

*The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.*

## **CPME feedback to the European Commission evaluation of the Legislative Framework for Tobacco Control**

On 16 June 2022, the CPME Executive Committee adopted the 'CPME feedback to the European Commission evaluation of the Legislative Framework for Tobacco Control' (CPME 2022/068).

# CPME Feedback to the Evaluation of the Legislative Framework for Tobacco Control

In order to achieve 'Tobacco-free Generation' by 2040, the EU directives should prioritise public health above all. Member States (MS) should be able to take further regulatory measures than described in the directives in order to react proactively when new trends emerge. In some MS, especially novel nicotine products have recently replaced tobacco smoking among young people. The directives should also enable MS to completely ban tobacco and nicotine products.

In view to the Tobacco Advertising Directive (TAD):

## **Inconsistencies in the definitions of tobacco products across EU law**

In particular, the definition of 'tobacco products' contained in the TAD is inconsistent with those included in other EU legislation such as TPD and may not reflect market developments.

## **Some TAPS may fall outside the scope of the EU Directives**

Some indirect forms of tobacco advertising, promotion and sponsorship (TAPS) pose a challenge to the implementation of the Directive, and should be included under the scope of the Directive. The TAPS ban should include tobacco brand names and corporate promotion.

## **No harmonised enforcement system to ensure the effectiveness of the ban on online advertising**

In order to ensure the effectiveness of the ban on tobacco advertising in information society services, there is an urgent need to introduce a targeted enforcement mechanism, suited for identifying and removing social media tobacco advertising, in particular, paid influencer content.

## **Other possible revision areas: tobacco promotion in entertainment media**

WHO Framework Convention on Tobacco Control (FCTC) Article 13 and its Guidelines should be fully implemented, introducing an obligation for producers to certify that no benefits have been received for any tobacco depictions, prohibiting the use of identifiable brands or imagery, requiring anti-tobacco advertisements and implementing a rating system that takes tobacco depictions into account.

## **Enhanced monitoring and enforcement rules**

There is growing confusion as to the concrete responsibilities across national authorities and the role of the civil society. There also appears to be a lag between monitoring and reporting of breaches tobacco advertising and sponsorship bans. Finally, the ongoing development of supplementary guidelines to Article 13 FCTC specifically focused on TAPS in entertainment media should be taken into account in any future legislative reviews.

In view to the Tobacco Products Directive (TPD):

## **Overarching issues:**

1. Harmonise definitions of tobacco and related products across EU legislation.
2. Include references to the FCTC Article 5.3 (protecting public health policy from tobacco industry interference) and Article 8 of the International Protocol to Eliminate Illicit Trade in Tobacco Products in the TPD in addition to the existing references in Recital (7) of the TPD.

**Specific policy recommendations**

3. Mandatory plain standardised packaging with 80% front and back pictorial health warnings for all tobacco products.
4. Introduce a definition for heated tobacco products and subject them to the full effect of the TPD, and revise the definition and regulatory pathway of “novel” tobacco products.
5. Eliminate responsibilities allocated to the tobacco industry in the tracking and tracing system in the TPD’s Art 15(8).
6. Measurement methods and regulation of filters
  - a. Introduce a ban on filter ventilation;
  - b. Explore the possibility and impact of a ban on plastic filters and allow MS to introduce plastic filter regulations or bans on health and environmental grounds;
  - c. Invest in independent measurements methods for tobacco emissions and in studies of the environmental impact of tobacco filters, whether made of plastic or biodegradable materials.
7. Eliminate TPD Article 7(12) which exempts tobacco products other than cigarettes and roll-your-own tobacco from the ban on characterising flavours.
8. Reinforce the conditions under which MS can take further domestic regulatory measures
  - a. Expand TPD Article 24(2), which allows MS to introduce more stringent provisions such as plain standardised packaging, by opening this possibility for a wider range of measures which are not currently covered by the TPD, e.g. environment.
  - b. Clarify the conditions and process for the application of Article 24(3) in order to reduce uncertainties around the adoption of national measures.
9. Ban cross-border distance (online) sales of tobacco products and electronic cigarettes to ensure the adequate implementation, monitoring, and enforcement of MS’ tobacco control and fiscal policies.

**“Keep as are” areas:**

10. Maintain the ban on tobacco products for oral use (“snus”)

# Smoke Free Partnership Response to the European Commission’s call for evidence on the legislative framework for tobacco control

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## A. Tobacco Advertising Directive 2003/33/EC

### Why is tobacco promotion harmful?

*Tobacco use is the single most preventable cause of death and disease, responsible for over 750 000 deaths in the European Region every year. Despite the considerable tobacco control efforts undertaken both at national and EU level and a steady decrease in tobacco use over the past decade, Europe still has the highest prevalence of tobacco smoking among adults amongst WHO regions. In the EU, over 26% of the adult population continues to smoke and tobacco prevalence among young people has increased in recent years, from 26% to 29% for those over 15 years of age.*

Tobacco initiation is heavily influenced by the continuous efforts of the tobacco industry to promote their products, with a special focus on young people. The effects of these promotion strategies of fostering tobacco consumption have [long](#) been documented and [recognised](#) by EU Member States. It is recognised by various EU policies that tobacco advertising, promotion and sponsorship (TAPS) encourages children and young people to start smoking, a population group of which studies show they are most receptive to advertising tactics; it stimulates current smokers to increase tobacco use; it reduces current smokers’ motivation to quit; it stimulates former smokers to restart using; and it portrays tobacco use as socially acceptable.

### The need to revise the current Tobacco Advertising Directive

The main instrument tackling the promotion of tobacco products at EU level is the Tobacco Advertising Directive (TAD), which has been implemented across EU Member States since its entry into force in 2003. This [resulted](#) in reduced tobacco outreach and consumption, especially among young people. Most of the Member States introduced tobacco sponsorship and advertising bans which go beyond the provisions of the Directive, such as sponsorship bans at local events and advertising bans in cinemas or at points of sale.

As the last evaluation of the TAD dates from 2008, we welcome the recent steps taken by the European Commission to assess the implementation of the current rules on tobacco advertising, promotion and sponsorship. Reviewing the implementation and enforcement of the current legal framework could provide a momentum to revise this legislation in order to address current and future challenges more effectively. A

stronger and more effective legal framework would lead to better alignment of EU legislation with the WHO FCTC and the requirements as set out in the Article 13 Guidelines.

