fighting cancer mentioned in the Plan (2021) is bringing the prevalence of smoking to 5 % by 2040, with an interim goal of 20 % of smokers in the population by 2025 across the EU. This is overly ambitious for a number of reasons.

First of all, in the past 15 years, smoking prevalence was reduced only by around 5 percentage points (Eurostat, 2021). This is despite the fact that many of the measures described in the Plan as ways of achieving the new goal have already been in effect, such as advertising bans, coverage of e-cigarettes or ban on flavours (Report on the Application, 2021). To achieve this goal, the European Commission would need to reduce the number of users by 20 percentage points from current rates in the next twenty years, three times the current speed.

To show how far Europe is from reaching this goal, we extrapolated linearly the current trend for usage of cigarettes, cigars, cigarillos or pipes (Figure 1), only to reveal that continuing the current course would bring us to 11,46 % of smokers in adult population by 2040, 6 percentage points more than the goal established in the Beating Cancer Plan.

Figure 1: Linear extrapolation of combustible tobacco prevalence trend from 2020 to 2040



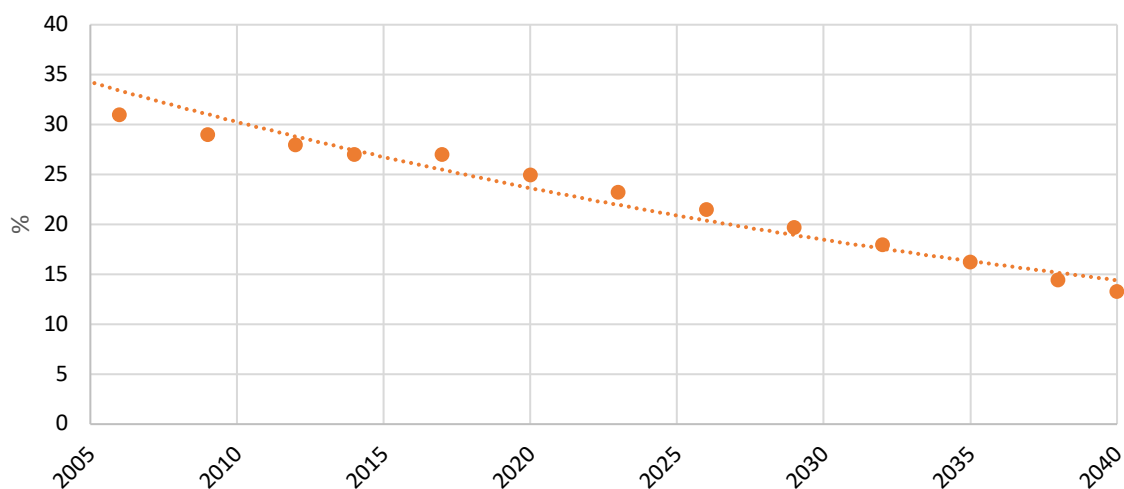
Source: Eurostat 2006-2020, own calculations 2021-2040

Not to mention that the model in Figure 1 operates with the optimistic assumption that bringing people to quit will continue to be similarly difficult as it is today. There are however reasons to believe that this is not the case – naturally, people who find quitting easier quit sooner, meaning that the remaining smokers will increasingly find it more difficult to cease smoking. Another explanation is that anti-smoking policy impacts mostly richer inhabitants of cities, who also have higher availability of substitutes. Thus, the remaining smokers will be inhabitants of rural areas with few options and low reachability by information campaigns (Christiansen et al., 2012).

Because of this, we propose another model in Figure 2, which takes this into consideration by using exponential rather than linear extrapolation, leading to the prediction that the current trend will see the prevalence of smoking at 13,31 % of the adult population in 2040, and around 22 % by 2025.

This number for combustible tobacco products needs to be interpreted as a lower bound for overall tobacco prevalence, as more recent data also include heated tobacco products and other alternatives. Tobacco prevalence will always be higher than just combustible tobacco products usage, and therefore the goal of tobacco-free Europe is far less realistic than that of smoke-free Europe.

Figure 2: Exponential extrapolation of combustible tobacco prevalence trend from 2020 to 2040



Source: Eurostat 2006-2020, own calculations 2021-2040

This is the case despite the introduction of the initial Tobacco Products Directive (TPD) in 2001, its revision in 2016, and a number of recommendations by international bodies such as WHO and numerous more restrictive regulations by Member States. The more or less smooth decline in smoking rates without major breaks in years when significant policy changes were implemented indicates that smoking cessation is not driven primarily by regulatory restrictions but by gradual changes in consumer behaviour and attitude to smoking.

These two factors are admittedly not independent. Much of the research on health risks associated with smoking was conducted by public institutions and international organisations and disseminated by European and local authorities, which thus influence public perception of smoking.

It nonetheless seems that given all the available data, even if the EU continues to tighten the restrictions placed on tobacco products, the 5 % goal by 2040 appears to be far from realistic.

The goal of tobacco-free generation by 2040 may cause harm

Attempts to introduce overly strict regulations to curb the smoking rates might easily backfire: for instance, placing some alternative tobacco products, such as e-cigarettes, on the same regulatory level and placing them in the same tax brackets as objectively far more harmful traditional cigarettes, or severely limiting access to information about these products would most likely adversely affect public health, regardless of the effect on smoking prevalence (Fraser et al., 2018). Overly strict taxation schemes may also lead to worsened living conditions for marginalized groups without leading them to stop smoking, as Christiansen shows (2012).

The methods proposed by the European Commission are based on disputed scientific claims

In this study, we also look at the opinions of both medical and economic policy experts on existing and proposed regulations. We pay special attention to the regulation of e-cigarettes and generally alternative tobacco products.

A letter of scientists (Fagerström et al., 2021), sent to the European Commission in reaction to the publication of SCHEER's opinion on e-cigarettes' harm, describes the arguments supporting SCHEER's conclusions as misleading. They state that:

"...the SCHEER Final Opinion on electronic cigarettes leaves the users of electronic cigarettes without guidance and clear information about the level of risk of these products compared to traditional cigarettes. Without clear information on the relative risk associated to the electronic cigarettes, users of electronic cigarettes may be led to the wrong conclusion that electronic cigarettes are as harmful as traditional cigarettes and so go back to smoking cigarettes... the Final SCHEER Opinion added to the confusion, since it did not provide any answer, nor indication about a risk of e-cigarettes compared to smoking."

Others, like O'Leary et al (2021) join this criticism, describing the poor evidence behind claims of e-cigarettes and alternatives to conventional smoking being of little or no help in cessation. Their conclusion is supported by Eurostat's own data (Eurobarometer, 2021).

We further consult with harm reduction and medical researchers with expertise in a range of local contexts. The overall conclusion is that the European Commission's goals of achieving a tobacco-free generation is more a result of ideology and a useful campaigning talking point, and less so a well-thought-through policy proposal. As such, it stands little chance of improving health in an enforceable and financially viable way.

There are better alternatives

Seeing that the goal of a tobacco-free generation is unattainable, European policymakers should consider harm reduction as an alternative approach. As the name implies, the core of harm reduction policies is to minimize the negative impact of smoking on public health. If evidence shows that we cannot stop smoking altogether without incurring more harm than benefits, European decision-makers should enable the creation of incentives for smokers to switch to less harmful products and thus help them to begin phasing out smoking and tobacco products, in general, more gradually.

This approach is taken by McNeil et al. (2015) in their study, which finds that in e-cigarettes, *"most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger"*. Their conclusion is that e-cigarettes are a safer alternative to smoking, and it would benefit both public health and budgets to encourage the switch from smoking to vaping. This approach has proven to be successful: today the United Kingdom is the country, right after Sweden, with the lowest smoking prevalence in Europe (12% and Sweden 7%) (Fagerström et al., 2021). As a first step, smoke-free rather than tobacco-free generation should be set as the policy goal, to set realistic goals and indicate the focus on reducing first the most harmful products usage.

Good harm reduction policy also includes active engagement of the policymaker with both the academia and the industry to share information with the goal of making informed and evidence-based policy decisions. Furthermore, it also means that decision-makers should not discourage innovation and development of safer products that could assist current smokers in cessation, or at least allow them the option of a less harmful legal alternative to the products they are currently using.

The report published by the Special Committee on Beating Cancer (2022) and approved by the European Parliament is a good step in this direction, as it advocates for “*measures supporting the elimination or reduction of harm*” through evidence-based policies.



Good harm reduction policy also includes active engagement of the policymaker with both the academia and the industry to share information with the goal of making informed and evidence-based policy decisions.

The content of the study

In the course of this study, we analysed the existing European legislation and its principles through the optics of evidence-based research. We look at their effects on public health and public finances, in order to identify the strongest and weakest points of the current EU regulatory framework.

Consequently, we examine the policies introduced by the CEE Member States on top of the European regulation, as well as those of several other countries that took distinctive stances on anti-smoking policy. Our goal is to identify the best practices that could be adopted on the European level, as well as examples of regulations to be avoided.

After conducting an in-depth quantitative and qualitative analysis and recommending sound harm reduction policies that would stand a higher chance of significantly improving the lives of Europeans, we go on to develop the Harm Reduction Index, rating Member States in accordance with their current performance of harm reduction policy.

Our goal in this study goes hand-in-hand with the goals of the European Commission and the Member States, to save lives and improve the quality of life of smokers and non-smokers alike. On the other hand, we also understand that there are limits to which steeper taxes and stricter regulation can serve as motivation to combat addiction and that rather than making smokers’ lives more difficult in pursuit of a pipedream, we should seek ways to offer them safer options and actively help them in their struggle with smoking.

2 SCOPE OF THE STUDY

There are two main axes among which we can delineate what is covered as part of this analysis. The first is the material scope of the study, i.e., regulation of what types of products is discussed, and the second is the geographical scope, which determines for which Member States, apart from the EU as a whole, the analysis is conducted.

2.1 MATERIAL SCOPE

As the main focus of the study is the application of harm-reduction principles in European and local regulation, there is naturally a need to contrast the EU's and each Member State's approach to alternative tobacco products as opposed to traditional combustible products.

Over the course of the study, we, therefore, examine the successes and failures of policy towards cigarettes, and to a lesser degree also cigars, cigarillos, and RYO tobacco products. The focus on cigarettes is justifiable due to their continuing – although weakening – dominance of the market for tobacco products, and consequently also because of the focus put on cigarettes by policymakers, not the least in their taxation policy, which tends to be by far the strictest compared to both other traditional products and the alternatives.

When speaking of less harmful alternatives to combustible tobacco products, we mostly concentrate on e-cigarettes. The reason again is their market dominance among alternative products, as well as the fact that since they have been well established on the European market for about a decade, both the EU and Member States have already adopted various sets of policies towards their regulation that we can analyze as exemplary of the States' attitude towards smoking alternatives. The longer time that has passed since the introduction of vaping to the market also means that we have sufficient data on usage that make the analysis possible.

Among other alternative products, we also discuss heated tobacco products, although their lower popularity in Europe provides us with less data compared to e-cigarettes. Similar situation applies for oral tobacco products, which are discussed especially in connection to the particular case of snus in Sweden.

2.2 GEOGRAPHICAL SCOPE

The main focus of the study is the Central European region, among which we count the Czech Republic, Slovakia, Poland and Hungary, as well as neighbouring Germany and Austria. These countries on their own present a very good sample to observe the effect of differing harm reduction policies on, since, despite all being part of the common EU market, they took a range of different approaches to smoking and tobacco regulation.

For more context, the study also includes Sweden. The country is especially notable due to its open approach to harm reduction practices, even compared to the other Member States that try to apply harm reduction principles in their regulation, and also by being at the same time the country with the

lowest smoking prevalence in Europe. For these reasons, it is worth examining Sweden's policies so that they can be then used as a benchmark for harm reduction practice in the other Member States and EU regulation overall.

3 METHODOLOGY

When looking into the current state of affairs on the European level in Section 4 and in the individual Member States in Section 5, we ground our analysis in the rigorous theory of regulation and use the following three key points mentioned in the Introduction as our starting points:

- I. The European Commission's goal of a tobacco-free generation by 2040 is unrealistic.
- II. Certain findings and tools of analysis in the European Commission's materials are based on disputed scientific claims.
- III. Better alternatives for reducing the impact of tobacco usage on public health exist and are already practised in some countries.

The first two claims are discussed in more detail with supporting evidence in our analysis of European regulation. Proposition III defines the optics through which we approach the analysis, which are the harm reduction principles. This section introduces the basics of harm reduction and economic mechanisms of market regulation, with the hope of clarifying the tools used in our discussion of tobacco regulation and identifying recommendations for implementation on the European level, inspired by the findings from the Member States.

Section 3.4 also introduces the Harm Reduction Index.

3.1 HARM REDUCTION

Tobacco harm reduction (THR) is an approach to public health policy inspired by a broader set of tools that had been previously successfully used to combat the consequences of addiction in other areas. It starts with the recognition that despite the proven health risks associated with smoking, there is a limit to the good that repressive policies such as bans or tax hikes can achieve (Hawk et al., 2017).

While the concrete threshold is difficult to identify and varies by country and socioeconomic background of individual smokers, at a certain point additional restrictive measures will result not so much in smoking cessation, but rather in a move to the grey economy or decreased material well-being for smokers, who despite paying steep taxes are unable to stop. Clearly, this does not act towards better public health but instead leads to additional bad outcomes.

Good harm reduction policy takes these facts into account, and rather than focusing on restrictions to encourage cessation focuses on minimizing the health impact on current smokers and their surroundings, most often by incentivizing cigarette smokers to switch towards less harmful products. This is made possible due to technological progress and the development of alternatives to standard combustible tobacco products in recent years, as well as the fact that even though smoking is associated with several leading causes of death in developed countries, this health risk is not presented by nicotine.

"Most of the physiological harm attributable to cigarette smoking derives from the toxicants in tobacco and combustion products. Preventable morbidity and mortality has overwhelmingly been related to

combusted tobacco smoking, not to nicotine itself. Decoupled from combustion or other toxic modes of delivery, nicotine, by itself, is much less harmful,” says Niaura et al. (2017) on the address of health risks posed by different tobacco products.



Diseases such as lung cancer or cardiovascular problems are primarily caused by the chemical processes of tobacco burning

Nicotine, while highly addictive, is otherwise not too harmful (Fagerström & Bridgman, 2014). Diseases such as lung cancer or cardiovascular problems are primarily caused by the chemical processes of tobacco burning, meaning that products deliver nicotine without tobacco burning, such as heated tobacco products, e-cigarettes, snus, and others, are in comparison significantly less harmful to the user and those around them (Siegel, 2011).

The tools associated with tobacco harm reduction are:

- I. Differentiated tax rates, depending on how harmful the taxed product is, with less harmful products being taxed at a lower rate so that smokers are financially motivated to switch to less health-impairing alternatives.
- II. Objective public information campaigns on the relative risks of smoking and its alternatives, including regulation of advertisement scaled to the relative risks of the advertised products.
- III. General marketing regulation allowing companies to communicate with consumers to a greater extent about products with THR profile while introducing a limitation on the promotion of comparatively more harmful products. Plain packaging, point of sale, and online sales regulation are all examples of areas where relative risk assessment can play a role.
- IV. Abstaining from banning any new products with a lower level of health risk than conventional cigarettes, as such products have the potential to become a tool for harm reduction and gradual cessation.
- V. Leaving the market open to new products and friendly to positive innovation in the industry, which results in new products with still lower risk to health to consumers.
- VI. Creation of simple, transparent, efficient, and enforceable regulation guaranteeing elementary consumer safety, and keeping harmful and faulty products off the market, while not curtailing innovation.
- VII. Encouragement of gradual cessation through switching to alternative tobacco products first and through available addict recovery and other care.

This list is by far not complete, and various other good practices exist. It is the purpose of our analysis in Section 5, where we focus on current measures in CEE countries, to identify successful (and less successful) applications of these principles by local regulators, and explore other paths that some countries have taken, which might inspire European policy.

As a good harm reduction policy to a large degree depends on correct estimation of harm and health risks, as well as reasonable predictions of effects of different regulatory steps, it is vital that any harm

reduction is evidence-based and grounded in solid scientific findings. To ensure this, we not only base our analysis on reliable data and articles published in peer-reviewed journals, but we also approach a number of independent experts in the field of harm reduction and tobacco policy to comment on the current state of affairs and recommendations outlined in this study.

3.2 THEORY OF REGULATION

When devising regulation with the purpose of improving public health in mind, the policymaker must not neglect basic economic principles and certain adverse effects that poor legislation can have.

Market regulations consist of creating barriers and limitations to access to certain goods and services, in the case of tobacco regulation with the purpose of achieving higher cessation rates. Good regulation manages to create incentives for cessation without generating any external effects leading to new problems in other areas of the economy.



Good regulation manages to create incentives for cessation without generating any external effects.

The policymaker should always remember the risks of introducing harmful regulation, given that the legislative process is always more open towards implementing new legislation than to amending or repealing existing regulation (Higgs, 1987). Bad regulation that introduces unintended adverse effects also has a tendency to snowball. Because of the ratchet effect, it is easier to solve deficiencies by introducing another piece of legislation or increasing expenditures on implementation and enforcement, rather than amending or repealing the original act, resulting in a non-transparent and complex set of bad regulation. A thorough prior regulatory impact assessment is a necessity, especially for public health strategy.

This especially concerns bans and limitations to market access. Well-intended bans and restrictions on information campaigns, advertisement or point-of-sale displays can easily lead to an under-informed public about the respective risks of different products and the availability of alternatives, thus increasing the pressure and necessary expenses on a good and unbiased public information campaign. Too little such regulation even on the most harmful products can on the other hand significantly slow down the journey toward a tobacco-free generation.

Jindřich Vobořil, director of the Think Tank for Rational Addiction Policy, states that for instance *“targeted measures to limit sale of e-cigarettes only lead to encourage smoking and consumption of more harmful standard tobacco cigarettes. Furthermore, passive exposure to vapors from new products pose in comparison only a negligible risk”* (e15, 2021).

Another problem that the regulator faces is the constantly changing nature of the market. While legislation is too often designed to target the current state of affairs, the market is dynamic, and often changes so quickly that regulation becomes obsolete before the legislative process is completed. Good regulation is forward-thinking and allows for the development of new products, while not leaving innovation altogether unregulated so that basic consumer safety is guaranteed. This is again especially important for the market for tobacco-related products, as new products are generally less harmful

than smoking tobacco products – for instance, snus is estimated to be 95 % safer than cigarettes (EurekAlert, 2017).

One of the most complex problems for the regulator is fiscal policy. The approach recommended by WHO and the European institutions has for a long time been ever-increasing tax rates on cigarettes and all tobacco-related products (WHO, 2021). *“Taxes are never popular, yet they are our strongest ally in saving lives through tobacco control,”* says Zsuzsanna Jakab, the former WHO Regional Director for Europe. Indeed, tax rates are one of the most effective tools the policymakers have at their disposal.

However, consistent with the principles of harm reduction, tax brackets must be set up to encourage smoking cessation and switching to less harmful products. Simply introducing high taxes leads to adverse effects, as numerous sources show (such as Priemer and Kulcik, 2016), such as the growth of illicit trade and grey economy, poverty and addiction trap for the less well-off, and, as a consequence, lower benefits to public health.

This is connected with another indicator of a good regulation, which is enforceability. Regulation must be clear, predictable, and fit for the current state of the industry and the openness of the society towards the regulation, so that the norms can not only be implemented but also realistically enforced. The main indicator for this is the clarity of the legal system and the size of the grey economy in tobacco and alternative tobacco products.



Regulation must be clear, predictable, and fit for the current state of the industry and the openness of the society.

When analysing the regulation at both European and Member State levels, we specifically identify all these outlined properties that good regulation should possess. We also examine the incentives that the policymakers face – whether there is clear professional and political responsibility for bad regulatory outcomes, whether goals for the regulators are satisfactorily outlined and how their achievement is measured, and whether alternative contingent strategies are in place in case of underperformance in fulfilling these goals.

3.3 STRUCTURE AND METHOD OF OUR ANALYSIS

To fully incorporate both the tobacco harm reduction optics and the economic insights from regulation theory, we split our analysis of current the European regulation and the legislation of each Member States into two parts: the first subsection is always devoted to qualitative analysis and description of current measures. In the case of the EU, we present a detailed summary of all major pieces of legislation and declarations of goals, with a special focus on the Tobacco Products Directive (TPD2), and present the findings in the form of a SWOT analysis.

Discussion of local regulation introduced by the Member States on top of the central European measures will follow up on its conclusions and will result in a detailed cross-country comparison for the CEE region as well as a within-country comparison of approaches to different product categories, which will also serve as an input into the Harm Reduction Index.

The second part of our analysis for the EU and each country will focus on quantifiable policy parameters and indicators of the success of tobacco policy on both public health and finances. Similarly, as with the qualitative indicators, this will result in a detailed comparison of how successful individual Member States are.

