

### **Abstract:**

The Council Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco (TTD) is currently under review. This reintroduces the question of how to proceed with the tobacco 'blind spot'. Against this background, two main challenges arise for the revision of the TTD. First, tackling the lack of integration of non-combusted alternatives (NCAs) into the current legal framework. Second, improving the alignment of the tax policy outlined in the TTD with the main public health objective - to curb smoking. Policymakers should take the harm produced by combusted products seriously. This means applying the principle of harm reduction and treating NCAs differently from traditional combusted cigarettes (CCs) in respect to both regulation and taxation.



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# Harm reduction: everybody's darling

Harm reduction can be defined as actions directed to reducing the damage resulting from harmful behaviour by both individuals and society (Levesque, 2018). This approach is often adopted in relation to addiction, where prohibition does not work and/or causes more harm than good to individuals and society. The history of prohibition is a history of failures (or suboptimal results, at best). In recent years, this traditional strategy has been gradually replaced by harmreduction policies related to drugs, alcohol, gambling, prostitution, sexual activity, and smoking. The targets of harm-reduction policies can vary as well as the success rates of the policies. Hence, there is no 'one size fits all' harmreduction policy due to the very nature of harmful behaviours and the differences in people targeted. In addition, it is not always clear how to measure the success of harm reduction. Sometimes inputs can be measured, for example the number of safer smoking kits provided for crack smokers (see Vancouver Coastal Health, 2013: 13). At other times outcomes are the centre of analysis, for example the change in the number of injuries because of the adoption of makeshift supplies (see Vancouver Coastal Health, 2013: 17f).

Harm-reduction initiatives are abounded and supported by numerous national and supranational institutions. The European Union (DG Santé) is funding initiatives to provide harm-reducing interventions as well as initiatives to monitor and benchmark harm-reduction activities in Member States, such as the European Harm Reduction Network, which is responsible for the Civil Society Monitoring Report of Harm Reduction in Europe. This report focuses on needle and syringe programmes, overdose prevention and drug consumption, hepatitis, tuberculosis, and HIV. Although the mission of the network is 'to strengthen harm reduction policies in Europe' (*Rigoni* et al., 2021: 12), when discussing tobacco, harm reduction does not feature. Harm Reduction International (HRI) is another NGO supported by, among others, the World Health Organization (WHO), the European Commission, and the UN Office of Drugs and Crime. The focus of HRI is comparable to that of the European Harm Reduction Network – including the 'blind spot' in relation to tobacco.

## Smoking still disproportionally affects the poor

Smoking is a behaviour linked to socio-economic status. It is largely prevalent among the poorer classes. While attempts to quit smoking have a low success rate across the board, they are even less likely to be successful among smokers with a low socio-economic status (see Hiscock et al., 2012; see Hatsukami & Carroll, 2020). Hiscock and colleagues (2012) suggest several measures to reduce

smoking including increasing the price of tobacco products, targeted cessation programmes, and mass media interventions. Once again, harm reduction does not feature in their suggestions (see Hiscock et al., 2012: 117f). This begs the question: given the low success rates of quitting, why does harm reduction play such a minor role?

The European
Commission should
consider harm
reduction policies to
reduce the negative
effects of tobacco.

Harm reduction related to smoking can be defined as 'minimizing harms and decreasing total mortality and morbidity, without completely eliminating tobacco and nicotine use' (Stratton et al., 2001: 25). Based on that definition, over the last two decades several products have been developed: SNUS, the abbreviation for smokeless tobacco with lower levels of tobacco-specific nitrosamines (TSNAs) and other toxicants; e-cigarettes; heated (not

burned) tobacco products; nicotine pouches; and alternative nicotine delivery systems (ANDS). The main feature of all these novel products is non-combustion to enable lower-risk nicotine consumption if cessation is unlikely to be achieved.

### Public health policy should entail harmreduction policies

One of the early reports on the potential of harm reduction concluded that '(f)or many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible' (Stratton et al., 2001: 5). Currently, public health policy does not consider that using NCAs or ANDS can reduce the harm of combustible cigarettes. The current tobacco control strategy is aligned on the fact that 'quitting entirely is the best option for reducing harm' (Tobacco Tactics, 2022). Additionally, fears such as the increased uptake of smoking in adolescents or nicotine-naïve consumers, dual use, and the uncertainty around long-term sequelae play a part.