Other areas and legal instruments should be considered with the aim to enhance the enforcement of the TAPS rules, such as the Digital Service Act. Better cross-sectoral cooperation on tobacco control at EU level is essential in order to ensure a comprehensive and consistent legal framework.

## Remaining challenges in the EU TAPS regulatory framework

The Directive pre-dates the entry into force of the [World Health Organisation's Framework Convention on Tobacco Control \(FCTC\)](#), which is a binding public health treaty to which the EU is a Party. Although the EU was a key facilitator in the discussions on FCTC's Article 13 and its [Implementation Guidelines](#), the TAD may not be fully aligned with the FCTC Article 13 guidelines, with Decision [FCTC/COP8\(22\)](#) and Decision [FCTC/COP8\(17\)](#).

### 1. [Inconsistencies in the definitions of tobacco products across EU law](#)

In particular, the definition of 'tobacco products' contained in the TAD is inconsistent with those included in other EU legislation such as the Tobacco Products Directive (TPD), and may not reflect market developments.

The TAD defines tobacco products as *all products intended to be smoked, sniffed, sucked or chewed inasmuch as they are made, even partly, of tobacco*.

The TPD defines tobacco products as *products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not*;

- *Para (5): 'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;*
- *Para (9): 'tobacco products for smoking' means tobacco products other than a smokeless tobacco product*
- *Para (14): 'novel tobacco product' means a tobacco product which:*
  - (a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and*
  - (b) is placed on the market after 19 May 2014;*

The current wording of the definition contained in the TAD does not clearly cover novel tobacco products (such as heated tobacco products). The consequence is that the tobacco advertising and sponsorship restrictions do not apply to them.

A similar, potential legislative gap in relation to the marketing of electronic cigarettes has been addressed in the TPD. According to Article 20 para (5) of the TPD, the advertising and sponsorship restrictions as described by the TAD and the AVMSD also apply to electronic cigarettes, which are not tobacco products. Unfortunately, no similar extension exists for the case of devices used for heated tobacco products, although the tobacco products themselves are covered by the TAPS ban.

As a consequence, there is a legislative loophole in some Member States that enables the tobacco industry to concentrate their efforts into largely unrestricted, aggressive marketing campaigns for heated tobacco products, thereby also jeopardising the effectiveness of the bans on traditional tobacco products.

**This results in a legislative gap for a significant and fast-growing group of tobacco products, which should be addressed by a full alignment of the definitions and ensuring that the TAD applies to all tobacco products and devices accessories used exclusively for their consumption.**

## **2. Some TAPS may fall outside the scope of the EU Directives**

Despite the tobacco industry's long-established recourse to indirect advertising to circumvent direct advertising restrictions, indirect advertising largely falls outside the scope of the TAD (Recital 12). As recognised by the FCTC Article 13 and its Guidelines, only a comprehensive ban on tobacco advertising and sponsorship can deliver a significant reduction in tobacco consumption, as partial bans encourage recourse to tobacco advertising in areas not covered by the bans. In order to be effective, such a ban should address all persons and entities involved in the production, placement and/or dissemination of tobacco advertising and sponsorship. In this context, the promotion of tobacco companies themselves (**corporate sponsorship**) is a form of indirect TAPS, even without the presentation of brand names or trademarks. This remains a common marketing practice, through which the tobacco industry promotes itself with a positive image of 'socially responsible' market operator, which results in the [indirect promotion of the company's reputation](#) and their products.

Such social responsibility attempts of the tobacco industry [have been evident](#) during the COVID-19 pandemic: tobacco industry actors have promoted various types of corporate social responsibility actions. It is important to emphasise that any contribution to health systems' ability to cope with the COVID-19 pandemic is welcome. However, the tobacco industry has a long, documented [track record of undermining public health](#) and should not be able to advertise and promote such CSR activities to draw a reputational advantage.

**As stated in the TAD's Implementation Report, such forms of indirect TAPS pose a challenge to the implementation of the Directive, and should thus be included under the scope of the Directive. The advertising and sponsorship ban should include tobacco brand names and corporate promotion.**

## **3. No harmonised enforcement system to ensure the effectiveness of the ban on online advertising of tobacco products**

[Recent reports](#) have shown a surge in social media advertising of tobacco products, which is rarely disclosed and straightforward, and takes the form of indirect online advertising. In attempts to glamourise and normalise tobacco products, the tobacco industry often uses strategies involving young influencers which engage in a subtle promotion of the products on social media, using pictures and specific messages and hashtags and effectively reaching out to young people.

Although prohibited by the TAD for nearly two decades, tobacco advertising on internet platforms poses the biggest challenge for the implementation of the advertising ban. This stems from the difficulty of identifying covert forms of tobacco advertising and monitoring the numerous instances of indirect advertising, lack of

proper reporting mechanisms, identification of responsible entities and the inherently cross-border dimension.

For example, several leading tobacco control entities have recently put in a complaint about BAT's online advertising of their e-cigarettes in the UK, in particular on Instagram. The [UK Advertising Standards Authority \(ASA\) upheld](#) most of the complaint and ordered BAT to stop using public Instagram accounts in December 2019. Recent reports showed that BAT just started using a different Instagram account but continued to engage in most of the same promotional activity.

In addition to the EU tobacco advertising ban, many social media platforms' internal policies prohibit paid advertising for tobacco products, but these rules are not consistently enforced by the media companies, or they don't include paid influencer content. The existing EU provisions on tobacco advertising in information society services are outdated, lacking appropriate enforcement elements, and inadequate to respond to the challenges posed by the rapid-changing virtual environment. The [Digital Service Act](#) provides an opportunity to address this enforcement issue, in the wider context of regulating online content and advertising.

**In order to ensure the effectiveness of the ban on tobacco advertising in information society services, there is an urgent need to introduce a targeted enforcement mechanism, suited for identifying and removing social media tobacco advertising, in particular, paid influencer content.**

#### **4. Other possible revision areas: tobacco promotion in entertainment media**

Given the cross-border nature of films, any tobacco sponsorship in films and television is prohibited under the current TAD. However, potential arrangements through which contributions are made by the tobacco companies to a film producer or actor may be difficult to prove, but tobacco use is increasingly depicted in films, TV shows and streaming services on the EU market. In this context, FCTC Article 13 and its Guidelines should be fully implemented, introducing an obligation for producers to certify that no benefits have been received for any tobacco depictions, prohibiting the use of identifiable brands or imagery, requiring anti-tobacco advertisements and implementing a rating system that takes tobacco depictions into account. The adequate framework to tackle this issue would be the [AVMS Directive](#).