The observed indicators are:

Qualitative indicators:

- Level of implementation of European legislation
- Harm reduction officially part of public health strategy
- Quality of communication and existence of campaigns informing objectively about tobacco products and health risks
- Existence of plain packaging regulation on top of the EU requirements
- Existence of flavour bans and limitations on top of the EU requirements
- Existence of public space bans on smoking/vaping
- Existence of point-of-sale regulations / display ban exceeding the EU regulation
- Existence of other policies specifically aimed at encouraging smokers to switch to less harmful products
- Market openness

Quantitative indicators:

- Shares of FMC (factory-made cigarettes), THP and vapour-based products in the country
- Excise tax rate on cigarettes
- Difference of excise tax rates on cigarettes and e-cigarettes (and other brackets, if they exist)
- Affordability: fraction of a cigarette pack price to average income
- Share of taxes collected on tobacco on the overall tax revenue
- Size of illegal trade of tobacco products

3.4 HARM REDUCTION INDEX

The Harm Reduction Index summarizes our findings about the application of harm reduction practices, as well as feedback from local policy and medical experts. Comments of the experts participating in the questionnaire will also be included elsewhere in the study, especially in sections 4 and 5. Each Member State is assigned points representing its success in applying these practices, with more points

meaning a more extensive presence of harm reduction in the country's policy. Based on their respective scores, the countries can then be ordered into a ranking.

For the construction of the Index, we use data from two different categories:

- a) **The current state of local regulation**, focusing on the differences between rules for smoking and usage of less harmful products. Strict regulation of cigarette packages for example increases a country's score, as it is an efficient tool of smoking deterrence (Kralikova & Zvolska, 2019). However, if the same level of strictness is applied also for alternatives to smoking, like vaping or nicotine pouches, the efficiency of the measure against smoking is lowered and so is the score the country receives in the regulation category of the Index.
- b) **The current tax policy**, again with special attention to the differences between traditional factory-made cigarettes and tobacco products, and alternatives like e-cigarettes, nicotine pouches, heated tobacco products, or in Sweden's case snus.

Among the main areas that do not inform the Index is current and predicted smoking prevalence and usage of alternative products, public opinion on smoking and on less harmful alternatives as a cessation tool, or current medical statistics from the Member States (such as the prevalence of diseases associated with smoking).

The reason for omitting these inputs is that they measure the success of past policies, rather than the policies in place today, which are our main focus. A country could have reduced smoking significantly through successful policies in the early 2000s, and later go on to introduce legislation contrary to the harm-reduction principles. Such a country would score badly on the Index, despite possibly still having low cigarette usage.

More in detail, the criteria used in the construction of the Index in the regulation component are packaging regulation, which incorporates the difference between combustible tobacco packaging regulation and regulation of packaging of alternatives. The maximum score of 10 points would mean a total plain packaging for combustible tobacco and no strict packaging requirements on alternatives. The implementation of TPD in all the Member States naturally limits the attainable points in this section.

Category cigarette advertising and point of sale regulation includes limits on where and how cigarettes can be advertised (Tv, magazines, during sports or live entertainment, display at point of sale, etc.). It also incorporates limits on sales of cigarettes – mandatory distance from schools, bans on vending machines sales, or sales only in specialized shops. A higher score means a more restrictive policy toward cigarettes.

Similarly, regulation of advertising and display norms, as well as sales and product regulation are included, with higher scores awarded to the Member States where the rules for less harmful alternatives differ from rules imposed on smoking. The same applies to indoor usage bans and bans on flavours and different intensities. If these policies are less restrictive towards less harmful products than to cigarette smoking, the countries gain points. Finally, based on expert opinion, this section also

includes the recognition of harm reduction practices by public officials and policymakers and general market openness.

For taxation, we look at the relative degree of affordability and tax rate differentials between smoking, e-cigarettes and vapour-based products, HTP, and oral products. The score assigned to each of the tax differentials is weighted by the prevalence of the given alternative product in the Member State in question. Based on the experts' opinions, we also include the enforceability of the regulation and share of illicit trade on the market – with more successful enforcement of regulation and tax compliance yielding higher scores. For the obvious reason of smuggling, this indicator is adjusted for proximity to non-common market countries.

The points are standardized to a 0-to-50-point scale, with regulation being around 60 % of the total weight and taxation the remaining 40 %. It is important to note that given the existing EU regulation as well as general feasibility, the highest scores are not realistically achievable, which is why all countries scored less than 30 points on the scale.

In the future, the Index can be expanded to cover more countries outside the CEE region.

4 WHERE ARE WE AT THE EU LEVEL?

This chapter focuses on describing the existing legal framework for tobacco products and tobacco-related products as described in Chapter II: Scope of the Study, or lack of thereof. Standard tobacco products regulation and its development are discussed to provide context for the current debate, as well as to illustrate regulatory trends.

There are several baseline documents used for the assessment of the existing legislation and its future prospects. Naturally, the focus is put particularly on the existing Tobacco Product Directive (TPD2) as the main piece of European legislation covering these markets, as well as the related TPD2 Application Report issued by the European Commission in May 2021, which provides certain important take-aways from the experience with applying the Directive. The supporting document to the Report is the Support study to the report on the application of the Directive 2014/40/EU, published by RAND Europe and ICF S.A.

Another document that warrants discussion is the Final Opinion of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), published in April 2021, which reviewed some of the newer scientific findings on electronic cigarettes and their health impacts and conducted an analysis of the commonly hypothesized risks.

Other documents are mentioned to provide context for current legislation and its origin, but a thorough analysis of out-of-date documents or documents whose outcomes have been assimilated into later legislation is not provided.

The first several sections of this chapter focus on the content and especially the coverage of the existing legislation, and its omissions and qualitative deficiencies, while the second part supplements this outline with a quantitative analysis of the health and fiscal outcomes of the application of the existing legislation, as well as certain predictions in connection to the most likely future scenarios. Most importantly, following up on the forecast from Introduction, the section also analyses consumer behaviour in CEE Member States in the context of the Commission's proposed goal of tobacco-free generation in 2040, with less than 5 % of the European population using tobacco.

4.1 QUALITATIVE AND CONTENT ANALYSIS OF EXISTING EU REGULATION

While the EU member states have had to deal with the challenge of regulating the market for tobacco and later alternative tobacco products for some time, a central harmonized European tobacco policy has only relatively recently become an important part of the European project, although it quickly gained significance as a major element of the coordinated health, and to some extent also fiscal policy.

Among the first results of this coordinated effort was the Tobacco Product Directive of 2001 (TPD1), regulating the manufacture, presentation, and sale of tobacco products in the EU member states. Among the main goals of TPD1 (Directive 2001/37/EC) was to reduce the wide variance of approaches to tobacco regulation among the member states.

Following its introduction in the early 2000s, the attention to harms caused by smoking and related social phenomena continued to grow, with tobacco identified as the leading preventable cause of death, and pressure for further legislation intensified, which many member states attempted to accommodate by going beyond the TPD (as discussed in more detail in the following chapter). Among the results of this trend was the WHO Framework Convention on Tobacco Control (WHO FCTC), ratified in May 2003 and coming into effect in 2005. The treaty attempted to identify the threats to public health and outline the main pillars of tobacco control policy, including harm reduction practices.

Although some later researchers point out that the practical effect of WHO FCTC has been overestimated due to errors in reporting and compliance (Hoffman et al., 2012), certain practices were successfully introduced by the majority of participating countries, such as obligatory health warnings (Nikogosian, 2010). Moreover, WHO FCTC became an important steppingstone for future European regulation.

Another development was the introduction of electronic cigarettes and other alternative tobacco products. This market development further contributed to the need for updated regulation. The review process that resulted in TPD2 started in 2009 with an Impact Assessment of the previous Directive – consisting of opinions by European bodies, independent experts, stakeholder meetings, and Eurobarometer surveys, which was completed in 2012. The revised Directive was approved in 2014 and came into effect in May 2016.

In this section, we provide content analysis of the TPD2 and connected legislation and documents and recommendations suggested by the reports on the application of said regulation, as well as a qualitative analysis of the strengths and weaknesses and the resulting threats and opportunities for the alternative tobacco products market regulation.

4.2 TOBACCO PRODUCTS DIRECTIVE (TPD2)

As mentioned above, TPD2, as the most extensive piece of central legislation covering tobacco and tobacco alternative products to-date, was signed in 2014 and became applicable in 2016, replacing the 2001 Directive.

TPD2 extended the legislation's coverage to apply to cigarettes, cigars, pipe tobacco, waterpipe, cigarillos (short and slim cigars), smokeless tobacco (snus), Roll-Your-Own tobacco (RYO), and E-cigarettes. The main changes and regulations contained in the Directive were:

Mandatory health warning on packaging: The reviewed TPD2 further specified the rules outlined in the original Directive and increased the health warnings for cigarettes and RYO from the previous 30-35 % of the pack text warnings to 65 % on the front and on the back side of the pack picture and text warnings. The first proposal contained even stricter regulation of 75 % of the pack but was later reduced. An implementing act specifying the health warnings on tobacco products for smoking, including cigarettes and roll-your-own tobacco, was passed in 2015. These health warnings, required by the TPD, should comprise a photograph in colour, a text part on smoking-related harm and information on smoking cessation. The warnings are grouped in three sets, to be rotated every year, to ensure that they retain their impact for as long as possible.

Ban of cigarettes and RYO products with flavours: Cigarettes and RYO tobacco products may no longer have characterising flavours such as menthol, vanilla or candy that mask the taste and smell of tobacco. menthol, one of the most commonly used flavourings, had a 4-year derogation in implementation.

Modification of labelling and further regulation of packaging: Contents labelling regulation on cigarettes and RYO products was changed, so that the tar, nicotine and carbon monoxide contents is replaced with a message reading 'tobacco smoke contains over 70 substances known to cause cancer.' Manufacturers and importers of tobacco and RYO products must submit reports in standardized format on the ingredients of said products.

Furthermore, the shape of the tobacco packages was regulated to ensure good visibility of health warnings, meaning that slim packs and packs with irregular shapes are banned, as well as packs of under 20 cigarettes. Also banned is promotional messaging on packages, including suggestions that a particular product is less harmful.

Safety regulation of e-cigarettes containing nicotine: One of the landmark aspects of TPD2 is that it is the first European regulation to cover e-cigarettes. The Directive sets the maximum nicotine concentration of 20 mg/ml and maximum volume of the e-cigarettes' tank to 2 ml and nicotine liquid refill containers to 10 ml. They also need to fulfil additional safety requirements, such as being child-proof and tamper-proof and contain a mechanism for preventing spillage during refilling. The ingredients are required to fulfil minimal conditions on purity, and the devices should be delivering a consistent amount of nicotine.

E-cigarette packaging regulation: Packaging is required to include a warning covering 30 % of the packaging, stating that e-cigarettes also contain nicotine, along with information on the product's nicotine content and a leaflet with instructions for use and information on adverse effects, risk groups and addictiveness and toxicity. Just as for cigarettes, promotional elements are prohibited on e-cigarette packaging, and cross-border advertising and promotion of e-cigarettes are not permitted. Advertising is also forbidden in printed publications, on the radio, and through audiovisual commercial communication.


Monitoring of e-cigarettes: Given the novelty of the product at the time of TPD2's introduction, member states, manufacturers, and importers are required to submit reports on available products on the market and 6 months before introducing a new product to the market, the volume of their sales and customer preferences, allowing the states and the Commission to collect evidence on the addictiveness and risks of the products, especially for young people, to be presented in an implementation report five years after introduction (the report is discussed below).

Provision for banning cross-border trade and combating illicit trade: Member states retain the right to prohibit cross-border distance sales of tobacco products. Certain new measures are nonetheless implemented to help fight illegal sales of tobacco and alternative tobacco products, such as the EU-wide tracking and tracing system in the legal supply chain and security features on products comprising of watermarks, holograms, and other elements. These measures were implemented for cigarettes and RYO products in 2019 and are to be implemented for other products by 2024. Mandatory age verification for cross-border distance sales was left at member state discretion in the final text.

Finally, the ban on snus (tobacco product for oral use typically consumed in Sweden) continues to be applied throughout the EC, with the exception of Sweden.

Article 28 of the TPD2 introduced a timeline for a further review of the Directive, setting 2021 as the next review date, a process which is already ongoing, as the reports below document.

Table 1: Summary of TPD2 contents

	
Contents pertaining to alternative tobacco products	Wider range of products covered, including e-cigarettes or snus.
	Elementary consumer protection in terms of safety and quality.
	Central coverage of e-cigarettes packaging rules, including the 30 % product packaging for warning messages rule.
	Monitoring of new alternative tobacco products to increase safety.
	Advertising regulation and bans, levelling the field with standard tobacco products.
Notably missing from TPD2:	Measures to combat illicit trade with e-cigarettes.
	Temporary provision for later developed products.
	Central plain-packaging regulation (although originally proposed) and point of sales advertising ban, leading to different measures being taken by individual member states.
	Central public space usage regulation.

4.2.1 TPD2 APPLICATION REPORT

As previously mentioned, Article 28(1) of TPD2 required the Commission to submit a report the on application of TPD2 by May 20, 2021, evaluating how TPD2 succeeds at fulfilling its goals of harmonizing tobacco regulation and fulfilling the WHO FCTC objectives, and generally protecting the public health of the EU's citizens. The Report builds on findings published in the extensive RAND EUROPE & ICF Support Study to the Report, which is referred to in the quantitative section of this chapter.



Smoking prevalence among citizens above 15 years of age decreased from 26 % in 2014 to 23 % in 2020.

The Report finds conflicting results, stating that while smoking prevalence among citizens above 15 years of age decreased from 26 % in 2014 to 23 % in 2020, and youth smoking rates decreased by 5 percentage points to 20 % during the same period, indicating a positive behavioural trend and a change in the public perception of smoking, the usage of electronic cigarettes has increased during the same time period.

While the level of compliance in transposition was relatively standard, the initial analysis revealed discrepancies in definitions and especially in relation to packaging and labelling norms and norms concerning novel products, which threatens the TPD2's goal of market harmonization. A number of states did not manage to implement the necessary legislation by the 2016 deadline, resulting in infringement proceedings, which have however since been resolved.

Further problems are presented by different degrees of enforceability of the legislation in various states, and widely varying sanctions for non-compliance. A special case of non-compliance was presented by the ban of menthol flavour, despite the fact that all flavours were to be banned by 2020, including those with a high market share. Enforcing this ban proved to be highly resource-intensive, states the Report, while the effective added value for human health and the efficiency of certain provisions is negligible.

Regarding novel tobacco products, the Report contends that the coverage of TPD2 is inadequate and in need of revision, as many new products, such as oral nicotine pouches and generally nicotine products not containing tobacco, are not covered at all, or are covered only minimally. A similar situation applies to heated tobacco products (HTPs), whose presence in the market continues to grow, and which require additional provisions covering health warnings, product safety regulation and use of flavours, to remove disparities compared to other products on the market.



Coverage of TPD2 is inadequate and in need of revision, as many new products, such as oral nicotine pouches and generally nicotine products not containing tobacco, are not covered at all

Besides the proper legislative definition of these products, the Report identifies the inflexibility of defining new categories as one of the reasons for the legislation's rigidity and tardiness in reaction to market developments. While they present many opportunities as cessation tools, concludes the Report, novel products are also a source of legislative loopholes.

The narrative of the TPD2 Application Report seems to reveal that the European Commission favours the approach of merely including new products in existing categories. An example of this is nicotine pouches and their inclusion under the regulatory category of oral tobacco, thus possibly banning these products in the EU.

A special case of alternative products are electronic cigarettes, which have already been covered in TPD2 as a special case, and the regulation of which the Report finds highly successful in terms of its scope and implementation, although certain issues with labelling and health warning are identified. The most challenging aspect of e-cigarettes' regulation was the ban on commercial communication and sponsorship activities to promote the products, especially with the simultaneous growth of popularity of social media.

The popularity of flavours in e-cigarettes liquid is further identified as worrying, and extending the flavour ban to e-cigarettes is strongly suggested to decrease attractiveness to non-smokers and to level the playing field.

Finally, the Report concludes that TPD2 has contributed to the improvement of public health, and through harmonization provides added value, meaning that member states could not have accomplished the same objectives alone. Generally, it recommends tighter tobacco market regulation in order to fulfil the EU's provisional aims for 2025 outlined in Europe's Beating Cancer plan.

4.2.2 SCHEER FINAL OPINION

The body of existing EU legislation and practices pertaining usage of alternative tobacco products, namely e-cigarettes, were further reviewed by SCHEER at the request of the European Commission, which published its final opinion on April 16, 2021. Focusing on the potential risks and harms of usage of electronic cigarettes, SCHEER finds:

Strong evidence for: the risk of poisoning and injuries due to burns and explosion, albeit with low incidence; the hypothesis that nicotine in e-liquids is implicated in the development of addiction and that flavours have a relevant contribution for the attractiveness of use of electronic cigarettes and initiation.

Moderate evidence for: risks of local damage to the respiratory tract of e-cigarettes users, albeit with low incidence; long-term risks of damage to the cardiovascular system; risks of local irritative damage to the respiratory tract mainly due to exposure to glycols to second-hand users; the hypothesis that electronic cigarettes serve as a gateway to smoking/the initiation of smoking, particularly for young people.

Weak evidence for: risks of carcinogenicity of the respiratory tract due to long-term, cumulative exposure to nitrosamines and due to exposure to acetaldehyde and formaldehyde and metals in aerosol; risks of other long-term adverse health effects, such as pulmonary disease CNS and reprotoxic effects; risks of systemic cardiovascular effects in second-hand exposed persons due to exposure to nicotine; the support of electronic cigarettes' effectiveness in helping smokers to quit or reduce smoking.

No data for: the claim that specific flavourings used in the EU pose health risks for electronic cigarette users following repeated exposure.



Some of the key findings by SCHEER have not gone unchallenged. This is particularly the case for the gateway hypothesis.

Some of the key findings by SCHEER have not gone unchallenged. This is particularly the case for the gateway hypothesis, for which SCHEER finds moderate evidence, and for the weak evidence that SCHEER finds for the effectiveness of e-cigarettes as a cessation instrument.

O'Leary et al. (2021) for instance conclude that the SCHEER's opinion is inadequately backed by scientific evidence and did not attempt to test the hypotheses of various potential health benefits of using alternative combustion-free nicotine-containing products as substitutes for tobacco cigarettes. As a consequence, they argue, individual and population health benefits of e-cigarettes as a replacement for smoking are underreported.

They further dispute the validity of the gateway theory, as alternative hypotheses were not evaluated, and cited data do not represent current patterns of use, leading to erroneous statements on trends in e-cigarettes prevalence. This is supported by Farsalinos (2021), who cites US data on e-cigarettes usage and accuses SCHEER's data of anti-vaping bias. Lastly, O'Leary et al. claim that the role of flavours in youth usage initiation is over-emphasized, and cessation effects are not sufficiently discussed.

These claims are supported by McNeill & Hajek et al. (2015), who state that youth usage of e-cigarettes is rare, and most users are current or former smokers, which is also supported by the findings of the 2020 Eurobarometer survey, and that there is significant positive correlation between the prevalence of electronic cigarettes and cessation rates. They also dispute the conclusion on flavours, claiming that vapers who use flavours are 2.3 times more likely to quit smoking than those using tobacco-flavoured e-cigarettes.

Overall, SCHEER's conclusions about health risks associated with e-cigarettes are generally undisputed. This includes the moderate degree of evidence for respiratory tract harms and risks to the cardiovascular system and a number of other factors – with the limitation of discovered incidence. However, its conclusion regarding behavioural patterns, such as cessation or initiation of usage (the gateway hypothesis), has repeatedly been challenged by a number of researchers, as well as the fact that it compares vaping to non-smoking rather than cigarette smoking as an alternative hypothesis.

4.2.3 REPORT BY SPECIAL COMMITTEE ON BEATING CANCER

The Report on strengthening Europe in the fight against cancer by Special Committee on Beating Cancer (BECA), adopted in December 2021, could mark an important milestone in European policy against cancer.

The Report recognizes that alternative products present a different level of risk and the benefit of these products as tools of cessation. The Committee suggests the application of a relative-risk informed approach to the regulation of tobacco products. More specifically, BECA:

“Calls on the Commission to follow up on the scientific evaluations of the health risks related to electronic cigarettes, heated tobacco products and novel tobacco products, including the assessment of the risks of using these products compared to consuming other tobacco products, and the establishment at European level of a list of substances contained in, and emitted by, these products; considers that electronic cigarettes could allow some smokers to progressively quit smoking; considers at the same time that e-cigarettes should not be attractive to minors and non-smokers; calls on the Commission, therefore, to evaluate, in the framework of the Tobacco Products Directive, which flavours in e-cigarettes are in particular attractive to minors and non-smokers, and to propose a ban on these, and furthermore, to propose a ban on all characteristic flavours in heated tobacco products and novel tobacco products.”

All these recommendations are very encouraging in terms of the future role of tobacco harm reduction in the EU's approach to tobacco products, with the exception of a ban on flavours in new products and e-cigarettes. Despite SCHEER's speculations of e-cigarettes as potential gateway to smoking, the flavour ban has been proven not too cost-effective to enforce, as described in Section 4.1.2, and the

evidence in Section 4.2.1 below shows that the group of people, not to mention minors, who begin smoking because of e-cigarettes even in the environment of legal flavours remains insignificant. On the other hand, imposing such regulation on alternative products might slow down the process of cigarette smokers switching to e-cigarettes or other products.