### The UK: harvesting low-hanging fruits

Despite these concerns, public health authorities in some countries are already exploring the potential of harm reduction delivered by NCAs or ANDS. For example, in the United Kingdom, nicotine replacement therapies, patches, and nasal sprays were accepted in 2013 by the National Health Service as risk-reducing alternatives to initiate smoking cessation. In this case, the first National

Institute for Health and Care Excellence (NICE) guidelines on harm-reduction approaches to smoking acknowledged the fact that tar and other toxins – and not nicotine – are the drivers of disease and premature death. The guidance was updated in 2021 to include e-cigarettes as well. The update was encouraged by the evidence review on e-cigarettes, performed by Public Health England in 2015, which concluded that e-cigarettes are roughly 95 per cent safer than smoking. Based on this, NICE guidance adopted e-cigarettes as a support to quit or reduce the level of intoxication.

With this experience and remaining prejudices in mind, there is a need to explore the ANDS harm-reduction potential including heated tobacco products and pouches. Exploration should start quickly given the time lag between the intervention (ANDS) and consumer-relevant outcomes (morbidity, mortality). Current available evidence suggests that ANDS are potential harm-reducing interventions. Further research on the dual use of combustible and non-combustible products is needed. Moreover, the 'gateway-effect-hypothesis' – which suggests that NCAs trigger the adoption of smoking behaviour in adolescents – should be tackled in longitudinal studies to clarify its relevance for harm-reduction strategies based on NCAs. What we do know is that the latest Eurobarometer shows a very low initiation rate for e-cigarettes (2 per cent), and a virtually non-existent (0.5 per cent) initiation rate for HTPs.

# Beyond taxation: new products require new strategies

In discussions on combusted products, historically speaking tobacco taxation has been considered a best-practice prevention strategy to curb smoking. Excise taxes normally change relative prices, if taxes are not fully absorbed by producers, they can contribute to channelling consumer demand. Therefore, the behavioural significance can be estimated based on the price elasticity of demand. A global literature review executed by Chaloupka and colleagues (2019) on the association of taxes, prices, and consumption demonstrated that in high-income countries 'price elasticity estimates are around –0.4, implying that a 10% increase in price reduces overall consumption by 4%. Estimates from LMICs [low- and middle-income countries] range from –0.2 to –0.8, clustering around –0.5' (Chaloupka et al., 2019: 189). For Europe Gallus and colleagues (2006) have estimated price elasticates between –0.5 and –0.7 on average. Price elasticities change over time and depend on alternatives. This needs to be considered. Given the advent of NCAs, there are good reasons to advocate a novel EU strategy on smoking regulation, including tax policies.

### Incentivise low-risk substitutes via tax policies

Given the advent of NCAs, tax policies should take the differential harm potential into account.

Wang and Hagedorn (2020) found evidence for NCAs to substitute cigarette smoking. Using a difference-in-difference approach exploiting a natural policy experiment in the US, they analysed the effect of the e-cigarette tax introduced in Minnesota on 1 August 2010, with 'an initial tax rate of 35 percent, followed by another 60 percentage points on July 1,

2013, increasing the total tax rate by 95 percent' (Wang & Hagedorn, 2020: 17). In this setting, the treatment group – Minnesota – and the control group – the rest of the US – had equally high smoking rates before the tax was introduced. Subsequently the e-cigarette and smoking prevalence rates started to diverge with more notably falling rates in the US, Minnesota excluded (Wang & Hagedorn, 2020: 18). The shift of relative prices raised the smoking prevalence rate by 0.9 percentage points, 'equivalent to a 5.4 percent prevalence increase relative to the pre-tax increase level in Minnesota' (Wang & Hagedorn, 2020: 20).

In general, a literature review supports the e-cigarette substitute hypothesis. Zheng and colleagues (2017) found that the own-price elasticities of demand are exclusively and highest for e-cigarettes as substitutes for cigarettes (Zheng et al., 2017: 1077). In their study, a 10 per cent e-cigarette price increase results in a 0.04 per cent increase in cigarette demand, while an equivalent cigarette price increase leads to a 18.59 per cent increase in e-cigarette demand (Zheng et

Policymakers should advocate risk-based regulation and call for differentiation in the taxation of nicotine products in the upcoming TTD revision.

al., 2017: 1079). Huang and colleagues (2018) indicate that the market-store level demand of e-cigarettes is elastic and a price hike of 10 per cent will reduce consumer demand by roughly 14 per cent for reusable and 16 per cent for disposable e-cigarettes, respectively. These findings are consistent with the estimates from Wang and Hagedorn (2020).