#### **5. Enhanced monitoring and enforcement rules**

The TAD provides for a large margin of discretion for Member States in taking the appropriate measures in enforcing the rules. This widely varies across Member States, but lately, there seems to be growing confusion as to the concrete responsibilities across national authorities and the role of the civil society. There also appears to be a lag between monitoring and reporting of breaches tobacco advertising and sponsorship bans. The Digital Services Act should aim to close the gaps of current tobacco advertising legislation; any new rules should address online tobacco advertising

Finally, the ongoing development of supplementary guidelines to Article 13 FCTC specifically focused on TAPS in entertainment media should be taken into account in any future legislative reviews.

#### **Relevant resources**

1. *Examples of tobacco/e-cigarettes pages on social media:*
  - *Vype Ireland page on Instagram: <https://www.instagram.com/govypeirl/> and on Facebook: <https://www.facebook.com/Vype-Ireland-2059486554179731/> The content is identical to Vype's other pages in Europe/globally that have tens of thousands of followers. The hashtags that BAT is using on these Irish brand pages are part of the global marketing for Vype, but also for e-cigarettes more broadly. Take for example, the most recent post that uses #vypechargebeyond, #govype, #epod and #vape. Each of those hashtags will take you to thousands (if not significantly more) of images promoting e-cigarette and/or BAT campaigns from all over the world. The Irish pages are entirely public and can be followed by any Instagram or Facebook user, **regardless of age.***
    - [Italy](#)
    - [Spain](#)
    - [Germany](#)
2. *CTFK in partnership with UK ASH and Bath University have previously put in a complaint about BAT's online advertising of Vype e-cigarettes in the UK, in particular on Instagram. The UK advertising standards authority (ASA) upheld most of the complaint and ordered BAT to stop using public Instagram accounts in December 2019. Recently reports showed that BAT just started using a different Instagram account but continued to engage in most of the same promotional activity.*  
*This is the link to the original ASA ruling from last year, <https://www.asa.org.uk/rulings/british-american-tobacco-uk-ltd-G19-1018310.html>.*
3. *the Italian law that implements the TPD is Legislative Decree No. 6 of January 12, 2016 (see here <https://www.tobaccocontrollaws.org/legislation/country/italy/laws> ). There has also been one enforcement action under that law by the Associazione dei Consumatori against 2 e-cigarette manufacturers for advertising including online advertising (although not on Instagram). See here for that ruling: <https://www.tobaccocontrollaws.org/litigation/decisions/it-20191115-national-council-of-consumers->*
4. *CTFK report on the tobacco industry's corporate social responsibility actions in the COVID-19 context (global, but also includes EU Member States examples) [https://www.tobaccofreekids.org/media/2020/2020\\_05\\_covid-marketing](https://www.tobaccofreekids.org/media/2020/2020_05_covid-marketing)*
5. *179 Organizations Worldwide Call on Google to Ban Apps that Encourage Smoking and Vaping from Google Play Store (we also signed, shows a bit the issue with apps) [https://www.tobaccofreekids.org/press-releases/2020\\_10\\_28\\_google-smoking-vaping-apps](https://www.tobaccofreekids.org/press-releases/2020_10_28_google-smoking-vaping-apps)*
6. *A recent example of a Gala taking place exclusively online, in the video game Minecraft sponsored by IQOS (PMI) and it includes a concert from a popular music band broadcasting live from QREATOR by IQOS space: [https://business-review.eu/tech/online/the-awards-gala-of-the-internetics-2020-competition-to-take-place-tonight-in-minecraft-213988\\_QREATOR](https://business-review.eu/tech/online/the-awards-gala-of-the-internetics-2020-competition-to-take-place-tonight-in-minecraft-213988_QREATOR)*
7. *More on Qreator in STOP's comprehensive report on PMI tactics at page 36: [https://exposetobacco.org/wp-content/uploads/STOP\\_Report\\_Addiction-At-Any-Cost.pdf](https://exposetobacco.org/wp-content/uploads/STOP_Report_Addiction-At-Any-Cost.pdf)*
8. *A factsheet on tobacco companies' tactics when promoting tobacco to children: <https://www.tobaccofreekids.org/assets/factsheets/0008.pdf>*

## ***B. Tobacco Products Directive 2014/40/EU***

### **Overarching issues:**

1. **Harmonise definitions of tobacco and related products across EU legislation.**
2. **Include references to the WHO Framework Convention on Tobacco Control (FCTC) Article 5.3 (protecting public health policy from tobacco industry interference) and Article 8 of the International Protocol to Eliminate Illicit Trade in Tobacco Products (the Illicit Trade Protocol, ITP) in the EU Tobacco Products Directive (TPD) in addition to the existing references in Recital (7) of the TPD.**

### **Specific policy recommendations**

3. **Mandatory plain standardised packaging with 80% front and back pictorial health warnings for all tobacco products.**
4. **Introduce a definition for heated tobacco products (HTPs) and subject them to the full effect of the TPD, and revise the definition and regulatory pathway of “novel” tobacco products.**
5. **Eliminate responsibilities allocated to the tobacco industry in the tracking and tracing system in the Tobacco Products Directive’s Art 15(8)- the manufacturers or importers should not be allowed to appoint data storage providers or auditors.**
6. **Measurement methods and regulation of filters**
  - a. **Introduce a ban on filter ventilation;**
  - b. **Explore the possibility and impact of a ban on plastic filters and allow Member States to introduce plastic filter regulations or bans on health and environmental grounds, e.g. through Article 24(2) or 24(3), as appropriate (see below);**
  - c. **Invest in independent measurements methods for tobacco emissions and in studies of the environmental impact of tobacco filters, whether made of plastic or biodegradable materials.**
7. **Eliminate TPD Article 7(12) which exempts tobacco products other than cigarettes and roll-your-own tobacco from the ban on characterising flavours.**
8. **Reinforce the conditions under which Member States can take further domestic regulatory measures**
  - a. **Expand Article 24(2), which allows Member States to introduce more stringent provisions such as plain standardised packaging, by opening this possibility for a wider range of measures which are not currently covered by the TPD, e.g. environment**
  - b. **Clarify the conditions and process for the application of Article 24(3) in order to reduce uncertainties around the adoption of national measures.**
9. **Ban cross-border distance (online) sales of tobacco products and electronic cigarettes to ensure the adequate implementation, monitoring, and enforcement of Member States’ tobacco control and fiscal policies.**

### **“Keep as are” areas:**

10. **maintain the ban on tobacco products for oral use (“snus”)**

### **Introduction:**

The TPD as adopted in 2014 contributed significantly to improving the functioning of the internal market through measures which removed obstacles to trade and distortions of competition. It also marked a significant milestone in the implementation of the FCTC at EU level and contributed to a reduction in tobacco

use<sup>1</sup>. However, new market and legislative developments in the EU gave rise to new challenges to the functioning of the internal market and to the protection of public health, which must be addressed through the revision of the current Directive.