Overall, however, the Report endorses differentiation of e-cigarettes regulation (and ban only on certain favours that evidence shows are particularly appealing to minors) from other products. This is to be considered a good step in the direction of evidence-based policy-making that puts emphasis on incentivizing usage of less harmful products in cases where cessation is not immediately possible, and the most realistic way to fulfilling the goal of a tobacco-free (or at least smoke-free) generation by 2040.

4.2.4 SUMMARY

As described in the previous sections, TPD2 is currently undergoing a detailed review and a new version is being drafted. TPD3 is likely going to become a global benchmark for alternative tobacco products regulation and play a key role in achieving the goals of the updated vision set out in the WHO FCTC 2030 strategy and Europe's Beating Cancer plan introduced in February 2021. The Report from February 2022 also indicates that harm reduction may play a larger role in the new regulation.

Another tobacco related directive beside the TPD is the Tobacco Excise Directive (TED) of 2011. The TED harmonizes the definition and structural requirements of combustible tobacco products and sets the minimum rates to be applied by all Member States. The revision of the TED has been ongoing for some years and a proposal is expected in the second part of 2022. One of the issues the Commission is looking at is the harmonization of new products (e-cigarettes, HTP, oral products, ...) in a revised directive.

Given the impact of the expected regulatory outcome, it is vital that the best policy proposals are adopted. In Table 2 below, we identify some of these desirable – and also some of the least desirable – traits of the current legislation from the perspective of the viable goals discussed earlier and in accordance with the principles of harm reduction, by conducting a SWOT analysis that summarises this section of qualitative evaluation of current legislation. The following section provides quantitative evidence that further develops and supports the outlined qualitative evaluation.

Table 2: SWOT ANALYSIS

Strengths

- Successful introduction of unified European legislation in many areas that benefit both public health and create a more transparent legal environment for producers.
- Reduction of costs due to central requirements on product labelling and health warnings on packaging as compared to fragmented regulation across member states.
- Provision for consumer protection by guaranteeing a reasonable level of product safety and quality, at least for e-cigarettes.
- Positive returns to messaging by the legislators: lasting changes in public view of smoking.
- Existing regulation creates a reasonable level of awareness of the risks and harms of smoking as well as alternative tobacco products usage.

Weaknesses

- Both member states and even more strongly European regulation lags behind the development of the industry and the market and fails to react adequately quickly to new products.
- Problems with compliance and cross-state differences in implementation, as revealed by the Application Report, weaken the benefits of market harmonization.
- Nuisance regulation (such as cartridge volume limits for e-cigarettes) discourages smokers from switching to comparatively less harmful products.
- The absence of a mechanism allowing the regulator to react flexibly to changes in the market and technological innovation, or the creation of an automatic temporary baseline regime for new products in the market before a more targeted regulation is drafted. The monitoring mechanism of TPD2 may serve as a convenient basis for such a mechanism.
- Insufficiently extensive coverage of the current legislation gives rise to loopholes for producers and forces member states to enact local legislation.
- No comprehensive regulation of alternative tobacco products taxation in the EU regulatory framework in general, leading to wildly varying tax rates, which in turn create uncertainty for manufacturers and frictions in trade.
- Harm reduction practices are not sufficiently implemented and not discussed and examined in later documents, such as SCHEER's opinion, apart from the Special Committee's Report.
- Complete bans on certain less harmful products across Europe, such as snus, tend to create negative direct public health effects, as well as negative indirect effects in terms of slower innovation and market development.

Opportunities

- Extension of coverage to new products while applying harm reduction methods to dissuade users from conventional smoking and increase manufacturers' certainty.
- Application of new research and past experience in setting up the new norms to optimize public health and revenue from tobacco products taxation.
- Implementation of norms favouring the development of new products with less potential for posing health risks, for improving public health, and also for encouraging further innovation by manufacturers towards less harmful products.
- Setting up a robust European tobacco tax system through proper regulatory tools in relation to each product's harmfulness, so that users are incentivized towards using less harmful products, in order to improve health and also the state of public budgets.

Threats

- Fragmentation of the common market due to different regulatory frameworks if insufficient central regulation exists. Distortion of trade and supply chains in absence of harmonized legislation.
- Implementation of an inappropriate scope of legislation, that would force member states towards more uncoordinated regulation on one hand, or stifle innovation towards new less harmful products on the other.
- Introduction of regulation equating alternative tobacco products, which are consistently being identified as comparatively less harmful, to standard tobacco products, leading to negative public health outcomes and more complicated cessation.

4.3 QUANTITATIVE ANALYSIS OF EXISTING AND PROPOSED REGULATION

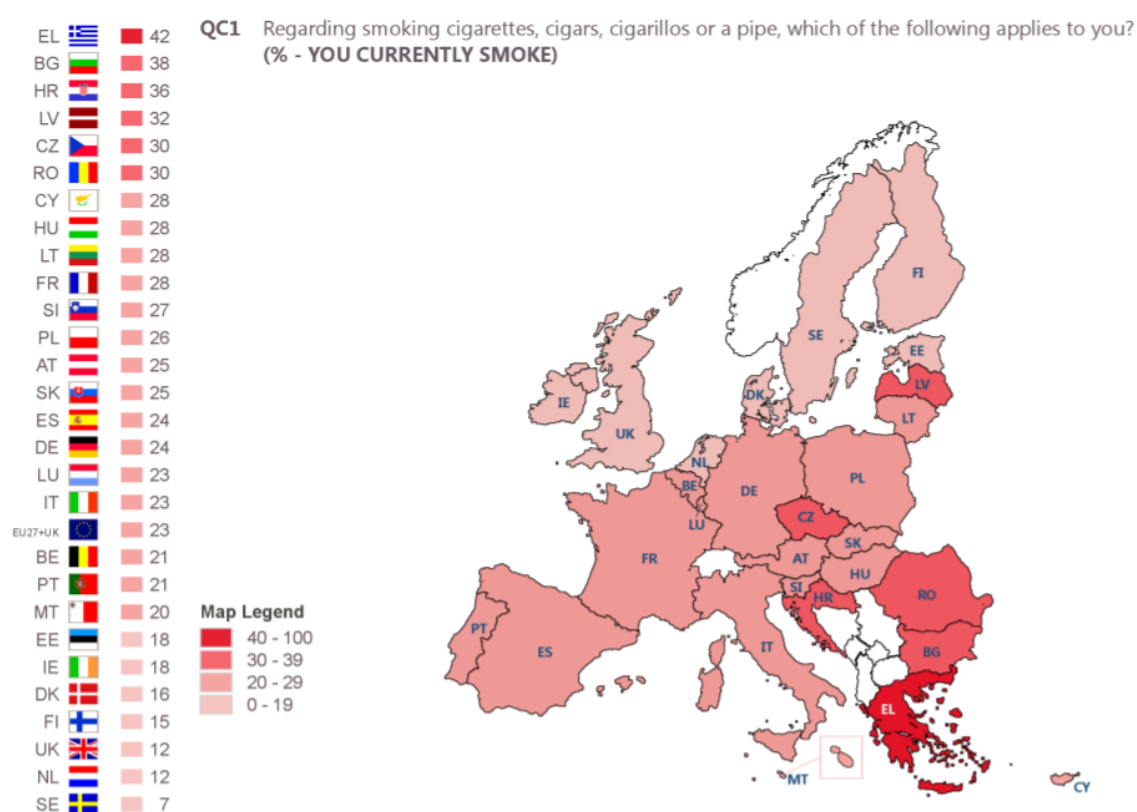
This part of the study discusses the quantifiable merits of the current European legislation in several broader categories: the impact on consumer behaviour and through it on public health, as well as the impact on public finances. Together with the chapter on additional Member State regulation discussed and evaluated below, it provides the necessary empirical basis for future legislative steps and recommendations.

Apart from the findings of SCHEER and other bodies, the European Commission has its own feedback channel in the form of the Eurobarometer. The latest Eurobarometer output on the attitudes of Europeans towards tobacco and e-cigarettes regulation was published in February 2021 and provides valuable feedback on the development of consumer behaviour.

4.3.1 CONSUMER BEHAVIOUR

The Eurobarometer finds that less than about 25 % of the respondents in the EU27 use boxed cigarettes, cigars, cigarillos, or a pipe, a decrease by two percentage points since 2017, and 21 % used to use some of these products but have stopped, a 1 percentage point increase compared to 2017. The number of people who never smoked also increased by 1 percentage point, which are all desirable trends. The countries in the CEE region, which will be of special interest in later parts of this study, are generally among the member states with higher smoking rates, although they also mostly reflect the discussed positive developments.

Figure 3: Percentage of respondents currently smoking by country



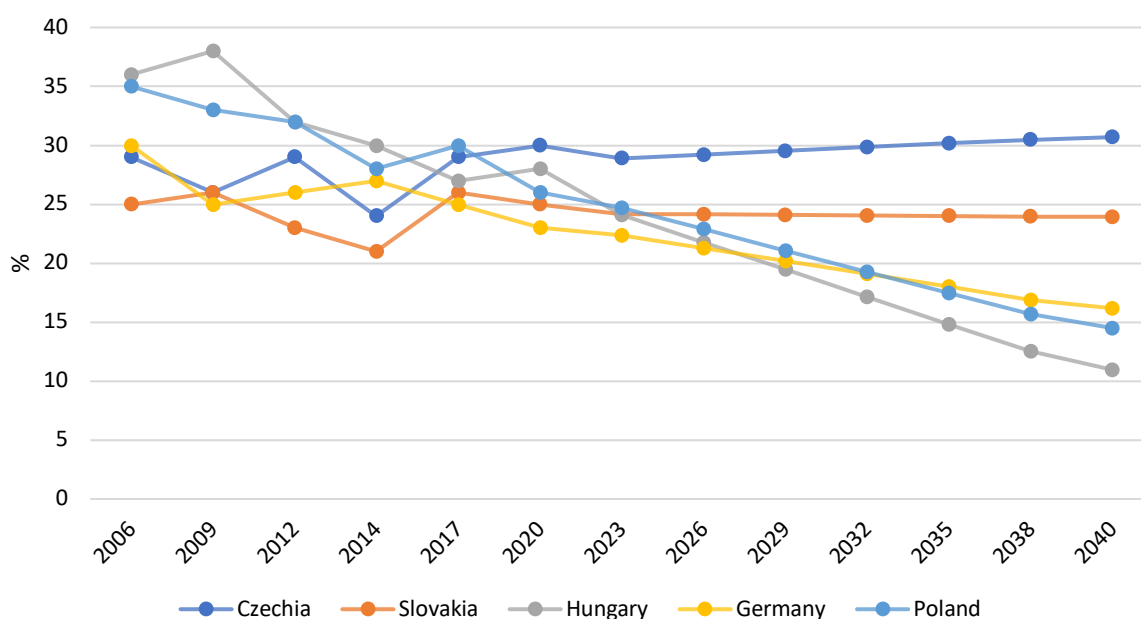
Base: All respondents, N = 28,300

Source: Eurobarometer, 2021

Reflecting on this development, it is important to return to the goal of less than 5 % of smokers in the population by 2040, set by the European Commission, which was discussed in Section 1 Introduction. We already showed on Eurostat's data that extrapolating the trends in smoking cessation, the decline we are likely going to see will not be enough to fulfil this goal and that policies aimed at harm reduction and minimizing tobacco's impact on public health, rather than the number of smokers, might be a more beneficial course of action.

Following up on this discussion, let us have a look at similar trends in the CEE countries, which generally have higher smoking rates. We look specifically at Czechia, Slovakia, Hungary, Poland, and Germany, and using a linear forecasting model, we see in Figure 4 that none of these states is likely to come close to the proposed goal of 5 % of smokers, with the closest being Hungary, estimated to reach 11 % by 2040. Czechia and Slovakia, on the other hand, are expected to stray away from the Commission's goal, with the Czech Republic's smoking rate actually increasing to 31 % of the population.

Figure 4: Linear extrapolation of smoking prevalence in select CEE countries from 2020 to 2040



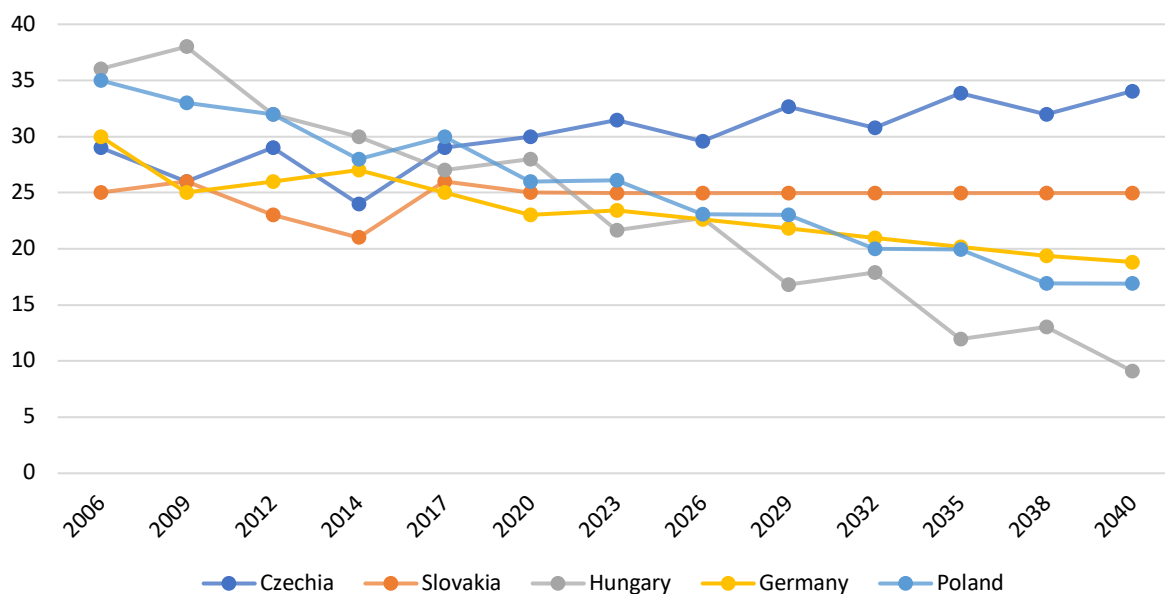
Source: Eurostat 2006-2020, own calculations 2021-2040

Using the more appropriate exponential forecasting model in Figure 5, we see more uniform results, with more Member States being further away from the goal, again with the exception of Hungary. Our model for the EU average smoking rate in the Introduction estimated 17 % and 19 % for the linear and exponential version respectively. We noted that the exponential model performs better due to the fact that it is reasonable to expect that the more people quit smoking, the harder it will be to reduce this number further, since people who have less difficulty quitting cease smoking sooner.

Comparing the exponential models, only Hungary and Poland perform better than the EU average, with Germany being on the average EU level, and Slovakia and Czechia performing worse. Curiously however, Poland and Hungary had the highest smoking rates at the beginning of the observed period. This leads us to think that even the exponential model does not fully capture the effect of higher smoking rates that are easier to reduce than low smoking rates.

Overall, the forecasts nonetheless convincingly show that in CEE countries, even more so than in the EU as a whole, the goal of a tobacco-free generation is unrealistic.

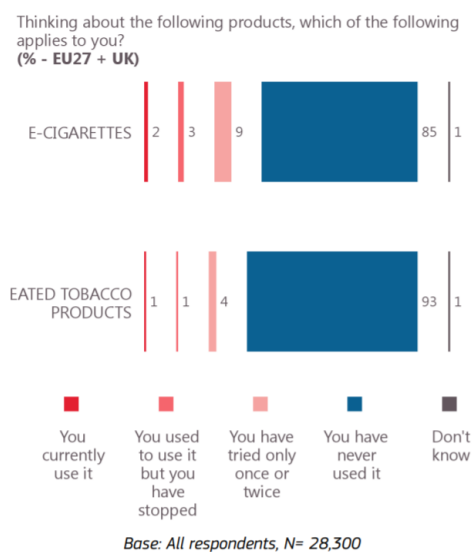
Figure 5: Exponential extrapolation of smoking prevalence in select CEE countries from 2020 to 2040



Source: Eurostat 2006-2020, own calculations 2021-2040

Regarding alternative tobacco products, 14% of respondents have at least tried e-cigarettes once or twice, and 6% say the same for heated tobacco products. Furthermore, there seems to be a reverse relationship between traditional tobacco products and e-cigarettes and heated tobacco products, meaning that in countries with more alternative products usage, we tend to see less traditional tobacco products consumption. This might indicate that the alternative products serve as a good harm reduction tool.

Figure 6: Percentage of respondents who have tried e-cigarettes and other products, EU average

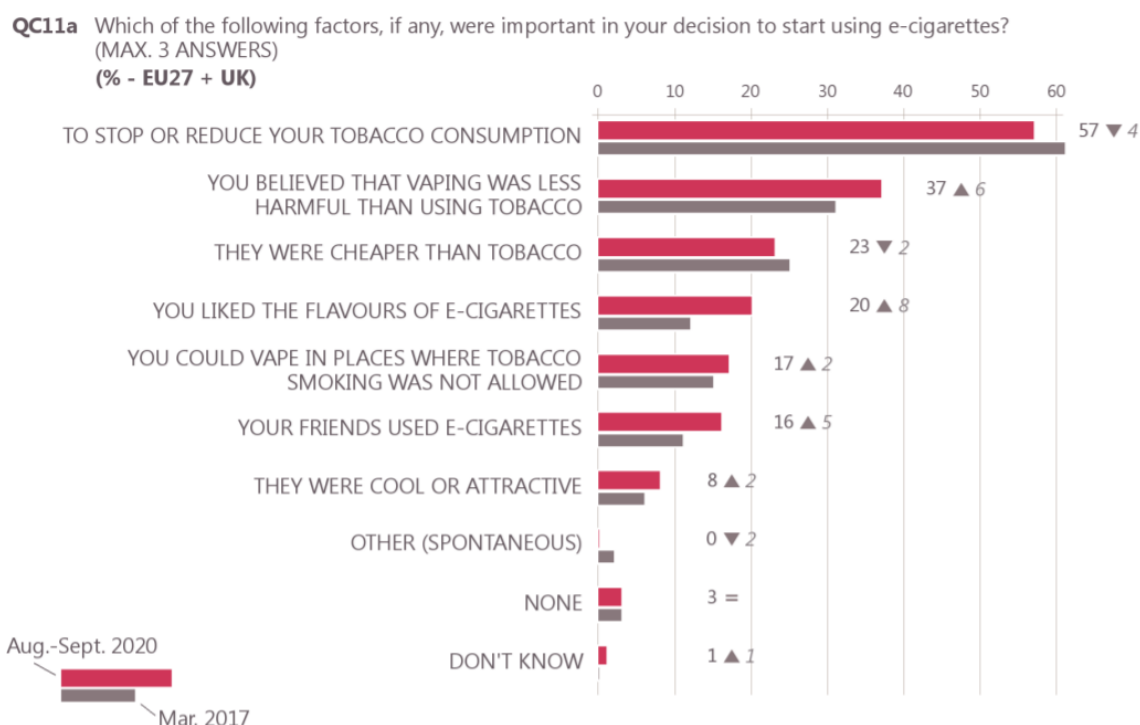


Source: Eurobarometer, 2021

Another similar indicator is the fact that EU-wide, 15 % of smokers (21 % in the UK) used an alternative tobacco product – either e-cigarettes or heated or oral tobacco products – to quit smoking (with 53 % of users trying to cease smoking overall), and only 2 % of tobacco products users listed e-cigarettes as the first product they started using. 3 % of those who used to consume alternative tobacco products ceased usage altogether. This contradicts the gate-way theory discussed by SCHEER, and instead supports the view of alternative tobacco products as effective cigarette deterrents.

Furthermore, e-cigarettes are generally more popular with smokers, with 36 % of traditional cigarettes smokers having tried e-cigarettes, as opposed to only 8 % of non-smokers, and 57 % of vapers having started using e-cigarettes with the intention to curb their tobacco production, and 37 % indicated that they believe that vaping is less harmful than smoking. The same applies to tobacco heated products. 16 % of smokers have experience with THPs, compared with 4 % of non-smokers, and 37 % of THP users mention their belief that they are less harmful than cigarettes, and a third indicates that they started using THP in order to curb smoking. Since 2017, e-cigarettes usage has dropped by 12 pp, which indicates that the revisions to TPD2 were probably successful in discouraging consumption, which in the case of e-cigarettes might in fact have adverse effect on health.

Figure 7: Reasons why respondents decide to start using e-cigarettes



Base: Respondents who use or used e-cigarettes, N= 1,696

Source: Eurobarometer, 2021

A third of respondents indicate that e-cigarettes or heated tobacco products helped them to actually quit smoking, and further 17 % said that they helped them quit for a while. On the other hand, only 3

% of users claim to have increased their consumption thanks to alternative tobacco products. This is a significant improvement from 2017, when only 14 % claimed to cease smoking thanks to alternative tobacco products and 52 % of respondents believed it did not help them towards quitting at all.