### Different harm potential should lead to customised regulation

In the absence of broad-scale tax adjustments on all tobacco and nicotine products, the individuals at risk can be clustered into four behavioural types: first, the group of ex-smokers who switch back to cigarettes, responding to changes of relative prices and resubstituting products. Second, the group of dual users falling back on exclusive cigarette use. Third, the group of current smokers, who are motivated to quit cigarette smoking and are discouraged by one-sided tax adjustments. Finally, the fourth group, the real quitters who cease vaping or cease heated tobacco product use entirely and do not relapse into the use of more damaging products such as cigarettes. Unilateral tax increases are therefore solely effective in respect of limiting the consequences of a single-item non-communicable disease, but in a broader health context all close substitutes with 'similar benefits to the consumer' (Wang & Hagedorn, 2020: 1) should be targeted.

Besides relative price adjustments, similar effects can also be identified amongst more incisive regulations, which further backs the substitute hypothesis. Based on a difference-in-differences analysis, Friedman (2021) revealed that the San Francisco flavour ban was 'associated with more than doubled odds of recent smoking among underage high school students relative to concurrent changes in other districts' (Friedman, 2021: 864). Friedman taps into one of the two major targets of criticism here: the potential gateway effect of smoking initiation, especially among teenagers. He raises concerns that 'reducing access to flavoured electronic nicotine delivery systems may motivate youths who would otherwise vape to substitute smoking' (Friedman, 2021: 865). In other words, Friedman claims that the attractiveness created by flavours could represent a tool to decrease smoking amongst youth. In line with the policy effects of bans, Dave and colleagues (2019) produced similar results evaluating the relationship of e-cigarette minimum legal sale age laws and youth cigarette smoking, as well as alcohol and marijuana consumption. While vaping was successfully inhibited, alternative harmful consumption patterns were fostered.

### **Policy recommendations**

- Policymakers should investigate and adapt novel harm-reduction strategies.
- In practice, this would require treating non-combusted alternatives differently from traditional combusted cigarettes with respect to regulation and taxation.
- As a short-term policy target, the reduction of smoking intoxication should be prioritised by policymakers, which could mean promoting lower-risk nicotine consumption in the short- to medium-term.

- From a fiscal perspective, a short- to medium-term decrease of tax revenues on non-combusted alternatives could be compensated by substantial health cost savings in the future, which would decrease financial pressure levels in the EU Member States' health care systems.
- Therefore, a revision of the excise rules for tobacco should be very cautious
  with respect to minimum tax level adjustments of non-combusted products.
  It should propose only minor tax increases on non-combusted alternatives
  within the European Union.

### **Concluding remarks**

The current WHO Framework Convention on Tobacco Control (FCTC) is based on obsolete evidence on the 'role of innovative nicotine delivery devices in assisting the transition from cigarettes to much less harmful products' (Beaglehole & Bonita, 2022: 1865). Policymakers should explore and incorporate harm reduction into WHO and FCTC policies to reduce 'the harm caused by burnt tobacco by replacing cigarettes with much less harmful ways of delivering nicotine' (Beaglehole & Bonita, 2022: 1865).

As a first step, non-combusted alternatives should be treated differently from traditional combusted tobacco products. This differential treatment includes taxation. The substitution of more damaging products with less harmful alternatives should be incentivised by public authorities to improve public health outcomes. The Council Directive 2011/64/EU (Council of the European Union, 2011) on the structure and rates of excise duty applied to manufactured tobacco (TTD) is under review in 2022. The overarching objective of this directive is to promote 'a high level of health protection' (Council of the European Union, 2011: 24) of citizens and maintain a single market for tobacco products, considering 'any new developments based on scientific facts' (The European Parliament and the Council of the European Union, 2014: 2). Against this background, two main challenges arise for the revision of the TTD: first, tackling the lack of integration of NCAs into the current legal framework. Second, improving the alignment of the tax policy outlined in the TTD with the main public health objective to curb smoking. A central question of the directive's review process is how minimum tax levels of different tobacco and nicotine products can be set in the TTD to achieve the policy objectives most efficiently and without undesirable - and counterproductive – side effects. The TTD offers the opportunity to finally make progress on the tobacco front.

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