Although tobacco consumption in the EU has been decreasing<sup>2</sup> since the entry into force of the TPD in 2016, the smoking prevalence remains high<sup>3</sup>, as confirmed by the latest Special Eurobarometer 506 (nearly a quarter of the respondents, 23%, reported smoking<sup>4</sup>). About 20% of Europeans aged 15-24 have smoked as of 2020, a decrease of about 9% since 2017<sup>5</sup>. The observed decreases demonstrate that legislative developments such as the TPD's entry into force in 2016 laid the groundwork for the long-term eradication of tobacco consumption. Strong European commitment on this was established through Europe's Beating Cancer Plan, and its goal of creating a Tobacco-Free Generation in Europe<sup>6</sup>. To reach this goal, the Plan outlines two important targets,

- 1) Reducing tobacco use by 30% by 2025 compared to 2010 to meet the United Nations Sustainable Development Goals (SDG) and WHO NCD targets, and
- 2) Achieving a 5% tobacco prevalence level by 2040<sup>7</sup>.

At the international level, strengthening the tobacco control framework is necessary in order to make progress towards the abovementioned SDG targets (namely 3.a and 3.4)<sup>8</sup> and the target of reducing tobacco use by 30% in persons aged 15 and above by 2025<sup>9</sup>. This political commitment engages the EU globally and must be embraced as an overarching objective of EU's tobacco control legislation.

Below we outline the arguments and evidence supporting the policy positions outlined above.

## **Requested action 1: Harmonise the definitions of tobacco and related products across EU legislation**

### **Inconsistencies within the TPD**

Some definitions proved to be unclear in practice, such as 'novel tobacco products' in Article 2(14) further detailed in Article 19(4) by reference to smokeless tobacco or tobacco products for smoking Article 2(5) and (9). This definition of novel tobacco products created uncertainties amongst Member States when deciding how to register new products on their markets. The different regulatory approaches for the same products in

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<sup>1</sup> Eurobarometer, Feb 2021

<sup>2</sup> [https://ec.europa.eu/taxation\\_customs/sites/taxation/files/docs/body/tobacco\\_products\\_releases-consumption.pdf](https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/tobacco_products_releases-consumption.pdf)

<sup>3</sup> Tobacco use trends in the European region : [https://www.euro.who.int/\\_data/assets/pdf\\_file/0009/402777/Tobacco-Trends-Report-ENG-WEB.pdf?ua=1](https://www.euro.who.int/_data/assets/pdf_file/0009/402777/Tobacco-Trends-Report-ENG-WEB.pdf?ua=1)

<sup>4</sup> European Commission, Special Eurobarometer 506, p. 8,

<https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/survey/getsurveydetail/instruments/special/surveyky/2240>

<sup>5</sup> Ibid. p.15

<sup>6</sup> European Commission, Europe's Beating Cancer Plan, p.14,

[https://ec.europa.eu/health/sites/health/files/non\\_communicable\\_diseases/docs/eu\\_cancer-plan\\_en.pdf](https://ec.europa.eu/health/sites/health/files/non_communicable_diseases/docs/eu_cancer-plan_en.pdf)

<sup>7</sup> Ibid. p.8

<sup>8</sup> World Health Organisation, Sustainable Development Goals, Goal 3, [https://www.who.int/health-topics/sustainable-development-goals#tab=tab\\_2](https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2)

<sup>9</sup> World Health Organisation, About 9 voluntary global targets, <https://www.who.int/nmh/ncd-tools/definition-targets/en/>

different Member States across the EU affects the level of health protection and creates new obstacles to the functioning of the internal market.

There are also interpretation issues on the delimitation between snus and products for chewing in Slovenia and Germany, which resulted in the placing on the market of snus-like products and legal actions. A more clear, distinct definition for snus and chewing tobacco is needed.

### **Inconsistencies between the Tobacco Products Directive, Tobacco Advertising Directive, and the Tobacco Tax Directive**

The Tobacco Products Directive<sup>10</sup>, Tobacco Advertising Directive (TAD)<sup>11</sup>, and Tobacco Tax Directive<sup>12</sup> use different definitions for tobacco products. While the purposes of these directives differ, the differences may create loopholes in the rules governing these products. We therefore urge a thorough review and harmonisation of the definitions used for regulatory purposes.

#### **Example 1. Novel tobacco products**

The TAD defines tobacco products as *all products intended to be smoked, sniffed, sucked or chewed inasmuch as they are made, even partly, of tobacco*.

However, the TPD states in Article 2(4) that *'tobacco products' are products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;*

- *Para (5): 'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;*
- *Para (9): 'tobacco products for smoking' means tobacco products other than a smokeless tobacco product*
- *Para (14): 'novel tobacco product' means a tobacco product which:*
  - *does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and*
  - *is placed on the market after 19 May 2014;*

The current wording of the definition contained in Article 2(a) of the TAD does not **clearly** cover novel tobacco products (such as heated tobacco products), nor does the TPD explicitly extend the TAD rules to novel tobacco products as it does for electronic cigarettes [Article 20(5)]. The consequence is that some jurisdictions have not adopted or enforced tobacco advertising, promotion and sponsorship restrictions regarding these products or their devices.