Compared to the previous Eurobarometer in 2017, the popularity of flavoured e-cigarettes grew, in particular of the menthol and mint flavours, the consumption of which grew by 8 pp, and candy and alcohol flavours by 2 pp. This might be partially caused by a demand shift as a consequence of the ban on flavoured cigarettes contained in TPD2 (indeed, 20 % of vapers list the flavours as a reason to switch to e-cigarettes). This would make the flavoured cigarettes ban a good harm reduction policy, leading smokers to switch to flavoured e-cigarettes, a less harmful product as compared to traditional cigarettes.

The CEE region tends to have lower e-cigarettes usage, only 6 % of responders in Poland and 9 % in Hungary have used them at least twice. The situation is reversed for heated tobacco products, which have the highest usage rates in the region, namely in the Czech Republic, where 15 % of respondents have tried them at least once or twice. The likelihood of having used alternative tobacco products generally increases the younger the respondent is – to illustrate, a quarter of people aged 15-24 have at least tried e-cigarettes, compared with only 8% of the oldest respondents aged 55 or over.



Campaign better aimed at young prospective smokers might be an effective policy.

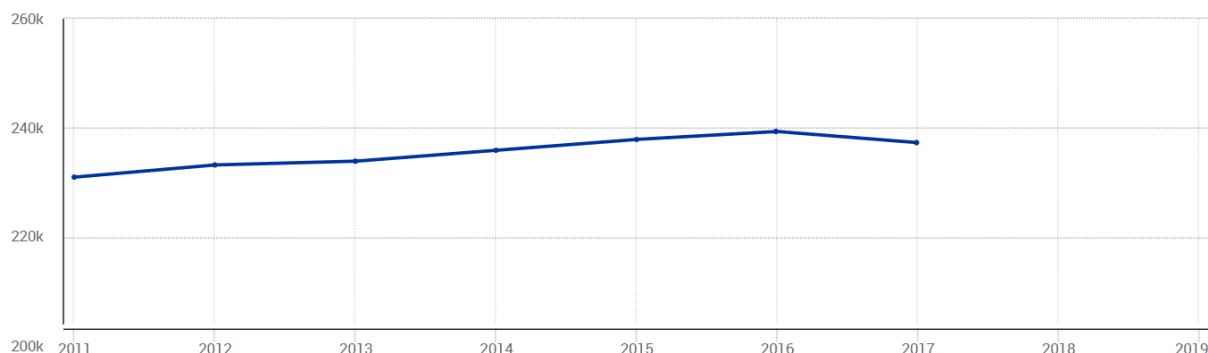
The youth are also generally at the highest risk of initiation – more than a half (54 %) of people starting with tobacco product usage are below 18. Only 4 % of users started smoking when older than 25. These numbers generally remained constant since 2017, meaning that a campaign better aimed at young prospective smokers might be an effective policy.

4.3.2 IMPACT OF CURRENT LEGISLATION ON PUBLIC HEALTH

Improvements in public health and longevity are naturally the main motivation behind any regulation of tobacco products. As has already been stated, *“Europe represents less than 10 % of the world’s population, but accounts for a quarter of all cancer cases, and cancer is the second leading cause of death in Europe after cardiovascular diseases and the first cause of death by disease in children older than one year (BECA, 2022)”*. To put this in perspective, there were 2,7 million new patients expected to be diagnosed in Europe in 2020 (Joint Research Centre, 2020).

There are significance differences in cancer incidence and rate of successful treatment among the Member States, and the overall fraction of population that suffers from cancer over their lifetimes is correlated with the expected length of life, which explains why developed countries account for vast majority of worldwide cancer cases. Regardless, cancer definitely is a significant problem the European policymakers are facing, and tobacco policy is an important part of the fight against cancer.

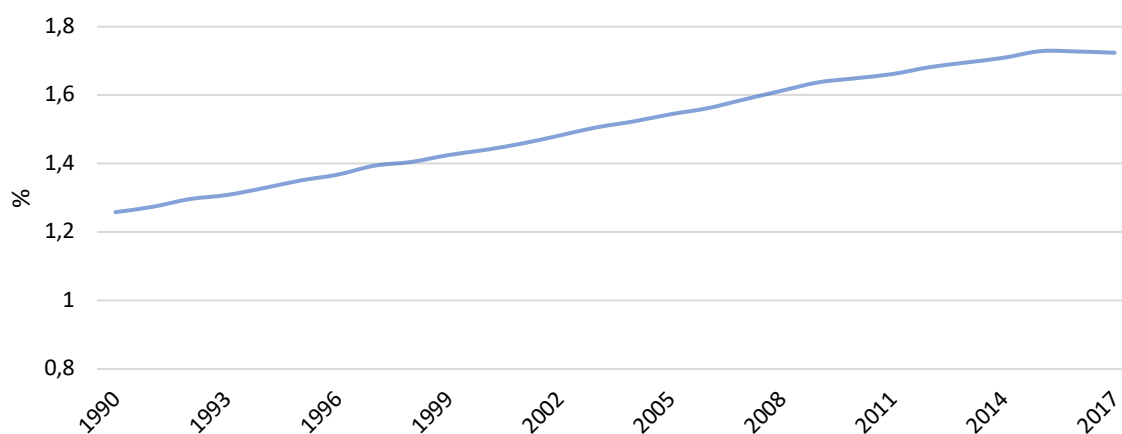
Figure 8: Total EU27 Deaths from Lung Cancer



Source: Eurostat, 2020

We can further observe in Figure 8 that the total deaths from lung cancer in the EU have been increasing at least 2016, and similar situation can be observed for number of cases diagnosed in Central Europe (Figure 9 below). The recent positive trend visible in both indicators of interest can unfortunately be short-lived, as the ongoing COVID-19 pandemic is expected to lead to an increased number of deaths from untreated or belatedly diagnosed cancer cases (BECA, 2022).

Figure 9: Share of Population with Cancer, Central Europe (percentage of population)



Source: Our World in Data, 2018

Furthermore, special care is needed in interpretation of the recent decline in cancer cases and deaths. While it is tempting to interpret them as a success of changes to tobacco policy, there are major limitations to this approach. Among them are numerous other causes of lung cancer, such as air pollution or working in a risky environment, and the slow and gradual response to cancer incidence to changes in lifestyle due to new policy.

This is especially relevant for tobacco harm reduction. There is yet to be a generation that has been using e-cigarettes and other alternative products for most of their adult lives. The majority of patients

with tobacco-using cancer patients are still smokers or former smokers, who have only been using alternatives to smoking for the last few years. For these reasons, the true impact of TPD and other regulation on public health will be measurable only retrospectively in the next two decades. The best approximation that we have at the moment is the effect on prevalence of smoking, described in greater detail in Chapter 4.2.1 on Consumer Behaviour above.

4.3.3 IMPACT OF CURRENT LEGISLATION ON PUBLIC FINANCES

In section Consumer Behaviour, we saw evidence that popular demand shifts from traditional tobacco products to alternatives, predominantly e-cigarettes, and in the previous section on the impact of current regulation on health, as well as the opinion of SCHEER and other bodies, we saw that these products are generally less harmful, and that this change in demand leads to an overall improvement in public health.

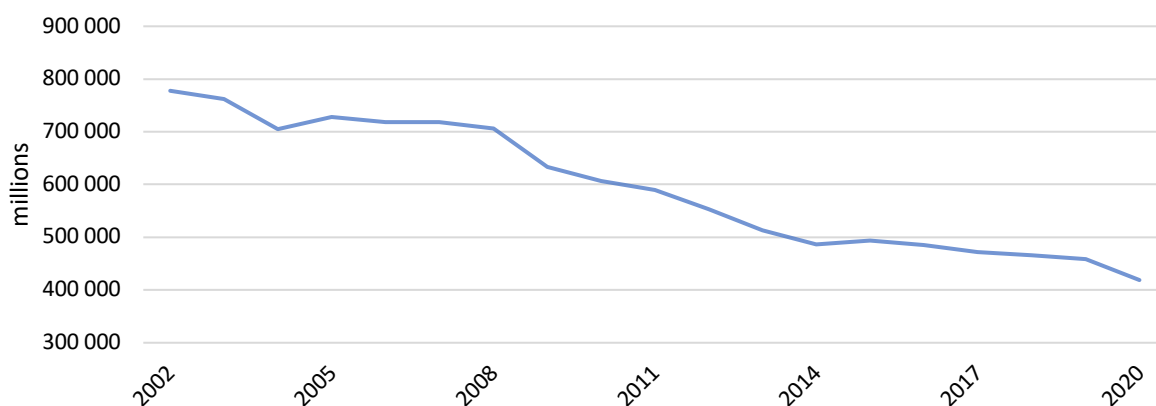
One of the largest gaps in coverage of the current regulation is the lack of a comprehensive tax scheme. Apart from direct bans or safety or product-design regulation, as is already contained in TPD2, tax rates are among the most efficient instruments in the policy-makers' toolset. The TED does set a minimal excise tax level for cigarettes and other combustible tobacco products, but overall, the range of this policy is incomplete, as alternative tobacco products are not yet covered. An alternative policy that would incentivize alternative tobacco products usage would be a policy that would also set a stated taxation gap between different product categories, or otherwise tie tax rates to harm.

Setting maximal excise tax rates is not possible, especially given different consumer demand elasticities in different countries and purchasing power, as well as because of numerous often discussed public interests; sometimes, raising taxes may be the only tool at a public-health policymakers' disposal. For this reason, a better alternative might be proposed, a norm that would introduce a gap between conventional combustible tobacco products and alternative products in terms of excise taxes, or a policy that would introduce tiered categories for products according to the risk to health they pose.

Currently, the most direct fiscal impact is through the changes in consumer behaviour as a consequence of the above-mentioned regulation: if more users cease successfully cease smoking as a consequence of European tobacco policy, this affects the tax revenue of individual member states. Regardless of the effects on local tax revenues, cessation is considered a positive effect of tobacco policy for the purposes of this study.

Nonetheless, member states have been trying to directly encourage cessation through excise tax increases (together with VAT and other taxes), which is discussed in more detail in the following chapter on the policies of individual countries and their effectiveness. Looking at the EU27+UK average figures, we can nonetheless make several observations on the tax policy in its decentralized form to date.

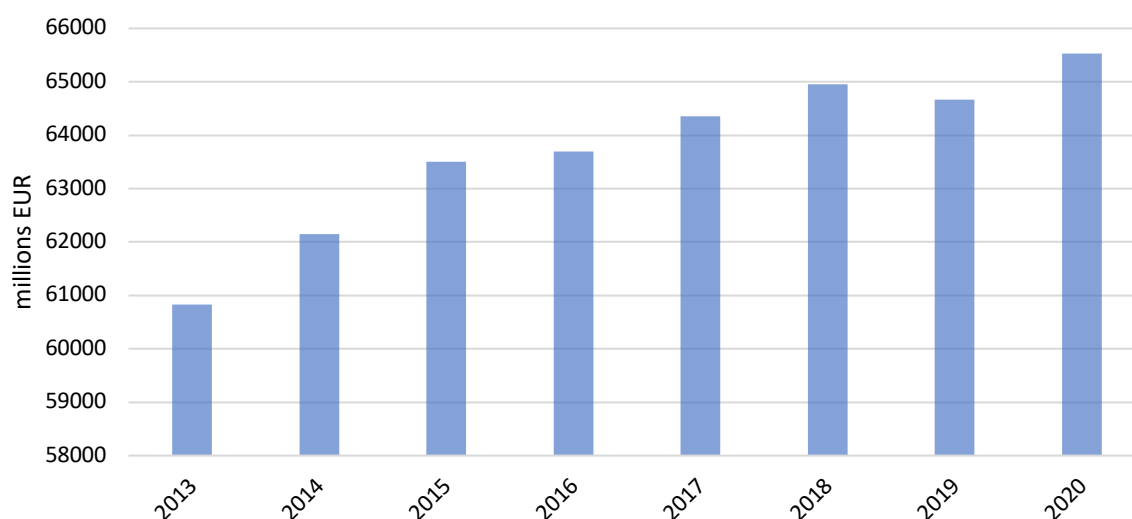
Figure 10: Total EU27+UK Cigarette Consumption



Source: Eurostat, Taxation and Customs (2021)

Firstly, we observe that not only is the prevalence of smoking decreasing, as this chapter already showed, but the number of cigarettes consumed is also decreasing, since the remaining smokers also smoke less than before (World Bank, 2017), especially in recent years. Despite this fact, the tax revenue from excise duties on cigarettes has in aggregate increased, as Figure 11 shows.

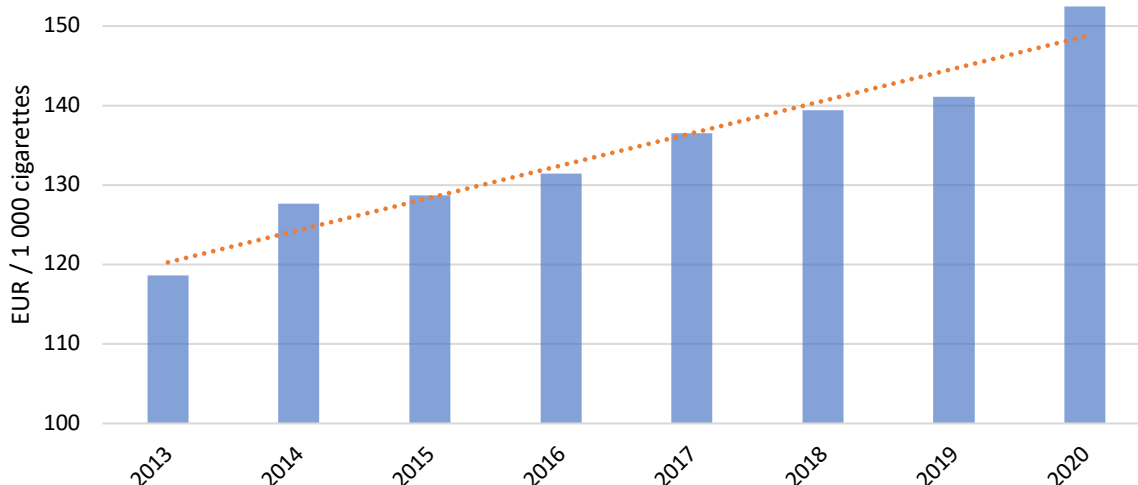
Figure 11: Total Revenue from Excise Duties on Cigarettes (Millions of EUR)



Source: European Commission, 2021

This logically implies that tax revenue per cigarette has been steadily increasing, which Figure 12 confirms:

Figure 12: Average Revenue from Excise Duties on Cigarettes (EUR per 1000 Cigarettes)



Source: European Commission, 2021, own calculations

This shows not only that excise taxes on cigarettes increase throughout the EU, but also that the current level of taxation contributes to cessation or change in consumer behaviour towards less harmful products, such as e-cigarettes, while constantly increasing the aggregate tax revenue as the next chapter discusses in more detail. According to the Tobacco Taxation Report (2020), the excise tax on tobacco together with VAT on tobacco products amounted to 4.4 % of all European tax revenue in 2016 (107 billion EUR in absolute figures).



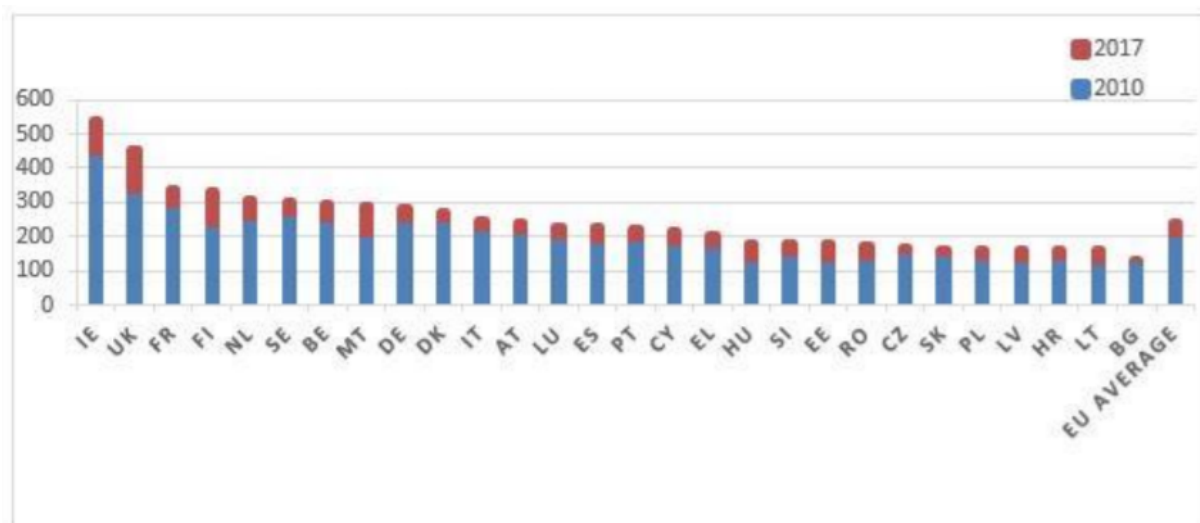
Across the EU, around 8.1 % of the total consumption of cigarettes are bought and sold illegally.

Tax collection of this magnitude naturally has also a number of downsides. One of them is the growth of grey economy and illegal tobacco (especially cigarettes) sales. Across the EU, around 8.1 % of the total consumption of cigarettes are bought and sold illegally (Tobacco Taxation Report, 2020). Illegal sales are by far the highest in Baltic states and Poland, and also somewhat higher in the Balkans and Greece, indicating that illegal trade is made possible by the proximity of markets where EU tobacco regulation does not apply. This indicates another problem of high taxation, which is incentivisation of illegal imports and loss of competitiveness for EU manufacturers.

It needs to be pointed out that not all illegal consumption is caused by taxes – a minority of illegal consumption of cigarettes is also a consequence of sensible regulations, such as the minimum age for smoking. Still, the European Commission estimates in a study from 2020 that the annual loss of excise tax revenue as a consequence of the illegal market was about 6,7 billion EUR in 2016. The same report also states that taxation has lower than expected success in dissuading youth from smoking and is more likely to simply incentivize them to move into the grey economy.

Another measurable indicator connected to taxation is the affordability of cigarettes, meaning the fraction of a person's income devoted to tobacco products, assuming stable consumption. Because of growing taxes, affordability has decreased, as Figure 13 illustrates.

Figure 13: Affordability Levels for Cigarettes in the EU (EUR/ 1000 units, nominal)



Source: Tobacco Taxation Report (2020)

Reduced affordability of cigarettes as opposed to novel tobacco products encourages a shift towards less harmful products, and as such is a good harm reduction practice, which is one of the reasons why the minimum tax rates were introduced. On the other hand, for smokers that are unable to cease smoking, very low affordability (such as in Ireland, or generally in western Europe) can lead to a poverty trap, with individuals spending a too large a part of their income on cigarettes while being unable to purchase additional care.

Fiscal policy is in more detail analysed on the level of individual member states, we can however conclude that on the European level, the current state of taxation of tobacco products seems mostly successful and could be considered as generally supporting harm reduction, as the decrease of affordability of cigarettes effectively encourages users to switch to other products, while the illegal market remains relatively small and tax revenue stable.



On the other hand, for smokers that are unable to cease smoking, very low affordability (such as in Ireland, or generally in western Europe) can lead to a poverty trap.

Convergence of tax rates for similar products should also be considered as beneficial in the long run. Tax levels of products of similar degree of harm should converge to effectively reflect harm.

On the other hand, introducing as high tax rates for e-cigarettes and other alternatives as for FMC, as is sometimes discussed (for instance the Tobacco Taxation Report), needs to be avoided. While a central holistic approach to tobacco taxation promises more clarity to the European taxation system, removing the difference in affordability between products of very different levels of harm would lead

to an adverse effect on public health. It would slow down smoking cessation, and in so doing, slow down Europe's progress toward a tobacco-free generation.

5 ASSESSMENT OF MEMBER STATES' LEGISLATION

In this section, we examine the development and state of the local regulation in the individual Member States in the Central European region and Sweden as a useful benchmark, as outlined in Chapter 2.2. In our analysis, we follow the steps and criteria outlined in Chapter 3: Methodology. For each Member State, we begin by accessing the current situation on the market and recent developments and then proceed to the discussion of the Member State's policies towards tobacco and tobacco-related products, paying special attention to potential harm-reduction elements.

In this analysis, we look for common features in terms of policy and market development among the States, which would then be helpful in accessing the effectiveness of these policies and explaining the situation in each country.

Due to regulatory harmonization in the European market, which was discussed in Chapter 4 in more detail, many regulatory aspects are very similar among most Member States in this analysis (such as packaging regulation or point of sale regulation). What tends to differentiate the Member States the most are their excise tax policies for cigarettes and other products, and tax differentials between cigarettes and standard combustible tobacco products and their alternatives, due to the absence of centralized European fiscal policy. For this reason, each country's fiscal policy is also a point of focus in this chapter.

Another significant variation within the region is the speed with which each government reacted to the introduction of European regulation, and although they are all for the most part compliant and transpose relevant regulation in time, they sometimes introduce similar regulation several years apart, which also gives us useful insight into its effectiveness, as we can compare the situation in reasonably similar countries that already have and those that have yet not introduced it.