#### **Example 2. Consequences of the lack of clarity in the registration of novel tobacco products**

The TPD sets minimum rules applicable to 'novel tobacco products', with Member States having to further decide and register specific products either as smokeless tobacco products or as tobacco products for smoking.' The industry often lobbies for the more favourable regime in terms of packaging and labelling, emissions limits, health warnings, application of TAPS rules, or tax regimes. As a consequence, loopholes have occurred in some Member States where the tobacco industry embarked in aggressive marketing campaigns for heated tobacco products, undermining public health.<sup>13</sup>

## **Requested action 2: Include references to Article 5.3 of the WHO FCTC and Article 8 of the WHO FCTC Illicit Trade Protocol in the TPD.**

<sup>10</sup> [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL\\_2014\\_127\\_R\\_0001](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL_2014_127_R_0001)

<sup>11</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32003L0033>

<sup>12</sup> <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32011L0064>

<sup>13</sup> *Refs: advertising in Ro, Bg, tax in IT see e.g. OCCRP, Politico*

Article 5.3 of the FCTC requires all Parties, when setting and implementing their public health policies with respect to tobacco control, to: “ [...] act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law”. This mandate has been expanded further in the Guidelines for Implementation of Article 5.3.<sup>14</sup> These emphasise through guiding principles and recommendations that Parties should implement measures to prevent interference by the tobacco industry in all branches of government that may have an interest in, or the capacity to affect, public health policies with respect to tobacco control. These measures are necessary due to the behaviour of the tobacco industry aimed at undermining tobacco control efforts — and the fact that, unlike other consumer products, there are no safe ways of using tobacco products. This has led governments and international agencies<sup>15</sup> to conclude that there is a fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests.<sup>16</sup> The WHO has a policy of not engaging with the tobacco industry or any actors working to further its interests.<sup>17</sup> At UN level, the tobacco industry was excluded from the Global Compact.<sup>18</sup>

As a Party to the FCTC, the EU institutions have an obligation to take steps to protect its policy setting and law making from the commercial and other vested interests of the tobacco industry. Unfortunately, the obligation under 5.3 is not appropriately fulfilled at EU level. The EU Ombudsman concluded<sup>19</sup> an inquiry into the European Commission’s failure to implement this obligation *with a finding of maladministration on the part of the Commission (arising from its refusal to apply the proactive transparency policy of DG Health across the entire Commission)*. **A reference to both Member States’ and the EU’s obligations under FCTC’s Article 5.3 in the TPD recitals would reaffirm the commitment to safeguard the public health policies from undue influence from the tobacco industry and provide for a clearer legal basis for applying Article 5.3 at EU and Member State level, with a view to enact appropriate measures.**

The Illicit Trade Protocol was not in force and had not been ratified by the EU at the time of the adoption of the EU TPD, even though the global discussions on the draft Protocol did inform the political discussions on the Directive at the time. However, as a binding Treaty to which the EU is a key Party and under which the EU and its Member States have obligations, it is now necessary to conduct a thorough legal and operational review of the compatibility of the EU TPD with its provisions and include it in the considerations for the directive. This will assert and strengthen the political and legal value of the Illicit Trade Protocol within the EU tobacco control framework and to highlight the importance of consistency with the Protocol. This requested action should be considered in light of our concerns on the independence of the tracking and tracing system.

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<sup>14</sup> See: FCTC Conference of the Parties. 2008. *Guidelines for Implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry*. Available at: [http://www.who.int/fctc/protocol/guidelines/adopted/article\\_5\\_3/en/index.html](http://www.who.int/fctc/protocol/guidelines/adopted/article_5_3/en/index.html), accessed 16 February 2012.

<sup>15</sup> [http://www.who.int/nmh/events/un\\_ncd\\_summit2011/political\\_declaration\\_en.pdf](http://www.who.int/nmh/events/un_ncd_summit2011/political_declaration_en.pdf)

<sup>16</sup> *Ibid.* See Principle 1, p2.

<sup>17</sup> <https://www.who.int/about/collaborations-and-partnerships/who-s-engagement-with-non-state-actors>

<sup>18</sup> <https://tobaccotactics.org/wiki/united-nations-global-compact-unqc/>

<sup>19</sup> <https://www.ombudsman.europa.eu/en/decision/en/73774>

### **Requested Action 3: Strengthen packaging rules by introducing mandatory plain standardised packaging with graphic health warnings covering 80% of the front and the back of all tobacco products, and introducing pack inserts**

#### **a) Introduce mandatory plain standardised packaging at EU level based on a common set of rules.**

Plain packaging is proven to be an effective public health measure to discourage tobacco use.<sup>20 21 22 23</sup> Article 24(2) of the Directive allows Member States to implement plain standardised packaging and 7 Member States have done it so far, while others are in the process of adopting or implementing similar measures. This results in different levels of public health protection for EU citizens and, in the absence of common rules, a possible fragmentation of the internal market.

The jurisprudence of the European Court of Justice enables<sup>24</sup> the use of Article 114 TFEU as a legal basis for the adoption of measures aimed at improving the functioning of the internal market. At the time of the 2014 revision of the TPD, plain packaging would not have achieved political majority,<sup>25</sup> but the Directive created the conditions for Member States to move forward in that regard, if they so desired to.

In the previous revision of the TPD, the legislator concluded that the differences in the implementation of graphic health warnings across Member States created a fragmentation of the internal market and justified the adoption of common rules for mandatory pictorial warnings. The same fragmentation exists to date through the adoption of plain packaging only by some Member States, justifying EU action. The disruption to the level of protection of public health and the internal market is exacerbated by the different ways Member States implemented plain packaging given the lack of harmonised standards for plain packaging at EU level.

There are reports from Member States that sales arrangements and displays of tobacco products were adapted in order to minimise the visibility of health warnings<sup>26</sup> and to undermine the effectiveness of plain packaging. For example, where the packs are lying down, with only the brand name visible from the top side of the pack, were reported in several member states.<sup>27</sup> In other jurisdictions changes in pack design were reported to make tobacco products more attractive.<sup>28 29</sup> These heterogeneous developments in Member States are likely to increase the fragmentation of the internal market and of the level of health protection. This shows the need to create a common EU set of rules for the implementation of plain standardised packaging, to address these common challenges and improve the functioning of the internal market.

<sup>20</sup> <https://www.tandfonline.com/doi/full/10.1080/16066359.2019.1579803>

<sup>21</sup> <https://tobaccocontrol.bmj.com/content/28/e1/e31>

<sup>22</sup> <https://smokefreepartnership.eu/our-policy-work/position-papers-briefings-reports/sfp-briefing-on-articles-11-and-13-of-the-ftc>

<sup>23</sup> <https://ris.govspace.gov.au/2016/02/26/tobacco-plain-packaging/>

<sup>24 24</sup> *Impact Assessment*, at 44 ; *Proposal, Explanatory memorandum*, §1

<sup>25</sup> Alemanno A., 'Out of Sight, Out of Mind. Towards a New EU Tobacco Products Directive', (2012), *Columbia Journal of European Law*, 18, 197-241

<sup>26</sup> <http://www.tobaccoinduceddiseases.org/Tobacco-packaging-strategies-aimed-at-undermining-graphic-health-warnings,109756,0,2.html>

<sup>27</sup> <https://bmjopen.bmj.com/content/bmjopen/9/9/e028506.full.pdf>

<sup>28</sup> <https://bmjopen.bmj.com/content/bmjopen/9/9/e028506.full.pdf>

<sup>29</sup> [https://dspace.stir.ac.uk/retrieve/327483ea-7f8b-4a6c-82d2-0f6e24b125ec/Standardised%20packaging%20PHRC\\_Final.pdf](https://dspace.stir.ac.uk/retrieve/327483ea-7f8b-4a6c-82d2-0f6e24b125ec/Standardised%20packaging%20PHRC_Final.pdf)

**b) Introduce graphic health warnings on devices used for tobacco use (e.g., HTP devices)**

In Decision COP/8/22 Parties to the FCTC acknowledged the regulatory challenges posed by novel and emerging tobacco products including those which can only be consumed through dedicated devices. This Decision calls on Parties to apply to the devices the same regulatory measures as for tobacco products, notably measures with respect to Articles 8, 9-10, 11 and 13.

**c) Introduce pack inserts with quitting information**

The Guidelines to article 11 of the FCTC recommend Parties to introduce “*further health warnings and messages on all sides of a package, as well as on package inserts and onserts*”. The inclusion of mandatory pack inserts with information on quitting as part of packaging requirements for tobacco products has been increasingly studied in recent years. To date, Canada is the only country requiring such inserts since 2012. Evaluation of this measure suggests that pack inserts with cessation related information are visible, increase the reach of health warnings, and appear to increase quit attempts made by smokers.<sup>30</sup> Recent research in Scotland showed that inserts, an inexpensive means of communication, offer regulators a simple way of supplementing on-pack warnings; adults in the study believed they increase the impact of plain packaging and health warnings, and offer support and hope to smokers in addition to the quitline labels<sup>31</sup>.

**d) Collect evidence and experience regarding standardised cigarettes and regarding reducing the number of brands on the market (1 variant per brand)**

These measures are starting to be considered in various jurisdictions including some member states. The EU should monitor these developments, including policy measures and scientific evidence, and consider taking evidence-based measures to further reduce the appeal of tobacco products.

**Requested action 4: Introduce a definition for heated tobacco products and subject them to the full effect of the TPD, and revise the definition and regulatory pathway of “novel” tobacco products.**

**a) Heated tobacco products (HTPs) are no longer “novel” and should be regulated as a separate category of tobacco products.** Regulation of these products should include plain packaging with pictorial health warnings for tobacco and devices, flavouring bans, emissions measurements and limits, and bans on misleading elements and notably any suggestions that a particular tobacco product is less harmful than others.

According to the WHO definition,<sup>32</sup> heated tobacco products are tobacco products that produce aerosols containing nicotine and other chemicals, which are inhaled by users, through the mouth. There are many types of these products that can be divided into 3 categories:

1. products that directly heat processed tobacco (conduction systems) such as IQOS, GLO;

<sup>30</sup>[https://www.researchgate.net/publication/269223988\\_The\\_Use\\_of\\_Cigarette\\_Package\\_Inserts\\_to\\_Supplement\\_Pictorial\\_Health\\_Warnings\\_An\\_Evaluation\\_of\\_the\\_Canadian\\_Policy](https://www.researchgate.net/publication/269223988_The_Use_of_Cigarette_Package_Inserts_to_Supplement_Pictorial_Health_Warnings_An_Evaluation_of_the_Canadian_Policy)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4542677/>

<sup>31</sup><https://tobaccocontrol.bmj.com/content/27/1/72>

<sup>32</sup>[https://www.who.int/tobacco/publications/prod\\_regulation/heated-tobacco-products/en/](https://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/)

2. products that heat processed tobacco in an evaporation chamber (convection systems) such as PAX;
3. products that generate vapor from a source not containing tobacco and then send vapor over processed tobacco in order to release the flavorings (and nicotine) such as PloomTech.

Regardless of the different heating principles, the basic idea is that tobacco is heated to a lower temperature than conventional cigarettes. There is a variation in which tobacco is heated across the different devices ranging from 30 to 40 ° C for products of category 3 to 350 ° C for products of category 1. HTPs mimic the behaviour of smoking conventional cigarettes. The Conference of the Parties to the FCTC (Decision COP/8/22 of 2018) has recognised that HTPs should be subjected to the full provisions of the FCTC.<sup>33</sup>

**b) Article 19 of the TPD establishes notification requirements for novel tobacco products.** The wide margin of appreciation as to the definition of these products either as smokeless products or as products for smoking has created difficulties and confusion in implementation and resulted in discrepancies across Member States, where regulations vary from effectively prohibiting the placing on the market of these products in some countries (e.g. Malta, Finland, and Belgium), to very weak rules in others (Romania, Bulgaria). In addition to a clear definition and a more robust regulatory pathway for novel tobacco products, the TPD should grant the Commission the power to determine – through implementing or delegated acts – to which category novel tobacco products should belong, based on the latest scientific evidence in order to avoid the fragmentation of the internal market.

The uncertainty about definitions and classification further creates obstacles to the functioning of the internal market, different levels of public health protection across the EU and the lack of legal certainty. As a result, some Member States faced legal actions with a view to establishing the classification of these products in their respective jurisdictions (for example, in Germany). Another distortion created by the classification uncertainties is that in some Member States, HTPs are regulated more leniently than e-cigarettes, and in others more strictly.