5.1 CZECH REPUBLIC


Among the countries of Central and Eastern Europe, the Czech Republic has for some time been a pioneer in putting emphasis on harm reduction approaches. This is evidenced by the statement of Jindrich Voboril, then the national coordinator for drug and addiction policy, who said in 2018 that: *"it is necessary to apply the approach of harm reduction. That can for instance take the form of the high cost of cigarette, which would allow the market to favour less risky substitute products, like heated tobacco products, which is less harmful to the user. Substitution is also the first step in cessation"*. One of the tools at disposal of Member States that Voboril mentioned as useful in achieving this goal is the excise tax on tobacco products.

More recently, this approach is seconded in the agenda of the newly elected Czech government, which promises the following:

"Regarding the problem of addiction, we will apply a policy based on scientific evidence-based and balanced concept of risk prevention and harm reduction, and we will secure sufficient funding for prevention programs and services and regulation of addictive substances that reflect their risk of inducing addiction. (Vláda ČR, 2022)"

While this value statement still needs to be converted into specific policy proposals, the Czech government clearly declared its commitment to more focus on harm reduction in its future tobacco policy.

Table 3: Czech Republic in Numbers

	
Current prevalence of smoking	30 %
Prevalence of regular usage of e-cigarettes and vapour-based products	3 %
People with experience with e-cigarettes and vapour-based products	18 %
Prevalence of regular usage of tobacco heated products	3 %
People with experience with tobacco heated products	15 %
People with experience with oral tobacco products	6 %

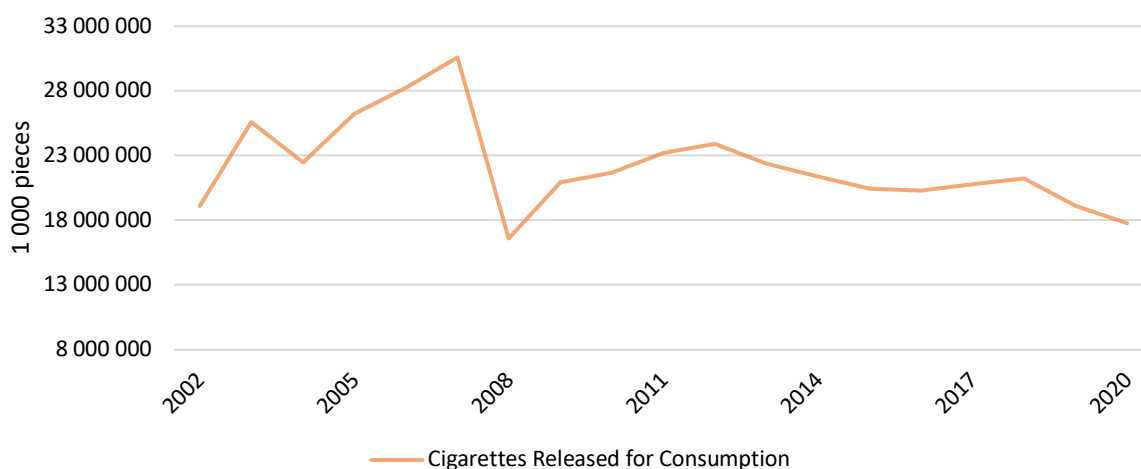
Sources: Eurostat, 2006-2020

From Table 3, we observe that the current smoking prevalence in Czech Republic is 5 percentage points above the EU average, and has stagnated for the past decade. At the same time, usage of alternative products, such as e-cigarettes, THP, and oral tobacco products has been steadily increasing.

Before interpreting these figures, it is however important to put them in more context; first of all, while the overall smoking prevalence – the percentage of the adult population using tobacco products with any frequency – remains more or less stable, the regularity of usage decreases. For comparison, ten years ago in 2012, 82 % of smokers used manufactured cigarettes daily (Eurobarometer, 2012), while according to the latest data, only 65 % of smokers used any tobacco product on an everyday basis in 2020 (Eurobarometer, 2020).

This is further complemented by the fact of decreasing boxed-cigarettes sales, shown in Figure 14 below. We observe that since the wider introduction of alternative products in the past decade, the sales of boxed cigarettes have been steadily dropping. Since 2012, this decrease amounted to 6 billion pieces per year, from 23 921 million pieces in 2012 to 17 795 million pieces sold in 2020. This translates into a 25 % decrease.

Figure 14: Cigarettes Released for Consumption in Czech Republic (in 1000 pieces)



Source: Eurostat, Taxation and Customs (2021)


Other factors also contribute to a more optimistic interpretation of the figures on smoking prevalence. First of all, evidence from the Eurobarometer (2020) shows that younger people tend to smoke less and with lower intensity. Smokers above 55 years of age smoke almost twice the daily number of cigarettes compared to individuals in the 15-24 age group. This is indicative of a changing attitude towards cigarette smoking.

Czechia also has one of the highest numbers of regular e-cigarettes users, second only to Austria. For comparison, 18 % of adult Czechs have experience with e-cigarettes, while only 13 % of Slovak and 7 % of Polish adults have ever tried vaping. A similar situation applies to heated tobacco products, where the Czech Republic has the second-highest rate of respondents who reported having at some point tried HTP in all of Europe, on par with Latvia.

Growing usage of vapour-based and heated tobacco products nonetheless also does not mean an increased number of tobacco users. As discussed in Chapter 4.2.1, only a negligible fraction of tobacco users (2 % of the adult population) list e-cigarettes as the first product they started using. Contrary to the gateway theory examined by SCHEER, it is most likely that individuals who now lean towards vaping and heated tobacco products are predominantly former smokers or smokers limiting their cigarette consumption in favour of alternatives.

All this leads us to believe that although the share of smokers in the Czech population remains mostly unchanging, the growing number of users of alternative products and falling boxed cigarettes sales signifies a shift away from traditional manufactured cigarettes, particularly among the younger generation more open to new products. For these reasons, in the following analysis, we focus on the impact of various policies on a number of cigarettes sold rather than smoking prevalence.

Table 4: Czech Republic Policy

	
Regulation of cigarette packages	Not exceeding EU regulation (warning covering 65 % of package surface, including graphic reducing attractiveness), implemented in 2016 (Sep 7).
Regulation of e-cigarettes packages	Not exceeding EU regulation (warning covering 30 % of package surface), implemented in 2016 (Sep 7).
Plain-packaging regulation	No rules in place except mandatory labels as per EU regulation.
Point of sale regulation	No rules in place exceeding EU regulation. Advertising banned for both cigarettes, e-cigarettes, and alternative products.
Ban on smoking indoors	Hospitals, schools, bus and train stops and public buildings since January 2006, separate smoking areas in bars and restaurants since June 2009, a complete ban on smoking in bars, restaurants, sporting and cultural facilities since May 31, 2017.
Ban on vaping indoors	Vaping banned in hospitals, schools, bus and train stops, and public buildings since May 31, 2017. Vaping is legal in restaurants and bars.
Ban on flavours	Flavoured cigarettes banned. Menthol cigarettes legal until May, 2020. Flavoured e-cigarettes remain legal.

The Czech Republic's policy on the regulation of cigarettes as opposed to e-cigarettes helps account for the large prevalence of the usage of alternative products in the country. In part, this is due to the beneficial aspects of the existing EU regulation mentioned in our SWOT analysis in Section 4.1.5. These aspects include the difference in packaging norms, both in the percentage of the package mandated for health warning labels and in the fact that e-cigarettes and alternative products, unlike cigarettes and RYO tobacco, do not bear images designed to reduce attractiveness.

According to Agata Cervenková (2017), this regulation of cigarette packages led 11 % of smokers to reduce their consumption, although Adam Kulhanek notes that due to ban on smoking in restaurants shortly after the introduction of packaging regulation, attributing the whole decrease in smoking to warning labels and images on cigarettes might be misleading (Srajbrova, 2017). Cervenková's view is also supported by prof. Eva Kraliková, who states that "regulation of packaging reduces attractiveness of combustible tobacco products and prevalence of smoking (Kraliková, Zvolška, 2019)".

Similarly, more relaxed norms on vaping in public in comparison to smoking and the absence on a ban on vaping flavours encourage smokers to switch to e-cigarettes. While it is difficult to distinguish between the effect of the labels and the ban on cigarette smoking in restaurants, bars and sporting and cultural facilities, it can be clearly seen from Figure 14 that after 2017, sales of manufactured

cigarettes quickly began to decline. Furthermore, the regulation seems to be popular among the Czech population, with a 72 % approval rate in a recent survey (Kucerova, 2021), and the number of users of e-cigarettes also started to increase in this period and rose from 1 % of the adult population in 2017 to 3 % in 2020 (Eurobarometer, 2020).

Last but not least, although it is too early to properly evaluate the effect of a ban on flavours, given that the popular menthol cigarettes were banned only in May, 2020, it seems that together with the decision to keep flavours legal for e-cigarettes and alternative products, this will also lead users towards less harmful products. There is already evidence that around 23 % of smokers formerly using menthol cigarettes switched to HTP, 21 % to e-cigarettes, and 2 % to nicotine pouches (iDnes, 2020), which, as they do not contain tobacco, face far less restrictive regulatory regime.

In relation to the enforcement and clarity of transposition of European smoking regulation into Czech legislation, tobacco and harm-reduction policy experts consulted by CETA for the purposes of this study agree that EU regulation is fully transposed in a clear way, although occasionally with detrimental riders, and that the regulation is generally reliably enforced.

Table 5: Czech Republic Tax Duty

	
Excise on cigarettes	135,97 EUR/000 on WAP (weighted average price). 0,073 EUR/pc + 30 % of the price.
Excise on e-cigarettes	No excise tax levied.
Tax on HTP	0,11 EUR/g

Table 5 shows the Czech Republic's excise tax policy. Following recent annual raises of both the fixed and ad valorem part of taxes on cigarettes, the country is now slightly above the European average in terms of the total share of taxes (including 21 % VAT tax, which is applied to both cigarettes, e-cigarettes, and HTP).

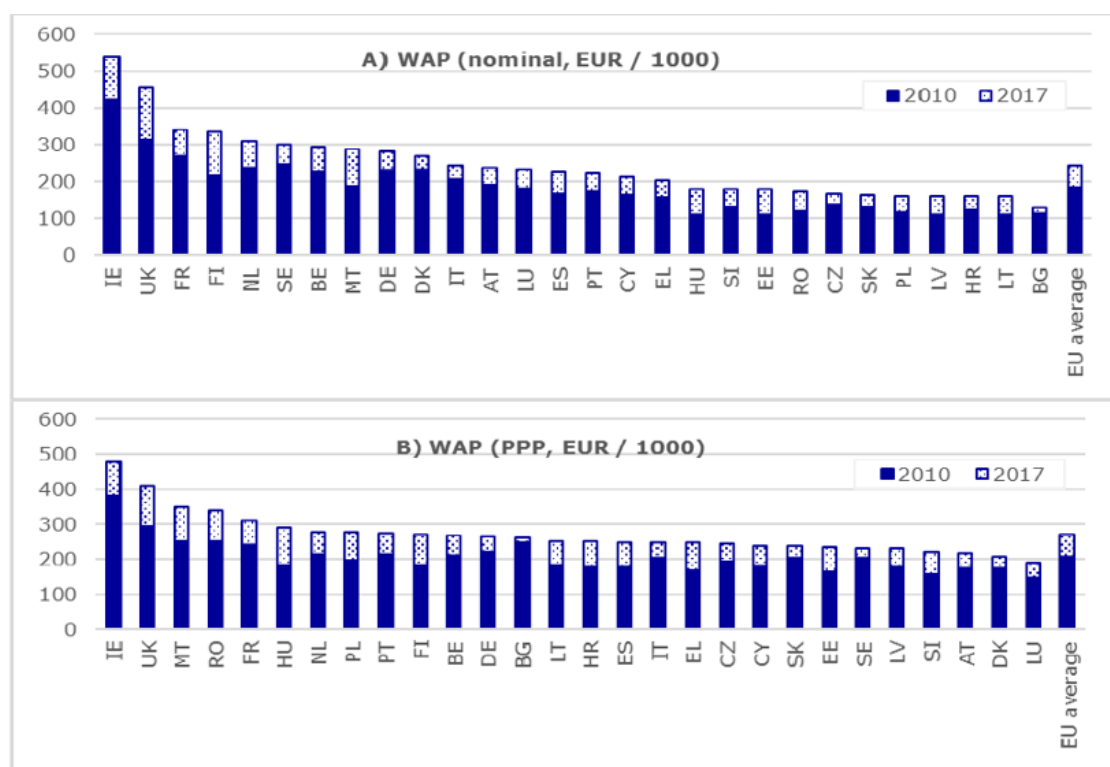
As the fixed part of the tax rose from 0,054 EUR to 0,073 EUR per piece (a 50 % increase) and the ad valorem excise tax rate rose from 27 % to 30 % between 2016 and 2022. Because of that, the total share of taxes on a pack of cigarettes increased from 65,8 % to 82,3 % over the last five years. During this time, e-cigarettes remain taxed only by the standard VAT rate of 21 %, and HTP have a fixed rate introduced only from 2020. HTP taxation is at 23% of cigarette taxation which is one of the lowest in the EU, where the current average of HTP excise vs. cigarette excise ratio is 37%.

This to some extent leads to distinguishing of products of different degrees of harm by different tax rates, and increasingly so, as excise duties on combustible cigarettes, cigars and RYO tobacco continue to rise, and data also confirms (Kolarova & Homola, 2020) that the increases led to decrease in smoking

prevalence and the number of cigarettes smoked. The increase in cigarette excise taxes was also pushed by the EU regulation, as when the mandatory minimums were introduced in 2014, Czechia was temporarily found non-compliant until the tax rates were increased (Tobacco Taxation Report, 2020). Despite the decreasing sales of cigarettes in the country, the government's revenue from the excise tax levied on tobacco continued to increase during the past ten years.

Figure 15 below shows that despite the raising taxes, the Czech Republic was, together in Slovakia, one of the Member States where cigarettes are more affordable, even adjusted for purchasing power parity (lower graph). Still, when attempting to increase tax rates, the policymaker needs to consider the threat of creating poverty traps due to low-income users not being able to stop smoking and having to pay excessive taxes, as cigarettes become relatively less affordable to these users.

Figure 15: Affordability of Cigarettes in Member States (EUR/1000 units)



Source: Tobacco Taxation Report, 2020

While Czech tobacco taxation policy is overall sound and aligned with the principles of harm reduction, the increasing taxes on combustible tobacco products naturally lead to the growth of illicit trade, which amounted to 45 million EUR in lost excise duty revenue in the Czech Republic in 2016 (Tobacco Taxation Report, 2020), and further loss on VAT.

In conclusion, Czech policy towards tobacco products is to a significant degree based on sound harm reduction principles – this is reflected in the country's excise tax policy, regulation of packages, flavours, and regulation of public space usage. The market is also comparatively quite open to new products, such as nicotine pouches, despite marketing bans that make it difficult for new and less harmful products to get established in the market. It is worth noting that many of said positive features of Czech regulation comes from not overly legislating on top of existing European regulation.

Nonetheless, there is still room for improvement. Doc Viktor Mravcik mentions *“promotion and incentivization of novel tobacco and nicotine products relative (NTNP) as opposed to combustible tobacco products, and use of NTNP in smoking cessation strategies and policies”* as a possible avenue forward in the country's anti-smoking campaign. Speaking on European policy more broadly, he recommends repealing the ban on the marketing of oral tobacco products. Dr. Ladislav Csemy, whom authors also consulted, further comments that *“the ban on the use of snus as an alternative product is completely absurd given the so-called Swedish experience”*.

Both experts agree on the lack of public awareness campaigns on the relative harm of smoking and alternative products, as well as the lack of incentives to develop and introduce new products in the country.

“The current regulations are not effective enough. In the Czech Republic, the prevalence of smoking is slightly declining, but there is still twenty percent of smokers in the adult population. This corresponds to the loss of health and economic damage. The introduction and widespread support of harm reduction approach would certainly help to shift some cigarette smokers to use less risky products (especially smokeless forms of nicotine intake).” Ladislav Csemy (2022)

Harm Reduction Index

The Harm Reduction Index, which is described in more detail in Chapter 6, assigns the Czech Republic the score of 25.86 and a total rank of 2. out of seven measured countries.

5.2 SLOVAK REPUBLIC

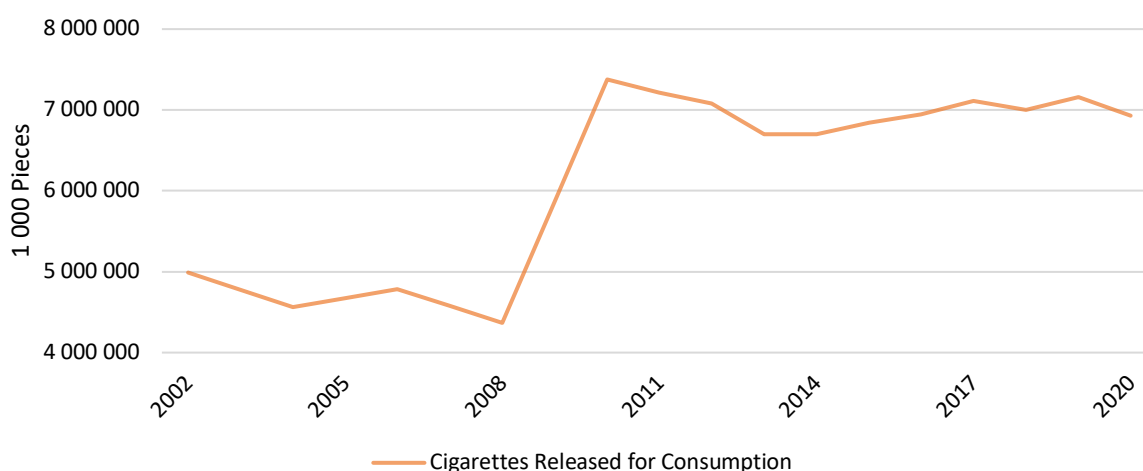
In both the current state of the market and its approach to tobacco regulation, Slovakia is very similar to the Czech Republic. Just like in Czechia, the prevalence of cigarette smoking has stagnated and was the same in 2020 as it was in 2006 (Eurobarometer, 2006-2021). Despite the fact that smoking prevalence is currently by 5 percentage points lower in Slovakia than in the Czech Republic, we can observe from Table A1 that active smokers in Slovakia have always tended to smoke more intensively (more cigarettes per day) than their Czech counterparts. Figure 16 below also shows that while sales of cigarettes in Czechia have been decreasing, in Slovakia they mostly stagnated.

Table 6: Slovak Republic in Numbers

ce ta	
Current prevalence of smoking	25 %
Expected prevalence of smoking by 2040 (linear prediction)	24 %
Expected prevalence of smoking by 2040 (exponential model)	25 %
Prevalence of regular usage of e-cigarettes and vapour-based products	1 %
People with experience with e-cigarettes and vapour-based products	13 %
Prevalence of regular usage of tobacco heated products	2 %
Prevalence of regular usage of tobacco heated products	10 %
People with experience with oral tobacco products	6 %

One possible explanation of why even though both countries have similar rate of cessation, in Czechia smokers seem to be lowering their consumption while in Slovakia they are not, is a different level of popularity of alternative tobacco products.

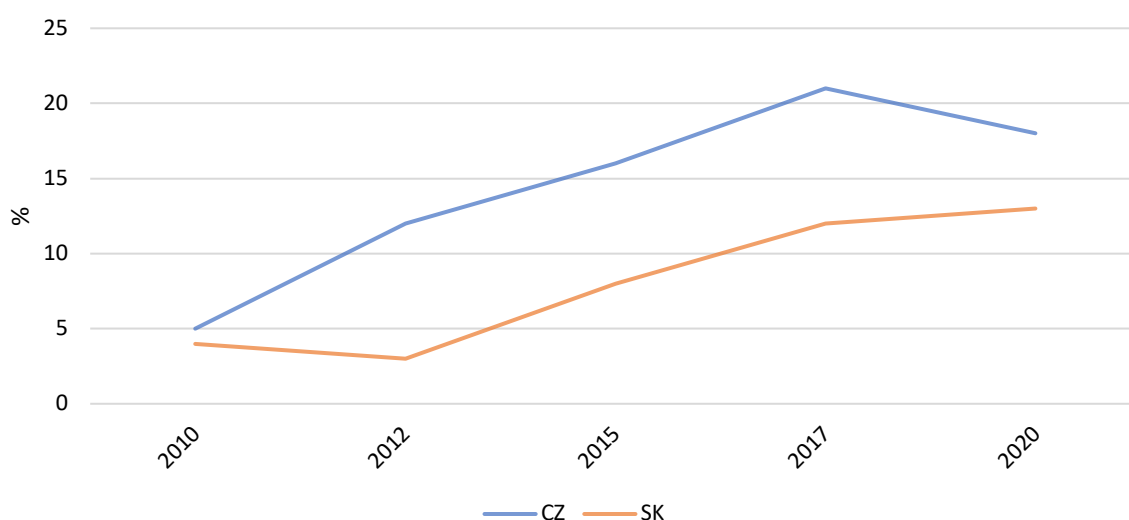
Figure 16: Cigarettes Released for Consumption in Slovakia (in 1000 pieces)



Source: Eurostat, Taxation and Customs (2021)

Figure 17 shows that after a similar starting point in 2010, the countries diverged and fewer Slovaks tried alternative products compared to Czechs. In later years, the countries started converging again, although the decrease for the Czech Republic between 2017 and 2020 might be a result of misreporting. The percentage of Czech who have tried THP at some point is also 50 % larger than the fraction of Slovaks who have tried this alternative.