**Requested action 5: Eliminate responsibilities allocated to the tobacco industry in the tracking and tracing system in the Tobacco Products Directive’s Article 15(8) including the ability to nominate data storage providers or auditors.**

The EU tracking and tracing system and security features, set up by **Articles 15 and 16 TPD**, entered into force for cigarettes and roll-your-own tobacco in May 2019 and was fully operational in May 2020. The details of the system are set in implemented and delegated Acts.<sup>34</sup> The EU and 15 Member States ratified the FCTC’s Illicit Trade Protocol<sup>35</sup> which foresees a global tracking and tracing regime and a global information sharing focal point, that will enter into force in 2023. Articles 8.12 and 8.13 of the ITP establish an obligation of

<sup>33</sup> [https://www.who.int/fctc/cop/sessions/cop8/FCTC\\_COP8\(22\).pdf?%22&ua=1](https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8(22).pdf?%22&ua=1)

<sup>34</sup> [Commission Implementing Regulation \(EU\) 2018/574 on technical standards for the establishment and operation of a traceability system for tobacco products](#) ; [Commission Delegated Regulation \(EU\) 2018/573 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products](#); [Commission Implementing Decision \(EU\) 2018/576 on technical standards for security features applied to tobacco products](#)

<sup>35</sup> [https://www.who.int/fctc/protocol/illicit\\_trade/protocol-publication/en/](https://www.who.int/fctc/protocol/illicit_trade/protocol-publication/en/)

independence of tracking and tracing systems from the tobacco industry. This obligation was established in response to the long-term evidence of tobacco industry involvement in illicit trade.<sup>36</sup>

The TPD Article 15 delegates the selection and payment of data storage operators (repositories) and the appointment of auditors of tracking and tracing to the tobacco industry, and Article 16 potentially allows it to provide some of the elements in the security feature. The implementing acts introduced independence criteria for the various actors selected by the industry. Despite this, several of the selected data storage providers had proven historical relationships with the tobacco industry, raising concern about the effectiveness of the independence criteria in protecting the tracking and tracing system from industry interference.

The EU tracking and tracing system, while based on a common set of rules and on the principle of interoperability, also allows a wide range of choices to Member States (for example countries can derogate from the country of origin unique identified rule or have a choice of 5 out of dozens of elements for the security feature, or a choice to use tax stamps or other types of features).

Together with other health and tobacco control organisations SFP welcomed the first regional tracking and tracing system, which covers the 28 countries and all economic operators from importers/manufacturers to the first retail outlet.<sup>37 38</sup> However, SFP has continued to express concerns regarding the independence of the system as regards the roles and responsibilities awarded to tobacco manufacturers in the operation of the system. Following the 1-year report on the EU tracking and tracing system operation, some difficulties remained.<sup>39 40</sup>

The EU should ensure that its system is fully compliant and interoperable at a global level when the global tracking and tracing regime under the ITP enters into force. For that to happen, the TPD should be revised in order to remove the roles and responsibilities awarded to the tobacco industry.

## Requested Action 6: Strengthen the regulation of emissions and filters

### a) Ban filter ventilation

**There is unproven benefit to public or individuals' health from consumption of filtered tobacco products.**

The tobacco manufacturers' response to the research showing smoking caused cancer in the 1950s was to put 'filters' on cigarettes, marketing them heavily as a healthier option.<sup>41</sup> Filter ventilation was introduced shortly

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<sup>36</sup> <https://tobaccocontrol.bmj.com/content/28/2/127>; <https://tobaccotactics.org/wiki/jti-involvement-in-smuggling/>; <https://tobaccotactics.org/wiki/imperial-and-gallaher-involvement-in-tobacco-smuggling/>; <https://tobaccotactics.org/wiki/bat-involvement-in-tobacco-smuggling/>

<sup>37</sup> <https://smokefreepartnership.eu/news/sfp-news/sfp-welcomes-the-entry-into-force-of-the-eu-system-for-the-tracking-and-tracing-of-tobacco-products>

<sup>38</sup> [https://www.fctc.org/wp-content/uploads/2019/07/FCA-Policy-Briefing\\_Why-the-EU-tracking-and-tracing-systems-works-only-for-the-EU.pdf](https://www.fctc.org/wp-content/uploads/2019/07/FCA-Policy-Briefing_Why-the-EU-tracking-and-tracing-systems-works-only-for-the-EU.pdf)

<sup>39</sup> [https://ec.europa.eu/health/sites/health/files/tobacco/docs/20200615\\_tt\\_news\\_en.pdf](https://ec.europa.eu/health/sites/health/files/tobacco/docs/20200615_tt_news_en.pdf)

<sup>40</sup> SFP Statement: One-year report on EU tracking and tracing system for tobacco products confirms civil society concerns about the risk of tobacco industry interference: <https://www.smokefreepartnership.eu/news/sfp-statement-one-year-report-on-eu-tracking-and-tracing-system-for-tobacco-products-confirms-civil-society-concerns-about-the-risk-of-tobacco-industry-interference>

<sup>41</sup> Stanford Research into the Impact of Tobacco Advertising. [Filter Safety Myths: Protects your Health](#). Downloaded 10<sup>th</sup> November 2019.

after. Ventilation makes cigarettes taste lighter and milder, making initiation by youth easier and reinforcing the idea that they are less dangerous.<sup>42</sup> When smoking machines draw a puff from the cigarette, the ventilation holes draw in air, thereby diluting the smoke so the machine measures low tar levels. Filter ventilation is used by manufacturers to ensure that ISO machine measurement methods show tar yields of cigarettes as in line with the Directive, but lower than the actual exposure of smokers. **There is therefore a case for calling for a ban on filter ventilation, which undermines other provisions of the TPD.**

**b) Support the development of alternative measurement methods without tobacco industry interference and adopt them as soon as possible**

**There is growing concern across EU Member States and civil society organisations regarding the ISO measurement methods prescribed in Article 4 of the TPD.** A number of EU Member States call for replacing the existing measurement standards in the TPD, which is likely to impact the consistent implementation of these provisions across Member States. Measurement methods should be able to evolve with the scientific and technological developments. Evidence is scarce on public health effect of measurement methods and researching alternatives should remain a priority in order to minimise potential unintended consequences. As a reminder, an unintended consequence of the 2001 TPD mandating the labelling of tar, nicotine, and carbon monoxide levels was the misrepresentation of health risks in certain brands.

As a response to evidence regarding the potential shortcomings and tobacco industry interference in the ISO methods, **the possibility of replacing them with industry-free methods, such as the one developed by the WHO TobLabNet, should be assessed under the TPD,** while recognising that no measurement method can mimic smoker behaviour perfectly, and that we must be careful about representing any method as better than another to avoid misleading claims. The EU should continue to invest in the development of independent measurements methods for tobacco emissions.

While the European Court of Justice deliberates on a preliminary ruling on the interpretation of the TPD Article 4 regarding measurement methods, and considering the ongoing research on alternative measurement methods, our recommendations might need further development at an appropriate time.

**c) Examine the environmental impact of all tobacco filters**

Cigarette filters are also a major hazard for the environment. Up to two-thirds of every smoked cigarette are discarded onto the ground, resulting in between 340 and 680 million kilograms of waste tobacco product litters the world each year<sup>43</sup>. Plastic and toxic substances<sup>44</sup> contained in filters are released into the environment, affecting biodiversity and human health.<sup>45</sup>

The Single-Use Plastics (SUP) Directive adopted in May 2019 (and applicable in 2021) makes producers of tobacco filters which contain plastic subject to an Extended Producer Responsibility (EPR) scheme. This means that producers will have to cover the costs for public collection systems for cigarettes stubs, for awareness raising measures, and for data gathering and reporting. The packaging of plastic filters will also have to bear

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<sup>42</sup> Kozlowski LT, O'Connor RJ. Cigarette filter ventilation is a defective design because of misleading taste, bigger puffs, and blocked vents. *Tob Control*. 2002 Mar;11 Suppl 1(Suppl 1):I40-50. doi: 10.1136/tc.11.suppl\_1.i40. PMID: 11893814; PMCID: PMC1766061.

<sup>43</sup> <https://apps.who.int/iris/bitstream/handle/10665/255574/9789241512497-eng.pdf;jsessionid=4571CA7C75332CB930438B3BFB94E779?sequence=1>

<sup>44</sup> [http://docs.wixstatic.com/uqd/eec87d\\_4aa4368b7c6e4a529e21f9402818716e.pdf](http://docs.wixstatic.com/uqd/eec87d_4aa4368b7c6e4a529e21f9402818716e.pdf)

<sup>45</sup> <https://www.bmj.com/content/367/bmj.l5890>

markings which inform consumers of the presence of plastic and the harm done to the environment if the cigarettes butts are thrown away elsewhere than in the bin. **The EU should invest in better understanding, evaluating and addressing the environmental impact of all tobacco filters, whether made with plastic or biodegradable materials.**

### **Requested Action 7: Ban characterising flavours in all tobacco products without exception**

As recognised by the European Court of Justice and the FCTC, *the fact remains that all flavourings, including menthol, mask or reduce tobacco smoke's harshness and contribute to promoting and sustaining tobacco use.*<sup>46</sup> The Court confirmed in its 2016 judgment that tobacco products containing a characterising flavour, whether that is menthol or another flavouring, have certain similar, objective characteristics and similar effects as regards initiating tobacco consumption and sustaining tobacco use.

In addition, the Court restated that the prohibition has a twofold objective of facilitating the smooth functioning of the internal market for tobacco and related products, while taking as a base a high level of protection of human health, especially for young people. It is important to note that the Court does not distinguish between the different tobacco products. Moreover, according to the wording of Article 7 of TPD the rule is that the placing of (all) tobacco products with a characterising flavour on the market shall be prohibited. **The provision in Article 7(12) effectively renders Article 7(1) into an exception by exempting tobacco products other than RYO and cigarettes from this prohibition.**

In line with the Court's judgment, the objectives of the TPD and the FCTC and its Guidelines, the ban on characterising flavours in tobacco products should be reinforced and the exemption should be removed. Recent reports showing the tobacco industry's efforts to overpass the menthol ban in cigarettes and roll-your-own which entered into force in May 2020, by increasingly marketing menthol cigarillos or other tobacco products reinforce the urgent need for a uniform system prohibiting all tobacco products with a characterising flavour.

### **Requested action 8: Reinforce the conditions under which Member States can take further domestic regulatory measures**

This exception allows Member States who want to go beyond EU TPD provisions to do so, however the cases in which this is possible must be clearly defined and not be vague. Such areas could, for instance, relate to filter regulation (other packaging elements standardised on environmental grounds)

**The TPD should expand Article 24(2), which allows Member States to introduce more stringent provisions such as plain standardised packaging, by opening this possibility for a wider range of measures not currently covered by the TPD, e.g. environment**

The condition regarding the specific situation in the Member State seeking to prohibit certain categories of tobacco or related products should be relaxed, as health grounds and circumstances often transcend national

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<sup>46</sup> [Case C-358/14 Judgement \(RE TPD\)](#)

borders. This condition resulted in legal uncertainty, as reported by several Member States and civil society advocacy in their initiatives to better protect the health of their citizens by prohibiting certain categories of tobacco or related products. In order to ensure that public health objectives can be effectively pursued in accordance with Article 24(3), there is also a need for a set of guidelines further explaining the applicability of the conditions enshrined in this Article.

**The TPD should clarify the conditions and process for the application of Article 24 (3) in order to reduce uncertainties around the adoption of national measures.**

## **Requested Action 9: Ban cross-border distance sales of tobacco products and electronic cigarettes**

**Article 18** allows Member States to prohibit cross-border distance sales of tobacco products to consumers. However, the risks were recognised in the TPD Recital (33):

*Cross-border distance sales of tobacco products could facilitate access to tobacco products that do not comply with this Directive. There is also an increased risk that young people would get access to tobacco products. Consequently, there is a risk that tobacco control legislation would be undermined. Member States should, therefore, be allowed to prohibit cross-border distance sales. Where cross-border distance sales are not prohibited, common rules on the registration of retail outlets engaging in such sales are appropriate to ensure the effectiveness of this Directive. Member States should, in accordance with Article 4(3) of the Treaty on European Union (TEU) cooperate with each other in order to facilitate the implementation of this Directive, in particular with respect to measures taken as regards cross-border distance sales of tobacco products.*

Currently 17 Member States<sup>47</sup> ban local and/or cross-border distance sales of tobacco products, while a further 7 Member State authorities impose registration requirements.

The different approaches taken by Member States regarding the cross-border online sale of tobacco products not only generate a fragmentation of the internal market, but also lead to possible circumventions of TPD provisions. Internet sales of tobacco inherently involve some form of promotion, but also tax evasion, illicit trade and sales to minors, access to non-compliant products, and undermines Member States fiscal and health policies. The TPD's measures aiming to prevent these breaches from happening proved weak and insufficient, including through reports showing the age verification systems' failure. An EU wide ban on cross-border sales of tobacco products and e-cigarettes would be in line with both internal market and health objectives.

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<sup>47</sup> (PwC Network Survey, National Authority Questionnaire and UK Government, 2019b)