Figure 17: Percentage of Adults with Experience with Vaping




Source: Eurobarometer, 2010-2021

Focusing first on the sales of cigarettes between 2008 and 2011 in Czechia and Slovakia (Figures 14 and 17), one possible explanation can be indoor smoking bans, which were introduced in the Czech Republic already in 2006 in certain public spaces, and in 2009, smoking outside designated areas was already illegal in restaurants and bars, whereas in Slovakia this remained regulation was introduced only in 2013.

Earlier introduction of these measures in Czechia helps explain the sharper increase in smoking in Slovakia, and also why around this time, the usage of e-cigarettes in Czechia also started diverging from stagnating usage in Slovakia (which coincidentally started increasing after the introduction of the ban). In this sense, it would seem that indoor smoking bans are an effective measure in diverting users towards less harmful alternatives, especially if these remain legal indoors.

Currently, the biggest policy difference between the two countries is the possibility to smoke in designated areas in restaurants in Slovakia, a practice banned in the Czech Republic. At the same time, vaping indoors is permitted in Czechia, while in Slovakia the same rules that are in place for smoking apply. Based on past development, the combination of these differences might lead fewer Slovaks to quit smoking in favour of less harmful e-cigarettes in the coming years. Radovan Durana, a tobacco-policy analyst from INESS, further comments that *“full equalization of tobacco products based on the preventive argument ... might hamper any innovation”*.

Table 7: Slovak Policy


	
Regulation of cigarette packages	Not exceeding EU regulation (warning covering 65 % of package surface, including graphic reducing attractiveness), implemented in 2016 (May 20).
Regulation of e-cigarettes packages	Slightly exceeding EU regulation (warning covering 40 % of package surface), implemented in 2016 (May 20).
Plain-packaging regulation	No rules in place except mandatory labels as per EU regulation.
Point of sale regulation	No rules in place exceeding EU regulation. Advertising banned for both cigarettes, e-cigarettes, and alternative products.
Ban on smoking indoors	Smoking banned in hospitals and public transportation since 2009, and in shopping centres and restaurants since 2013. Smoking remains legal in bars and clubs in designated sections.
Ban on vaping indoors	Same as smoking, vaping is prohibited in hospitals, public transport, and restaurants.
Ban on flavours	Flavoured cigarettes banned. Menthol cigarettes legal until May, 2020. Flavoured e-cigarettes remain legal.

Durana also comments on the clarity of Slovak legislation, saying that EU legislation is fully transposed in a clear way without detrimental riders and that the regulation is strictly enforced. This statement is supported by the fact that the size of the illicit market in tobacco products in Slovakia is twice smaller compared to the Czech Republic. According to Tobacco Taxation Report (2020), illicit trade in cigarettes in Slovakia amounts only to 1,7 % of total consumption.

Looking at Slovak fiscal policy in regard to tobacco products in Table 8, we again observe that the situation is very similar to the Czech Republic. While the structure of manufactured cigarette taxes is different, with the Czech Republic relying more on the percentual part of the final price and Slovakia more on the fixed per-piece part, overall, the share of the taxes on the weighted-average price of cigarettes is virtually the same. Similarly, the share of tobacco excise duty revenue on total government revenue is of the same magnitude.

A difference exists again in the attitude towards alternatives to smoking, especially THP, the excise duty on which is 20 % higher in Slovakia, with plans for further increases (CT, 2020). No excise duty is levied on e-cigarettes and other novel products, except for standard sales tax.

Table 8: Slovak Tax Duty

	
Tax on cigarettes	103,39 EUR/000 on WAP (weighted average price). 0,1322 EUR/pc + 23 % of the price.
Tax on e-cigarettes	No excise tax levied.
Tax on HTP	0.1322 EUR/g

Summing up, Slovakia still exhibits signs of applying harm reduction principles in its policy. Fiscal policy still differentiates products by their respective level of harm, with manufactured cigarettes being more taxed than alternatives to combustible tobacco products. On the other hand, Slovakia still has the highest tax on heated tobacco products from the Central European countries (Czechia, Slovakia, Poland and Hungary), while having the most affordable cigarettes within the same patch (Tobacco Taxation Report, 2020).

Unlike in Czechia, harm reduction is also not being mentioned as a guiding principle for public policy, and no campaign communicating respective dangers of various products and practices is ongoing. Most of the positive harm-reduction aspects, such as differences in packaging requirements for different products, come from the direct transposition of EU regulation without riders. Pavlikova and van Dijk (2020) share this scepticism on Slovakia's own policy, stating that *"Slovakian tobacco control policy is more focused on repression than on prevention"*.

Harm Reduction Index

The Harm Reduction Index, which is described in more detail in Chapter 6, assigns Slovakia the score of 20.89 and a total rank of 5. out of seven measured countries.

5.3 POLAND

In Poland, the approach to tobacco control is different from Czechia and Slovakia, and is in essence more similar to Hungary. While smokers currently represent 26 % of the adult population, similarly as in other CEE countries, looking back at Figure 4, we observe that smoking prevalence has not stagnated in the past years, but dropped to this level from the original 35 % of adults in 2006.

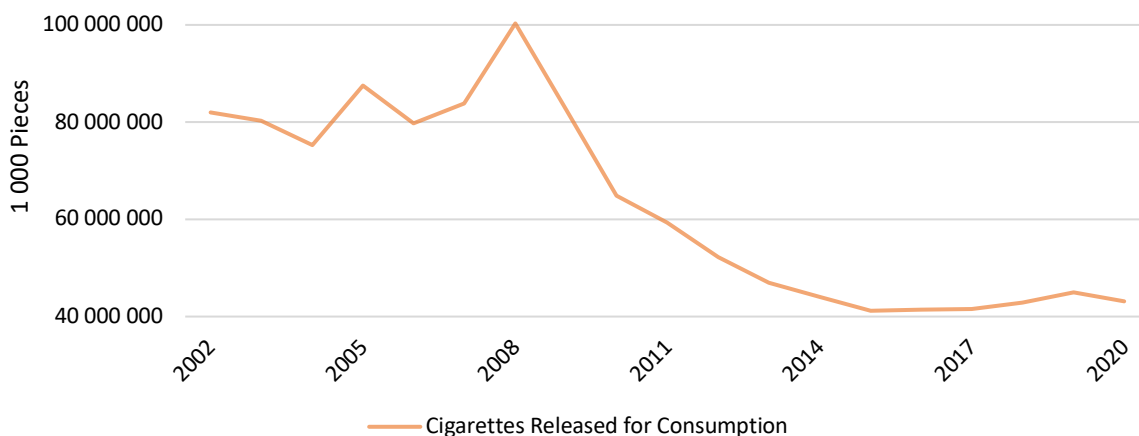
Table 9: Poland in Numbers

	
Current prevalence of smoking	26 %
Prevalence of regular usage of e-cigarettes and vapour-based products	1 %
People with experience with e-cigarettes and vapour-based products	7 %
Prevalence of regular usage of tobacco heated products	1 %
Prevalence of regular usage of tobacco heated products	5 %
People with experience with oral tobacco products	3 %

Figure 18 shows us another impressive development of consumption of cigarettes dropping by 50 % between 2008 and 2014. Nonetheless, since 2014, there have not been major changes in cigarette consumption, which has in fact slightly increased. Looking at Figure A2, we also see that with the exception of a possible outlier in the last year again, daily consumption of cigarettes by regular smokers has been very constant over the years, around 30 cigarettes per day per smoker, which is comparatively one of the highest results.

Returning to Table 9 sheds some light onto the recent development. While in Czechia and Slovakia, the use of alternative products has been growing since 2014, very few people have moved to these products in Poland. Only 7 % of people have ever tried e-cigarettes and only 5 % have tried THP. The number of regular users of these products is marginal, and the number of adults who tried oral tobacco products is twice smaller in comparison to the previous two countries.

Figure 18: Cigarettes Released for Consumption in Poland (in 1000 pieces)



Source: Eurostat, Taxation and Customs (2021)

This would indicate that the main reason behind the stopped development away from smoking in Poland was caused by not enough people switching to less risky alternatives. This could be the case if Poland's policy focused more on repression and prohibition rather than on harm reduction – in the early stages, restricting measures would account for Polish early success, possibly due to the high initial prevalence of smoking, but beyond a certain point, further restrictions would prove inefficient. In Table 10, we turn to Polish tobacco policy to see if this hypothesis holds.

Table 10: Polish Policy


Regulation of cigarette packages	Slightly exceeding EU regulation (warning covering 70 % of package surface), implemented in 2004.
Regulation of e-cigarettes packages	Not exceeding EU regulation (warning covering 30 % of package surface), implemented in 2015.
Plain-packaging regulation	Display bans exceeding EU regulation.
Point of sale regulation	No rules in place exceeding EU regulation. Advertising banned for both cigarettes, e-cigarettes, and alternative products.
Ban on smoking indoors	Smoking banned in all indoor spaces including hospitals, schools, public transport, restaurants, bars and clubs since 2011. Separate smoking areas in restaurants and bars are allowed under certain conditions.

Ban on vaping indoors	Vaping banned indoors under same conditions as smoking, implemented in 2016.
Ban on flavours	Flavoured cigarettes banned. Menthol cigarettes legal until May, 2020. Flavoured e-cigarettes remain legal.

We indeed see that Poland was quick to introduce packaging measures on cigarettes, mandating warning on 40 % of front side of the pack and 30 % of rear side as early as 2004 (Tobacco Control, 2022). It also introduced relatively early (2011) a strict, although not complete, ban on smoking in bars, restaurants and workspaces. Together with early introduction of taxes on cigarettes, which – although not significantly higher than in Czechia or Slovakia, adjusted for purchasing power parity make cigarettes the seventh least affordable in the EU (less affordable than in a number of Western European countries like Belgium, Germany or Italy for example) and costlier than the EU average (see Figure 15 above), this all helps explaining the initial drop in cigarettes sales that Poland achieved in early 2010s. Poland also has in place an almost total ban on tobacco and nicotine product advertising and products sold via vending machines, as well as certain display bans.

The country has however also taken strict measures against alternative products. As early as September 2016, Poland banned e-cigarette advertising, cross-border sales, and vaping indoors in places where smoking is banned, including restaurants, bars, and bus stops. It is likely that these measures stand behind the low usage of these products in Poland. However, as we have seen, tobacco alternative products are mostly used by smokers (Eurobarometer, 2021). Therefore, strict limits on these products limit smokers' motivation to switch and thus limit cessation.

Table 11: Polish Tax Duty

	
Tax on cigarettes	104,09 EUR/000 on WAP (weighted average price). 0.0464 EUR/pc + 32,05 % of the price.
Tax on e-cigarettes	0,11 EUR/ml.
Tax on HTP	0.06338 EUR/g + 32,05 % of the price.

Similar trends are also observable in the Polish excise tax system. As was already discussed, the taxes on cigarettes are not very different from those in other neighbouring states, even though this makes cigarettes in Poland comparatively somewhat less affordable overall, and the share of excise tax collected from tobacco on total government revenue is somewhat higher.

However, from countries in this study, Poland also has relatively taxation on alternatives to combustible tobacco products, as seen in Table 11. The tax on e-cigarette liquids belongs among the

higher ones in our sample. Despite that, with an average rate in the EU of 0,17 EUR/ml, the rate on e-cigarette liquids in Poland remains below the EU-wide average. The HTP taxation with an average rate of 105 EUR/kg results in an excise burden of HTP which is 30% of that for cigarettes. Compared to the average in the EU of 37%, this is lower than Slovakia and higher than Czechia.

Polish Ministry of Justice and some other politicians want to further increase taxes on heated tobacco to reduce the differences in tax burden between these lower-risk products and traditional cigarettes (Polish News, 2021).

Piotr Zielinski, president of Vaping Association Polska, comments on the increases: *“the increase in the cost of conventional cigarettes was a process that lasted 20 years. It is incredible that the one for e-cigs instead must be so drastically premature. We ask that there be at least the time necessary to not destroy the sector”* (CoEHAR, 2020).

This ambition to put alternative products on a more similar level to cigarettes in terms of taxation plays a role in the decreased cessation rates and stagnating (and no longer decreasing) sales of cigarettes in Poland. The country also has one of the largest illicit trade shares in the tobacco market in Europe, with only Baltic states having significantly larger shares (Tobacco Tax Report, 2020). While larger taxes and bans on cross-border sales might be contributing factors to the increase in illicit trade, it is also worth noting that Poland borders with non-EU countries, which naturally invites smuggling from countries where EU regulation does not apply. Nonetheless, neighbouring Slovakia, which also shares, albeit shorter, the border with Ukraine, has the second-lowest illicit trade level in the whole of the EU.

Overall, it is a fair assessment that while restrictive policies helped Poland curb smoking in the past, these tools are proving less efficient in recent years, and the efforts to put e-cigarettes, THP, and other novelties on the same level as combustible tobacco products actively harms smokers who might otherwise be persuaded to switch to these less harmful alternatives. In the words of professor Piotr Kuna from the Medical University of Lodz, it is a mistake that *“combustible products, which are the most harmful ones, require less efforts from the producers to enter the market, whereas new tobacco products must undergo lengthy and costly procedures, which in the end does not result in the option to present them as less harmful products, or simply present results of published scientific papers.”*

From positive aspects of the harm-reduction present in Polish policy, we can name for example differentiation between attitudes towards flavours in standard combustible products and their alternatives. Poland was particularly affected by the EU’s ban on menthol cigarettes, which came into force in May 2020, since around 30 percent of Polish smokers prefer menthol (Hayek Institute, 2022). It is still too early for the data to come in on the effect of the ban on menthol flavours, but it might lead menthol cigarettes smokers to switch towards e-cigarettes and other alternatives.

On future prospects, professor Kuna comments that he would like to see mitigation to the “*lack of the provisions to inform adult consumer about the reduction of harm when using different tobacco products,*” and that the Polish policymakers should address “*the deficiencies in the approach of taking into account the continuum of risk and the possibility to present adult consumers with less harmful alternatives*”.

Harm Reduction Index


The Harm Reduction Index, which is described in more detail in Chapter 6, assigns Poland the score of 14.31 and a total rank of 6. out of seven measured countries.

5.4 HUNGARY

Hungary, while in many aspects of its policy similar to Poland, remains the country most distant from applying harm reduction principles in its policies.

Examining the state of affairs in Hungary in Table 12 below and in Figure 4, we observe that the development of smoking prevalence also copies the same pattern as in Poland. Although current smoking prevalence is again at about the same level as in the other Central European countries, the starting point in 2006 was significantly higher than in Slovakia and Czechia and about the same as in Poland, around 36 % of the adult population. Smoking prevalence then dropped quickly between 2006 and 2014, and since then has stagnated. Figure 19 below confirms this development, with sales of cigarettes dropping almost by half between 2008 and 2014 and stagnating since then, or in fact increasing by around 13 % between 2014 and 2020. This again seems similar to the development in Poland, only the evidence of a trend reversal in Hungary seems more pronounced.

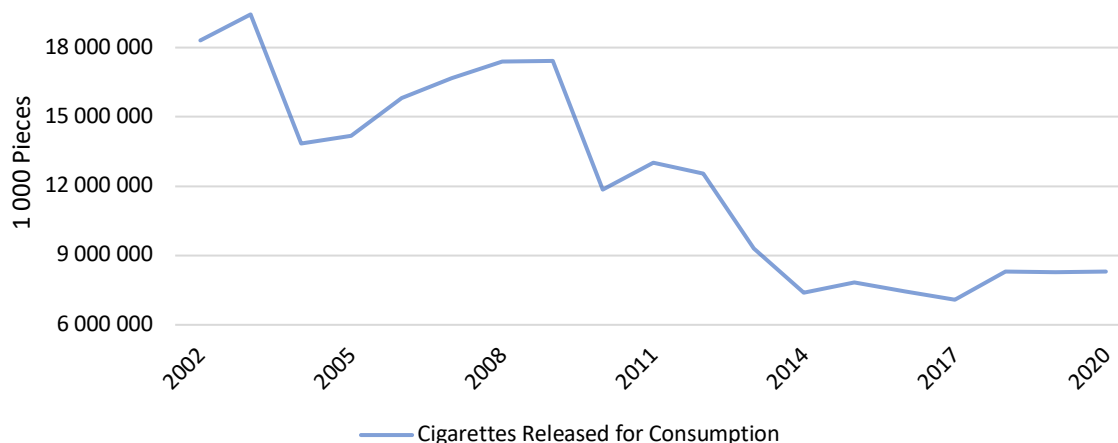
Table 12: Hungary in Numbers

	
Current prevalence of smoking	28 %
Prevalence of regular usage of e-cigarettes and vapour-based products	1 %
People with experience with e-cigarettes and vapour-based products	9 %
Prevalence of regular usage of tobacco heated products	1 %

Prevalence of regular usage of tobacco heated products	5 %
People with experience with oral tobacco products	3 %

Looking at the usage of alternatives to combustible tobacco products, we see data almost identical to Poland, with 9 % and 5 % of adults having experience with e-cigarettes and THP respectively, and 3 % of consumers having tried oral tobacco products. In Table 13 we look at the policies that Hungary implemented in order to explain this development.


Figure 19: Cigarettes Released for Consumption in Hungary (in 1000 pieces)



Source: Eurostat, Taxation and Customs (2021)

Again, similarly to Poland, the country introduced restrictive packaging regulation early on, in addition to very strict public space and point of sale regulation. Smoking has been illegal in all public spaces, restaurants, bars, cafes, public transportation, and workspaces since 2012. As late as March 2017, Hungary was still one of only seven EU member states that had a complete ban on smoking in all enclosed public places (SurferToday, 2017). Since 2013, Hungary has also had regulation, quite unique among countries in the CEE region, requiring a special licence in order to legally sell tobacco products, issued only to state-controlled businesses. All these restrictions likely contributed to the decrease in manufactured cigarettes sales in the early 2010s. Hungarian excise tax policy was also a major factor, as is discussed in more detail below. Between 2011 and 2014, FMC excise tax increase by 52 %, while fine-cut tobacco tax remained on its previous level, leading to a 47 % decrease in FMC consumption and 75 % increase in fine-cut tobacco consumption in this timeframe (CEBEX, 2019).

Table 13: Hungarian Policy

	
Regulation of cigarette packages	Plain-packaging rules exceeding EU regulation in place since 2022.
Regulation of e-cigarettes packages	Plain-packaging rules exceeding EU regulation in place since 2022.
Plain-packaging regulation	From 2022, plain-packaging regulation rules are in place for all nicotine products.
Point of sale regulation	Legislation exceeding EU regulation, with only limited state-control National Tobacco Shops allowed to sell tobacco products since 2013 (and also e-cigarettes since 2016). Heavy point of sale regulation and display bans.
Ban on smoking indoors	Smoking banned in all indoor spaces including workspaces, clubs, pubs, and restaurants in effect since 2012.
Ban on vaping indoors	Vaping is prohibited in all indoor spaces on the same level as smoking, unless the vaping device was at doctor's prescription.
Ban on flavours	Complete ban on flavours for both cigarettes and e-cigarettes.

Since then, Hungary has also taken steps to strictly regulate the market for alternative and novel products, effectively putting them on the same level as cigarettes. Until 2016, nicotine-containing e-cigarette fluid was effectively prohibited (Hayek Institute, 2022). Since 2016, the same licensing regulation as for cigarettes applies. E-cigarette advertising is banned, and vaping is prohibited wherever smoking is. A complete ban on flavours without distinction between cigarettes and alternative products is also in effect, and starting in 2022, plain packaging is mandated for both cigarettes and alternative products.

This stringent regulation, which essentially makes no distinction among products regardless of their harm level, explains why Hungarians are not motivated to switch from cigarettes to novel alternatives. Another contributing factor is the Hungarian tobacco excise tax policy, depicted in Table 14.

Table 14: Hungarian Tax Duty

	
Tax on cigarettes	108,05 EUR/000 on WAP (weighted average price). 0,067 EUR/pc + 23 % of the price.
Tax on e-cigarettes	0,08 EUR/ml.
Tax on HTP	0,041 EUR per piece.

First of all, we notice that Hungary has higher share of tobacco excise tax on all central government revenue than all previous Member States. Figure 15 also shows that cigarettes in Hungary are among the least affordable (Tobacco Taxation Report, 2020). After adjusting for purchasing power, Hungary has the least affordable cigarettes from all the countries which are part of this study, and only Ireland, Malta, Romania and France have costlier cigarettes. This is despite the fact, that Hungary has in the past been criticized for having cigarette taxes below the required minimum (Tobacco Reporter, 2021). Because of that, the country has been raising tax rates for cigarettes significantly also in recent years.

This in itself could be considered a good harm reduction practise, had the taxes on alternatives been lower and regulation comparatively less strict. This however was not the case in Hungary, which introduced special excise duty on e-cigarettes and novel products early on, not without consequences.

As cross-border sales were banned and all e-cigarette flavours prohibited, including tobacco flavour, it has been estimated that 85 per cent of e-liquid consumed in Hungary was bought illegally. A tax of 65 Hungarian Forints (€0.20) per ml was introduced in January 2017 but this was reduced to 20 Forints (€0.06) in March 2020 in an attempt to reduce cross-border shopping (Hayek Institute, 2022). Hungary taxes also other novel products like nicotine pouches (Tobacco Intelligence, 2021), which are taxed at 64,60 EUR per kg.

Overall, Hungary actively pursues a policy of complete product harmonization in policy and follows the path toward harmonization in its fiscal policy, which is not aligned with the recommendation of harm-reduction experts, and might thus limit the country's further prospects of reaching the goal of becoming a smokeless country going forward.

Harm Reduction Index

The Harm Reduction Index, which is described in more detail in Chapter 6, assigns Hungary the score of 7.95 and a total rank of 7. out of seven measured countries.

5.5 AUSTRIA

Austria has for many years been nicknamed the smoking capital and vaping center of Europe, as the combination of mostly lenient policies and high standard of living made tobacco products affordable and easily available. More recently, the country has been trying to shed this reputation while still mostly recognizing the importance of the harm-reduction approach.

Table 15: Austria in Numbers


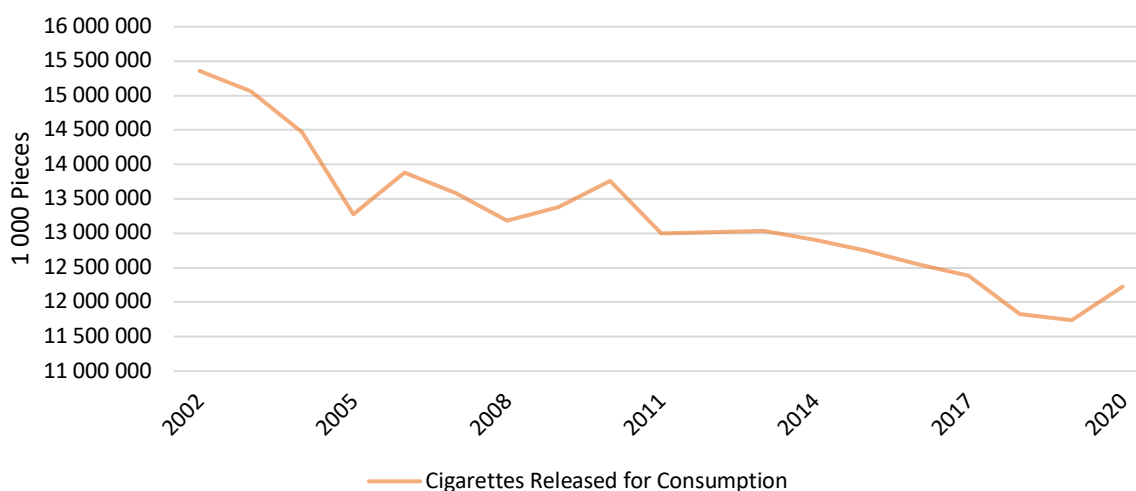
	
Current prevalence of smoking	25 %
Expected prevalence of smoking by 2040 (linear prediction)	15 %
Expected prevalence of smoking by 2040 (exponential model)	13 %
Prevalence of regular usage of e-cigarettes and vapour-based products	4 %
People with experience with e-cigarettes and vapour-based products	18 %
Prevalence of regular usage of tobacco heated products	2 %
Prevalence of regular usage of tobacco heated products	12 %
People with experience with oral tobacco products	16 %

Table 15 shows the current usage of various products in Austria, with current smoking prevalence being 25 %, again well within the standard levels for a country in this region. Compared to Czechia and Slovakia, where smoking rates have mostly stagnated, and compared to Hungary and Poland, where they dropped significantly and then stagnated or slightly increased, Austria has seen almost a linear continuous decline since 2006 (Eurobarometer, 2006-2021). Figure 20 shows very similar development for the sales of manufactured cigarettes, which have also been gradually falling, until right before the start of the pandemic.

Austria also has one of the highest usage of e-cigarettes, second only to the UK and France, with 4 % of adults using e-cigarettes regularly and 18 % (like in Czechia) having experience with these products. This has not always been the case; usage of e-cigarettes in the country rose quickly after 2015. Tobacco heated products are also popular and used widely, as are oral tobacco products and other novelties.

Figure 20: Cigarettes Released for Consumption in Austria (in 1000 pieces)



Source: Eurostat, Taxation and Customs (2021)

Looking at Austrian regulation in Table 16, it is clear what earned Austria the tobacco-friendly reputation, since for a long time, there were few restrictions, which explains why smoking rates were falling more gradually in the 2000s in Austria than in Poland or Hungary with their tougher restrictions. A partial ban on smoking in restaurants and public spaces, requiring separate spaces, was introduced in 2009, and was replaced by a complete ban only in 2019, delayed from initial plan of 2017 by political battles in the local parliament.

Apart from the smoking ban, the country mostly stuck to transposing European legislation, which according to Dr. Ernest Groman of Medical University of Vienna, whom the authors consulted on this aspect of Austrian regulation, is fully transposed in a good and clear manner. The country introduced no additional packaging regulation or additional point of sale or display bans.

This means that the packaging regulation distinguishes between combustible tobacco products like cigarettes and e-cigarettes and other novelties, thus adopting the positive harm-reduction aspects of the European regulation. Similarly, flavours are completely banned for cigarettes since 2020, but remain legal for alternative products. The only aspect of Austria's policy that goes against the harm-reduction practice is the equal ban on vaping in places where smoking is prohibited, which has also been in place since 2019.


Table 16: Austrian Policy

ce ta	
Regulation of cigarette packages	Not exceeding EU regulation (warning covering 65 % of package surface, including graphic reducing attractiveness).
Regulation of e-cigarettes packages	Not exceeding EU regulation (warning covering 30 % of package surface).
Plain-packaging regulation	No rules exceeding EU regulation.
Point of sale regulation	No point of sales and display bans exceeding EU regulation. Advertising at point of sale is allowed, e-cigarettes are purchasable from vending machines.
Ban on smoking indoors	Since 2009, ban on smoking in public spaces and mandatory separated smoking and non-smoking spaces in restaurants and bars. Complete smoking ban indoors, including bars and restaurants, in effect since January 2019.
Ban on vaping indoors	Complete vaping ban indoors, including bars and restaurants, in effect since November 2019.
Ban on flavours	Flavoured cigarettes banned. Menthol cigarettes legal until May, 2020. Flavoured e-cigarettes remain legal.

In terms of tobacco fiscal policy, we also see in Table 17 evidence of certain sound practices from the viewpoint of harm reduction. Although taxes on cigarettes expressed as percentage of weighted average price remain lower than in other CEE countries, and partly as a consequence, smoking remains very affordable (in fact, Figure 15 shows that adjusted for purchasing power, Austria has the third most affordable cigarettes in the whole of EU and the most affordable cigarettes out of all the countries in this study), what matters is that there is still a significant difference between taxes imposed on cigarettes and on their less harmful alternatives.

In that regard, Austria has no excise duty levied on e-cigarettes, and has an average fixed excise tax on heated tobacco products, with higher rates to be found in Germany and Hungary (after recalculating to tax per gram for comparison. However, the latter is to be increased in April 2022.

Table 17: Austrian Tax Duty

	
Tax on cigarettes	154,91 EUR/000 on WAP (weighted average price). 0,068 EUR/pc + 34,5 % of the price. 0,073 EUR/pc + 33 % of the price from April, 2022.
Tax on e-cigarettes	No special tax levied.
Tax on HTP	0,136 EUR/g. 0,149EUR/g from April 2022.

Overall, the share of tobacco taxes on government revenue is well below the EU average. Weiner Zeitung (2022) notes that Austria has for some time struggled with smuggling of cigarettes and illicit trade as high as 16 % of the market in 2019, which has then shrunk to 10 %. This supposed decrease in illicit trade would help explained the uptick in cigarette sales in 2020 which we observed in Figure 20.

Austria's approach towards tobacco is generally in agreement with the principles of harm reduction. As the country was initially slow to introduce measures against smoking – despite the existence of clear public messaging on the dangerous of cigarette-smoking, as is noted by professor Bernd Rode – cessation was more gradual in the 2000s than in the previously analyzed Member States, but in the 2010s, when more regulation was imposed on conventional cigarettes and less so on novel and alternative products, the established cessation trend was allowed to continue due to smokers being motivated to switch towards the alternatives.

Harm Reduction Index

The Harm Reduction Index, which is described in more detail in Chapter 6, assigns Austria the score of 28.30 and a total rank of 1. out of seven measured countries.

5.6 GERMANY

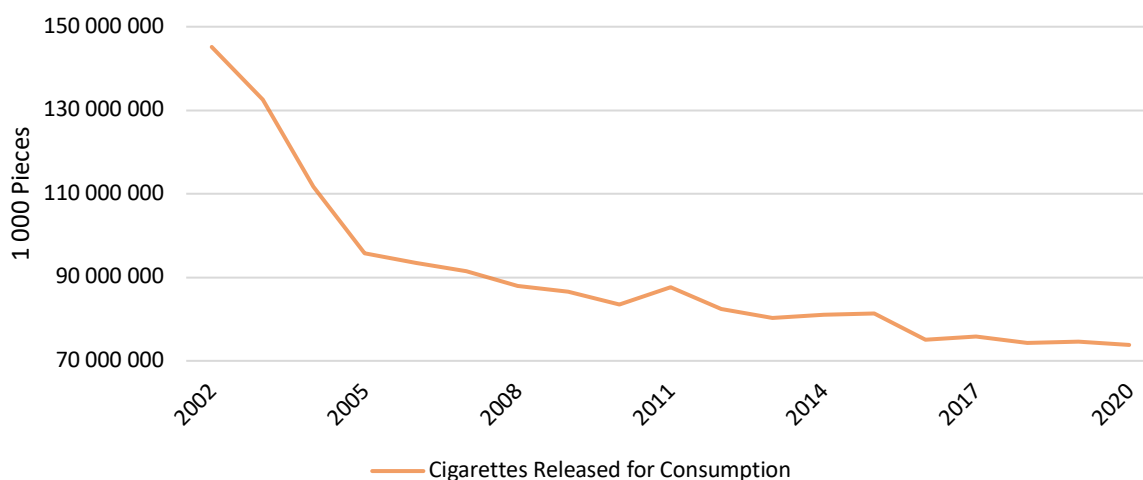
In many respects, Germany's approach to tobacco regulation is similar to the Austrian. The country's also been relatively friendly towards new products and rarely introduces regulation stricter than the EU directives. A certain degree of decentralization within the country also places a limit on regulation through competition among the 16 German states.

Table 18: Germany in Numbers

c e t a	
Current prevalence of smoking	23 %
Expected prevalence of smoking by 2040 (linear prediction)	16 %
Expected prevalence of smoking by 2040 (exponential model)	19 %
Prevalence of regular usage of e-cigarettes and vapour-based products	2 %
People with experience with e-cigarettes and vapour-based products	15 %
Prevalence of regular usage of tobacco heated products	1 %
Prevalence of regular usage of tobacco heated products	8 %
People with experience with oral tobacco products	12 %

Currently, the prevalence of cigarette smoking in Germany is the lowest of all the CEE countries in this analysis, although the difference is not significant. However, unlike most other countries, Germany has not experienced the decline in smoking rates in late 2000s and early 2010s. In fact, Eurobarometer data show that the prevalence of smoking among adults in Germany was the same in 2009 and 2017, amounting to about 25 % over the whole period. Only between 2017 and 2020 has it somewhat decreased to 23 %, as we observe in Table 18. Sales of manufactured cigarettes in Germany (Figure 21) have been continuously in decline, although again not as steeply as in other countries, but more or less followed the same trajectory since 2005 until current date.

Figure 21: Cigarettes Released for Consumption in Germany (in 1000 pieces)



Source: Eurostat, Taxation and Customs (2021)

Usage of novel and alternative products is also high compared to other countries. Electronic cigarettes and heated tobacco products are not used by as many people as in Austria, but are on about the same level as in Czechia and Slovakia, with 15 % of adults having tried vaping and 8 % having experience with HTP. On the other hand, Germany comfortably beats other CEE countries with the exception of Austria with its citizens' usage of oral tobacco products.


German policy is more complicated to analyze due to the aforementioned differences among the states. But generally speaking, Germany transposes the European regulation without many additions. This applies for packaging regulation, regulation of flavours – which remain legal for novel products while being prohibited for cigarettes, and point of sales regulation. The latest one is notably lenient, as Germany allows a significant amount of tobacco advertising (German Way, 2020). Germany is the only EU member state that still permits billboard and cinema advertising for tobacco products.

This is however going to be changed in the coming years (Hayek Institute, 2022). Tobacco advertising outdoors is going to be restricted and limit will be placed on cigarette commercials in cinemas to films that are aimed at an adult audience only. By 2024, these rules will also apply to e-cigarettes and heated tobacco products. Point of sale advertising will still be legal.

Regarding regulation of smoking and vaping in public spaces, federal rules restrict both only in federal government's buildings and on public transports. Restrictions in other public areas, such as cafes, restaurants or bars are in the competence of individual states. Only three states currently have complete bans on smoking indoors, namely Bavaria, North Rhine-Westphalia and Saarland, where in total around 40 % of Germans reside.

Restrictions on smoking indoors in other states depend on a number of factors such as the size of the premises, the status of the establishment (e.g. private clubs) and whether or not food or beverages are served. In most states, vaping indoors (outside the limits of the federal ban) is allowed.

Table 19: Germany's Policy

	
Regulation of cigarette packages	Not exceeding EU regulation (warning covering 65 % of package surface, including graphic reducing attractiveness). Implemented in 2016.
Regulation of e-cigarettes packages	Not exceeding EU regulation (warning covering 30 % of package surface).
Plain-packaging regulation	No rules exceeding EU regulation.
Point of sale regulation	No rules exceeding EU regulation in place. Point of sale advertising and product display allowed.
Ban on smoking indoors	Approach to smoking indoors differs by state. From 2016, Bavaria, North Rhine-Westphalia, and Saarland, have complete ban on smoking indoors. Remaining states require separate smoking and non-smoking indoors spaces. Federal smoking ban is in place for public transports and federal government's buildings.
Ban on vaping indoors	E-cigarette usage regulated similarly to smoking, depending on state. Vaping is prohibited in federal buildings and certain public spaces like public transports or restaurants.
Ban on flavours	Flavoured cigarettes banned. Menthol cigarettes legal until May, 2020. Flavoured e-cigarettes remain legal.

As evidenced in Table 20, despite the relatively high fixed component of cigarette excise duty, the overall tax on manufactured cigarettes as a fraction of the weighted average cigarette price is the lowest of all the Member States in this analysis. In terms of the general affordability of smoking, Germany is just on the EU-wide average. From the countries in this section, Figure 15 shows that cigarettes as comparatively cheaper in Czechia, Slovakia, Sweden, and Austria.

This situation is about to change in the coming years. The German government prepared a schedule from which it promises an overall cigarette tax increase. The price per cigarette is expected to increase annually and will reach 0,1111 EUR/pc by 2026 (Tobacco Reporter, 2021).

Table 20: German Tax Duty

	
Tax on cigarettes	163,59 EUR/000 on WAP (weighted average price). 0,1088 EUR/pc + 19,84 % of the price.
Tax on e-cigarettes	No special tax levied. 0,16 EUR/ml as of July 2022
Tax on HTP	0,01566 EUR/g + 13,13 % of the price + an additional 1,86 EUR based on a pack of 6g or 80 % of cigarette excise.

Looking further at the taxes levied on novel products, we observe a curious divergence between HTP, which suffer from the highest fixed tax rate among all countries in the study (although rivalled Poland due to it being the only other country that also has an ad valorem component to its HTP tax), and e-cigarettes, for which no excise tax is in place. This disparity is to be ended in July 2022, when Germany's new excise tax on e-cigarette liquid comes into effect.

Evaluating Germany's tobacco policy overall, it is fair to say that it is one of the most harm-reduction-friendly countries in the region. It benefits from the advantages of European legislation in terms of different regulation for packaging and flavours, and together with its tax scheme, this works towards leading users away from cigarettes. Germany's high tax on HTP is disproportionate, which also helps explain why Germany, although having about the same number of vapers as Austria, has much fewer users of HTP.

Contributing factors can be found also in differences in smoking and vaping bans, as well as legality of cross-border sales, which keeps illicit trade in line and increases compliance. Last but not least, Germany's lenient policy towards advertising, especially for novelty products, provides opportunity for innovators who can more easily penetrate into the market with new less dangerous products, and for manufacturers of less harmful products, in general, to inform on the properties of their products. When advertising becomes restricted in the coming years, Germany might lose its edge as a pioneer of harm reduction practices.


Harm Reduction Index

The Harm Reduction Index, which is described in more detail in Chapter 6, assigns Germany the score of 20.94 and a total rank of 4. out of seven measured countries.

5.7 SWEDEN

As has already been mentioned, Sweden is often used as an example of harm-reduction practices. At first sight, this is evidenced by the fact that Sweden has the lowest prevalence of smoking in Europe (7 %, as shown in Table 21), and is in fact the only country for which both our prediction models show that the EU goal of less than 5 % of smokers among adults by 2040 will be achieved (although it should be noted that the prediction models are less reliable around the lower bound, and it should naturally not be expected that smoking rates in any country will actually reach zero, as the models would have us believe).

Table 21: Sweden in Numbers

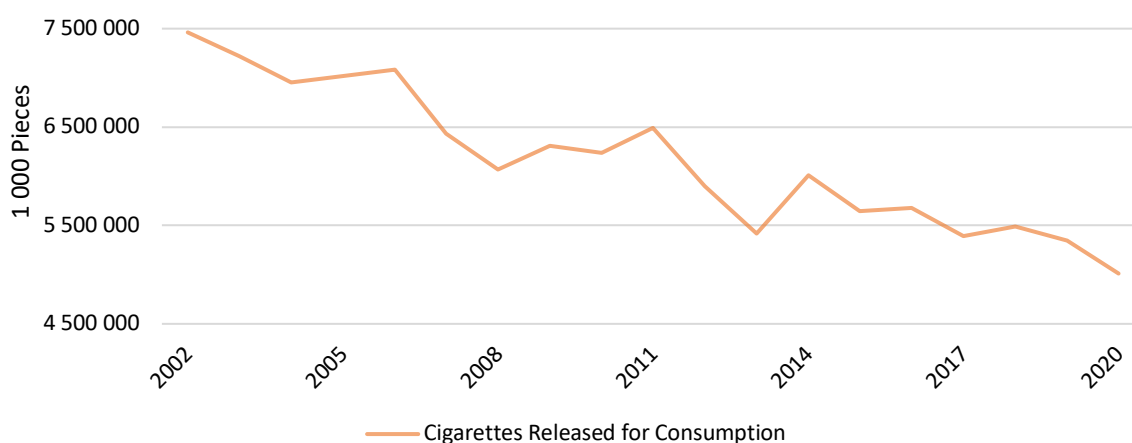
	
Current prevalence of smoking	7 %
Expected prevalence of smoking by 2040 (linear prediction)	0 %
Expected prevalence of smoking by 2040 (exponential model)	0 %
Prevalence of regular usage of e-cigarettes and vapour-based products	1,1 %
People with experience with e-cigarettes and vapour-based products	12 %
Prevalence of regular usage of tobacco heated products	0 %
Prevalence of regular usage of tobacco heated products	7 %
People with experience with oral tobacco products	46 %

Sales of manufactured cigarettes is on a continuous decline just as general smoking prevalence. Figure 22 shows that although this decline is not so steep, it is continuous and uninterrupted. Having observed similar sales trends for Germany and Austria, it could be said that a gradual decline is indicative of a country more focused on harm-reduction rather than restriction.

The usage of e-cigarettes and HTP in Sweden is lower than in all other countries with the exception of Poland and Hungary, but this is only because of the large popularity of Swedish snus, thanks to which 46 % of adults have experience with oral tobacco products, and which has displaced both traditional

smoking and alternatives used in other countries. Sweden is the only EU country in which snus can be legally bought because of an exemption negotiated when the country joined the EU in 1995.

Figure 22: Cigarettes Released for Consumption in Sweden (in 1000 pieces)



Source: Eurostat, Taxation and Customs (2021)

With the exception of certain point of sale regulation, we see in Table 22 that Sweden implemented very few policies exceeding the belatedly transposed EU legislation. This again means that there are positive differences between packaging norms for manufactured cigarettes and alternatives (no additional plain-packaging laws are in place), and the same applies also for restrictions on flavours.

Table 22: Sweden's Policy

	
Regulation of cigarette packages	Not exceeding EU regulation (warning covering 65 % of package surface, including graphic reducing attractiveness). Implemented in 2018.
Regulation of e-cigarettes packages	Not exceeding EU regulation (warning covering 30 % of package surface). Implemented in 2018.
Plain-packaging regulation	No plain-packaging rules exceeding EU regulation in place.
Point of sale regulation	Point of sale advertising legal provided it is not visible from the outside. Point of sale display allowed.
Ban on smoking indoors	Smoking is banned in restaurants, cafes, bars and clubs since 2005 with the exception of designated smoking rooms without served food or beverages.

	Smoking in public spaces such as public transports and playgrounds prohibited since 2019.
Ban on vaping indoors	Vaping banned indoors under same rules as smoking since July 2019.
Ban on flavours	Not exceeding EU regulation. Ban on flavours for e-cigarettes currently discussed.

Sweden was also among the first to introduce a comprehensive indoors smoking ban that affects restaurants, bars, clubs and other areas, which came into effect as early as 2005. Smoking in other public places such as playgrounds was further prohibited in 2019, together with imposing the same rules on vaping.

Cross-border sales, internet sales and vending machine sales remain legal, and cigarettes in Sweden are surprisingly affordable (that is if adjusted for purchasing power), as Figure 15 shows. From the Member States in this chapter, only Austria has relatively cheaper cigarettes than Sweden. Despite all this, the share of illicit trade in Sweden remains non-negligible, amounting to 7,9 % of the market (Tobacco Taxation Report, 2020).

Table 23: Swedish Tax Duty

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Tax on cigarettes	157,56 EUR/000 on WAP (weighted average price). 0,15 EUR/pc + 1 % of the price.
Tax on e-cigarettes	0,19 EUR/ml (0,39 EUR on highly concentrated liquids).
Tax on HTP	0,181 EUR/g.
Tax on snus	0,046 EUR/g.

In terms of taxation policy shown in Table 23, we see that Sweden, contrary to good harm reduction practices, imposes taxes on all major alternatives to combustible cigarettes. Furthermore, with the exception of Poland and Germany for HTP, the taxes on novel products are the highest of all those in this analysis, and at the same time leaving combustible tobacco products in Sweden among the most affordable (adjusting for purchasing power), as Figure 15 shows.

This should soon be changing, as new legislation to increase cigarette taxation is currently being discussed, which would increase cigarette tax by 3 percentage points from 2023 and by another 3

percentage points from 2024, but even after this change, cigarettes in Sweden will remain the cheapest of all Nordic countries, about half the cost of cigarettes in neighbouring Norway (Snusforumet, 2022). This tax increase should also affect the popular snus, the taxes on which have already been steeply increasing in recent years. If the tax change is implemented, by 2023 it would translate into a 300 percent increase for snus since 2007. Together with already high taxes on alternative tobacco products, this could impact Sweden's position as the European leader in tobacco harm reduction.

On the other hand, the country has an interesting tax policy element in distinguishing between different concentration of e-cigarette liquids. The tax rate for highly concentrated liquids with a nicotine content of at least 15mg per millilitre is double the standard rate. The lower rate on less concentrated liquid seems to be a sound reduction practice, although there are not yet data on whether the benefit was not outweighed by increase in usage of the less concentrated liquids (the measure was introduced in 2021).

Tax increases on snus and already high taxes on HTP and vaping are not the only issues threatening the country's leadership. In February 2022, the Swedish government announced a ban on vaping flavours (Vaping Post, 2022).

Michael Landl, director of the World Vapers' Alliance, states that: *"Banning flavours could force thousands of former smokers in Sweden to take up the habit once again. Research shows vapers are more than twice as likely to quit with flavours. If they are banned, 150 000 vapers ... would lose their flavours and could go back to smoking. This would be a major setback in the fight against smoking and its related illnesses."*

The increase of taxes on snus and ban on vaping flavours work especially badly in combination. On its own, the ban on flavoured e-cigarettes, as well as the recent ban on vaping indoors from 2019, could be considered as a push from one alternative product (e-cigarettes) to another (snus). Similarly for snus, or for generally high taxes on heated tobacco products in the country.

Introducing all these measures on alternatives to combustible tobacco products, combined with the relative cheapness of cigarettes in Sweden, threatens to undo or slow down the progress Sweden has made through its initial positive attitude towards alternatives to smoking and early introduction of limitations on traditional combustible products and them only, such as the indoor smoking ban of 2005.


Harm Reduction Index

The Harm Reduction Index, which is described in more detail in Chapter 6, assigns Sweden the score of 21.00 and a total rank of 3. out of seven measured countries.

6 HARM REDUCTION INDEX

The results of the Harm Reduction Index for 2022, summarized in Table 24 below, are in many ways expected based on the discussion of individual Member States in Section 5.

Table 24: Harm Reduction Index 2022, Summary

	Rank	Score	Regulation	Taxation
Austria	1	28.30	15.5	12.8
Czechia	2	25.86	16.5	9.36
Sweden	3	21	17.5	3.5
Germany	4	20.94	13.5	7.44
Slovakia	5	20.89	12.5	8.39
Poland	6	14.31	12	2.31
Hungary	7	7.95	4	3.95

Source: Own calculation

The low performance by Poland and especially Hungary is not surprising given the analysis of their policies in Section 5. Similarly, a good position of Austria and of the Czech Republic were to be expected. What is striking is the underperformance of Germany and Sweden, which are both known to be very liberal in their approach to nicotine and tobacco alternatives. Table 25 and the discussion below sheds more light on their ranking.

Out of the maximum of 50 points, most countries ended up in the 20–29-point bracket, with no Member States receiving 30 and more points. This is not entirely surprising, as indicated in Section 3.4; a score converging on zero means perfectly equal treatment of combustible tobacco and alternative products, which is a policy a Member State can choose to follow.


A score of 50 means a very large difference between policy towards smoking and alternative products, which in many cases is not possible due to EU regulation (for instance for packaging, a country cannot score more than 7 out of 10 available points), and in some cases is not realistically possible – for instance, no country will ever achieve 100 % regulation compliance.

For these reasons, scores in the upper 20s indicate good harm reduction tendencies, while a score around 35 points would indicate very good performance still well within limits of the possibilities of the regulatory EU framework.

6.1 HARM REDUCTION INDEX 2022 IN DETAIL

Looking into the scores of the seven Member States by components helps explain some of the less expected results in the overall standings. Starting with the two worst performing countries, we see that both Poland and Hungary scored very low in both broader categories, regulation and taxation, despite the fact that cigarettes are stringently regulated and comparatively heavily taxed in both countries, with cigarettes in Hungary being in fact the least affordable (adjusted for purchasing power) of all the observed countries, as Figure 15 showed.

Table 25: Harm Reduction Index, 2022

	Czechia	Slovakia	Poland	Hungary	Germany	Austria	Sweden	Range
Sum	25.86	20.89	14.31	7.95	20.94	28.30	21.00	0-50
Regulation	16.5	12.5	12	4	13.5	15.5	17.5	0-31
Packaging regulation	3.5	2.5	4	0	3.5	3.5	3.5	0-10
Cigarette advertising and point of sale regulation	3	3	3	4	1	3	3	0-5
Alternative products sales and product regulation	2	2	1	0	1	2	2	0-2
Alternative products advertising and display regulation	4	3	2	0	4	4	2	0-5
Indoor usage	1	0	0	0	1	0	0	0-2
Flavours and intensity	2	2	2	0	2	2	2	0-2
Snus legality	0	0	0	0	0	0	3	0-3
Recognition of harm reduction	1	0	0	0	1	1	2	0-2
Taxation	9.36	8.39	2.31	3.95	7.44	12.8	3.5	0-19
Tax on e-cigarettes	3.55	2.55	0.95	1.05	2.47	3.93	0.00	0-5
Tax on HTP	2.14	1.30	0.00	0.36	0.72	2.62	0.00	0-5
Tax on oral products	1.18	1.18	0.57	0.47	1.97	3.49	2.66	0-5
Regulation enforcement	2.48	3.36	0.79	2.08	2.28	2.76	0.84	0-4

Source: Own calculations

The reason is that while cigarettes are heavily regulated, the same applies to vaping, HTP, and other alternative products so the differences become marginal. Both countries have taxes on HTP (especially high in Poland) and are among the 3 observed Member States with a tax on vaping liquid, have indoor vaping bans and in the case of Hungary also strict sales regulation and ban on vaping flavours – thus partly explaining Hungary's lower score in regulation.

More puzzling is the case of the underperforming Sweden. While the country performs very well in terms of regulation, its taxes on alternative products together with comparatively very affordable cigarettes yield it one of the lower scores in the taxation category. Germany falls back behind Austria for similar reasons.

Overall, the Czech Republic and Austria fare the best in terms of regulation – clearly distinguishing rules for indoor usage between smoking and vaping or oral products usage, as well as allowing flavours for alternative products but banning them for FMCs. Both countries also transposed TPD2 packaging norms without alterations, meaning a difference in packaging rules for cigarettes and for alternatives. Both Austria and Czechia also don't tax vaping liquids or modern oral products and do not excessively tax THP. Adjusted for purchasing power parity, the difference in taxation between THP and e-cigarettes is higher in Austria, contributing to the country's better score on the Index.

Finally, Slovakia stands between Germany and Czechia in its policies, as Section 5 had indicated. The country legislated beyond TPD2 in some respects, such as packaging norms, and in other areas, such as indoor smoking bans, regulated less than neighbouring countries, which earned it a slightly lower score on regulation overall. Still, the country reached a high score overall, and one of the best scores on taxation, as it does not impose an excise tax on vaping liquid or modern oral products, and cigarettes are comparatively more taxed than in the other Member States.

7 CONCLUSION

We have observed in Section 1 and again in Section 5 that as a whole, it is unlikely that the EU will become tobacco-free by 2040 as was the ambition of the Beating Cancer Plan. The same also applies to each individual Member States including Sweden, due to large prevalence of snus in the country.

And while it is impossible to completely distinguish regulatory effects from cultural effects – such as change in public opinion on smoking or increase in public knowledge regarding the risks of smoking, our analysis of individual Member States seems to indicate that stricter policy towards smoking, like regulation of indoor usage, was indeed effective in reducing smoking. In recent years however, smoking cessation has often stagnated, showing that strict-on-smoking policies probably passed the peak of what they can achieve in terms of their impact on consumer behaviour. New strategies are clearly needed.

If complete eradication of tobacco is not realistic or would come at too high a cost to the users, the best available approach is harm reduction and focus on the goal of smoke-free Europe, aiming to limit and mitigate the harms of combustible tobacco usage instead. This approach, which has been steadily gaining popularity among experts in the field and described in more detail in Section 3.1, means treating different products differently through regulation and taxation policy, depending on their level of harm. The goal of harm reduction policies is to incentivize smokers, especially those who might not be able to quit altogether, to switch to using less harmful products instead, and thus positively affect public health.

Over the course of this study, we observed elements of harm reduction practices already present in the European and Member States policies, and also attitude to alternative products in reports published by the European Commission and other European institutions. These involve the labelling and packaging rules and general product safety regulation contained in the TPD2, or the prohibition of flavours that applies to FMCs only. On the level of individual Member States, this also includes regulation that regulates smoking indoors, but is more lenient – at least in the countries leading the Harm Reduction Index – towards vaping and modern oral products usage.

Harm-reduction aspects can be also observed in the Member States' approaches to taxing nicotine and tobacco products, with FMCs and traditional tobacco products typically being taxed at much higher levels, and e-cigarettes, heated tobacco products and modern oral products having lower tax levied on them or no excise duty at all. It however needs to be noted that while keeping less harmful alternatives more affordable is a good incentive for switching, making cigarettes too unaffordable ought to be avoided. The reason is that over a certain threshold, the impact of marginal increase of the excise duty has little effect on smoking prevalence, while the risk of trapping smokers who are unable to cease smoking in poverty through excessive price increases.

Aside from the regulation currently in effect on both the European and local levels, Section 4 also examines the impact of TPD2 on the European market and assesses reports and proposals that have been made on its basis. The conclusion from this assessment is that the views of experts advocating

for harm-reduction policies are severely underrepresented in the debate, regardless of the growing support for implementation of harm-reduction inspired measures.

Instead, some of the documents published by European institutions operate with the gateway theory, according to which novel products lead more people to take up smoking, rather than serve as a tool of cessation. We showed that this conclusion is not supported by the data, seeing as for instance almost 2 in 5 e-cigarettes users take them up in order to limit smoking, and only 2 % of vapers had not previously smoked. Naturally, policies proposed on the basis of the mistaken gateway theory will be inclined to place novel products on the same level as FMCs and traditional tobacco products, which would mean a setback not only for harm-reduction policy in Europe, but also for the fulfilment of the tobacco-free Europe goal.

So instead, what follows is a list of few most important categories in which, based on our analysis, a policy change with huge impact on tobacco usage and public health is possible. In the words of Dr. Csemy: *“the European legislation should dare to make a major shift in tobacco policy and work to promote a harm reduction approach. It would be in the interests and good of its citizens.”*

7.1 RECOMMENDATIONS

In July 2022, the Czech Republic assumes the 6-month presidency over the Council of the EU. This will give the country the chance to define the agenda and priorities of the Council of the EU, especially the speed and intensity of negotiating individual legislative proposals and to influence long-term goals and external visibility of the EU.

This is a huge opportunity for the Czech Republic, especially as a country that scored well on the Harm Reduction Index, to put more emphasis on harm reduction as a policy most likely to lead to the fulfilment of the goal of tobacco-free Europe.

More specifically, we believe that the introduction of and advocacy for the following steps would be successful in increasing the awareness of harm reduction principles and their benefits, and consequently leading to an improvement in public health in the long term:

More extensive involvement of medical and harm reduction experts in the policy-creation process:

In Section 4, and more specifically in 4.1.3, we discussed that some of the existing documents published by the European institutions tend to be one-sided and do not fully reflect the spectrum of expert opinions from the field of medicine, harm reduction policy and economics.

The Czech presidency in the Council of the EU should be seen as an opportunity to foster dialogue with experts from these fields and establish a network of professionals consulting on policy toward tobacco and nicotine products from the perspective of harm reduction. This should ensure that the new policy that the EU implements, and which is to become the new benchmark for the global approach to smoking, fully reflects the latest scientific findings.

Another consulted expert, Dr. Riccardo Polosa, expresses the need for evidence-based and research informed policy, when he comments that: *“consumer perspectives, sound THR research, and continuous post-marketing surveillance should be at the very heart of future regulatory schemes that will address concerns while minimizing unintended consequences of ill-informed regulation”*.

Inclusion of all relevant stakeholders into consultations of new legislation: When the EU and Member States will be evaluating TPD2 and working on a new TPD3, they should ensure broad stakeholder consultation of all relevant stakeholders, including: scientists, addictologists, representatives of civil society, patients addicted to tobacco, companies involved in the whole supply chain. And, from the perspective of the European Commission, it will be crucial to ensure broad participation of all relevant Directorate-Generals of the European Commission.

Consideration of impact on local economies: Following the inclusion of all relevant stakeholders, including representatives of local businesses, evaluation of the impact of TPD2 on local economies and especially SMEs that are impacted by changes in consumer behaviour resulting from the regulation needs to be considered in drafting future legislation.

In particular, DG GROW should be involved in the process as the relevant body to attempt to mitigate the impact of proposed regulation on SMEs. An interservice group should be formed to prepare a detailed impact assessment. This group ought to be as broad as possible, and include not only DG GROW, but also DG SANTE and other relevant DGs that can provide insight into the impact of TPD3 in their respective areas.

This would mean DG GROW for SMEs impact, DG ECFIN regarding overall macro-economic impacts, DG AGRI regarding tobacco farming, DG COMP regarding competition effects; DG EMPL regarding employment effects, and DG ENV regarding environmental impacts. These DGs would inform creation of policies in areas that are either affected by the TPD revision or contribute to the objectives and implementation of the policy.

Improved public information campaign: The experts from most of the Member States consulted for the purposes of this study agree that there is a lack of official information both on the European and local levels, and there have been no public information campaigns to date that would focus on the relative risks of different products and benefits of harm reduction practices. In the words of Dr. Piotr Kuna from the Medical University in Lodz, there is a *“lack of the provisions to inform adult consumers about the reduction of harm when using different tobacco products”* in public health policy.

Czech ministers in the Council should support a coordinated information campaign focused on communicating not only the dangers of smoking, but also the merits of alternatives as harm reduction and eventually cessation tools. This policy should be aimed at adult cigarette and tobacco users, in order to motivate them and support them to switch to less harmful products.

Adherence to the Czech government program statement: It has already been stated that the program statement of the newly elected Czech government from January 2022 endorses harm reduction practices as guiding principles in its approach to public health policy in this area.

The Czech representatives on the council and the Czech leadership should adhere to the national government program statement and should actively promote policies that lead to regulation of different product categories in proportion to their level of harm.

Namely, based on our analysis of the seven Member States and the results of the Harm Reduction Index, the promoted policies should:

- Favour differentiation between usage limitations for different product categories. Being able to use e-cigarettes or nicotine pouches in places where FMCs are forbidden is one of the main reasons for switching. Policies upholding this difference in usage regulation should be encouraged.
- Favour differentiation of packaging for different product types. In this respect, current TPD2 regulation is satisfactory, as it makes combustible tobacco products comparatively less visually attractive, especially for minors. Policies aiming to put alternative products on the same level as FMCs should not be supported.
- Support defining new categories for new product types such as nicotine pouches. These new less harmful products should not be included in existing categories of tobacco products and subject to the same regulation, but the regulators should instead be reactive to new market trends by defining new regulatory categories with their own rules, as has been the practise for example in the Czech Republic, Estonia, or Denmark.

Being quick to react on market trends in the short term without losing sight of long-term goals: Being fast in approving new products and placing them in proper regulatory categories not only increases consumer safety, but if properly assessed based on the novel products' risk, it also leads to large gains in public health in the long term, as smokers have more options of less harmful products to which they can switch. Furthermore, keeping the European market open to new products makes Europe more competitive on the global scale, and benefits not only innovators and entrepreneurs coming up with new and less harmful products, but also various SMEs such as local retailers.

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9 APPENDIX

Table A1: Daily Cigarette Consumption by Smokers by Country

	2012	2014	2017	2020
EU27+UK	14.7	14.9	13.7	14.2
BE	15.3	15.8	13	12.9
BG	15	15.6	15.8	15.7
CZ	13.8	14.2	15.3	15.4
DK	14.5	13.6	12.9	12.7
DE	15.6	15.4	14.7	15.4
EE	12.9	11.9	12.5	12.5
IE	16.4	16.1	13.3	13.1
EL	20	20.3	17.5	18.7
ES	14.5	15.1	11.4	12
FR	13.6	13.8	12.2	11.8
IT	13.8	13.8	13.3	12.8
LV	12.7	12.4	10.8	12.7
LT	12.4	12.1	12.6	12.6
LU	16.9	13.6	14.6	13.5
HU	15.6	16.3	16	15.9
NL	14.4	13.4	11.7	12.3
AT	32.6	19.5	18	18
PL	29.9	30	29.7	16.4
PT	27.2	26.8	24	12.9
SK	22	22.5	26.1	13.7
UK	15.9	16.4	13.8	12.8

Source: Eurobarometer, 2021

Table A2: Annual Releases for Consumption of Cigarettes by Country (1000 pieces)

	Austria	Czechia	Germany	Hungary	Italy	Poland	Slovakia	Sweden
2002	15,358,733	19,096,775	145,152,720	18,319,609	105,215,836	82,047,368	4,989,533	7,461,943
2003	15,062,233	25,613,577	132,603,170	19,435,456	101,581,626	80,244,262	4,777,016	7,221,843
2004	14,463,704	22,459,838	111,716,210	13,853,849	98,846,737	75,283,084	4,564,499	6,953,484
2005	13,280,238	26,231,340	95,826,690	14,184,287	92,822,302	87,553,826	4,675,743	7,018,436
2006	13,883,290	28,262,528	93,465,500	15,810,596	93,807,356	79,769,525	4,786,986	7,086,323
2007	13,583,454	30,595,808	91,497,320	16,685,080	92,821,293	83,815,006	4,577,080	6,436,000
2008	13,187,828	16,600,608	87,978,850	17,407,571	91,994,337	100,302,085	4,367,174	6,071,000
2009	13,383,631	20,931,982	86,606,770	17,429,547	89,148,720	82,616,991	5,872,382	6,311,000
2010	13,759,444	21,669,790	83,564,540	11,857,780	87,031,399	64,931,896	7,377,590	6,240,000
2011	12,994,256	23,232,760	87,555,787	13,009,695	85,467,892	59,276,996	7,212,418	6,491,398
2012	13,017,103	23,920,825	82,405,131	12,533,679	78,734,360	52,211,424	7,076,528	5,901,799
2013	13,034,736	22,354,677	80,274,940	9,312,300	74,027,717	46,931,286	6,696,981	5,416,113
2014	12,902,235	21,396,249	81,051,367	7,378,580	74,431,165	44,037,526	6,699,566	6,011,491
2015	12,749,726	20,437,821	81,266,691	7,842,097	73,815,494	41,189,448	6,839,853	5,648,479
2016	12,548,983	20,275,267	75,015,940	7,447,211	72,035,847	41,417,672	6,948,109	5,678,177
2017	12,382,166	20,772,206	75,837,781	7,086,879	69,311,181	41,616,286	7,110,566	5,393,688
2018	11,831,567	21,221,296	74,360,153	8,309,404	67,402,620	42,898,820	7,003,123	5,491,570
2019	11,739,180	19,097,070	74,595,508	8,281,077	64,595,602	45,030,616	7,158,245	5,348,395
2020	12,229,450	17,794,977	73,808,910	8,294,320	61,734,230	43,139,518	6,931,803	5,011,339

Source: Eurostat, 2021



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