

ESMO feedback - Evaluation of the EU legislative Framework for Tobacco Control

The [European Society for Medical Oncology \(ESMO\)](#) is the leading professional organisation for medical oncology, with more than 28,000 members from over 160 countries. ESMO is committed to preventing new cancer cases, improving the quality of cancer care and promoting equal access to optimal treatments for all cancer patients.

Introduction

Tobacco kills more than 8 million people each year.¹ There were an estimated 2.5 million cancer deaths attributable to smoking globally, representing 24.7% of all cancer-related deaths in 2019.² Smoking is a primary cause of lung cancer. Worldwide, roughly 80% of male lung cancer deaths and 50% of female lung cancer deaths are caused by smoking.³ Tobacco use not only causes cancer but also can negatively impact cancer treatment toxicity and survival.⁴

The COVID-19 pandemic has worsened the situation of cancer patients: delays in diagnosis were common, screening programmes were interrupted, and treatment services were disrupted.⁵ COVID-19 infected cancer patients have more severe symptoms and higher case fatality rates, particularly those who were receiving active treatment, compared to the general population.⁶

Tobacco smoking is associated with more severe illness and an increased risk of death in people who need hospital treatment for COVID-19.⁷ Therefore, stopping smoking is beneficial both for being more resilient against COVID-19 infections and for reducing cancer risks and increasing survival.

The European Union, together with the World Health Organisation (WHO) and national governments, need to intensify their efforts to implement comprehensive tobacco control measures and take decisive actions against the bane of cancer.

Revision of the EU tobacco legislation

Given the current scourge - an estimated 2.7m new cases and 1.3m deaths in the EU in 2020⁸ - of cancer and the increasing threat - lives lost to cancer in the EU are set to increase by more than 24% by 2035⁹, making it the leading cause of death in the EU - that it poses to Europe's patients, their families and friends. ESMO welcomes the opportunity to feed into the European Commission's work to review the EU tobacco control measures noting that about 40% of cancer cases in the EU are preventable.¹⁰

ESMO recognises the significant contributions made by the Tobacco Products Directive (TPD) 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 World Health Organisation Framework Convention on Tobacco Control (FCTC) at EU level and contributed to a reduction in tobacco use. However, new market and legislative developments in the EU pose new challenges to the functioning of the internal market and to the protection of public health, which could be addressed through a revision of the TPD.

To fight the tobacco epidemic and to achieve the ambitious goal of creating the Tobacco-Free Generation, set in the Europe's Beating Cancer Plan, the following ESMO's suggestions shall be considered while revising the EU tobacco legislation:

1. To introduce mandatory plain-packaging with 80% front and back pictorial health warnings for all tobacco products

Article 24(2) of the TPD allows for voluntary introduction of plain-packaging and such measure has been introduced in several members states. Plain-packaging has proven to be an effective public health measure to discourage tobacco use but the lack of harmonised rules creates different levels of public health protection for EU citizens.

2. To harmonise definitions of tobacco and related products across EU legislation

There are inconsistencies in the definitions of 'tobacco products' across EU legislation which may not reflect market developments.

The Tobacco Advertising Directive (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*
- *'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;*
- *'tobacco products for smoking' means tobacco products other than a smokeless tobacco product*
- *'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;'

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). The TPD sets minimum rules applicable to 'novel tobacco products', leaving member states to decide and register specific products either as smokeless tobacco products or as tobacco products for smoking. 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 across the EU affect the level of health protection and creates new obstacles to the functioning of the internal market.

3. To strengthen advertising rules on tobacco advertising, promotion and sponsorship (TAPS)

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 EU countries, and it is growing confusion as to the concrete responsibilities across national authorities and the role of the civil society. The current provisions on TAPS contained in EU rules are limited – don't unambiguously cover all tobacco and related products (such as heated tobacco products (HTPS) and devices) and don't unambiguously cover social media advertising.

The following challenges related to compliance with national rules on TAPS shall be addressed:

- Varying levels of advertising channels considered
- Lower compliance with rules concerning e-cigarettes and HTPs

- Out-of-date regulations considering entry into market of new products
- Difficult enforcement when there is cross-border advertising, promotion and sponsorship
- Lack of financial and human resources for monitoring and enforcement

The current wording of the definition within the TAD does not clearly cover novel tobacco products (such as heated tobacco products - HTPs) which consequently the tobacco advertising and sponsorship restrictions do not apply to them.

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, 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.

Evidence shows that advertising and promotion strategies of the tobacco and related products industry specifically targets young people.¹¹ As stated in the TAD's 2008 Implementation Report¹², such forms of indirect TAPS threaten public health by increasing a number of young smokers and pose a challenge to the implementation of the Directive. Therefore, ESMO calls for such a ban to be covered by the scope of the Directive, including tobacco brand names and corporate promotion.

4. To introduce a definition for HTPs and subject them to the full effect of the TPD and revise the definition and regulatory pathway of 'novel' 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, emissions measurements and limits, and bans on misleading elements and notably any suggestions that a particular tobacco product is less harmful than others.

5. To ban cross-border distance (online) sales of tobacco products and e-cigarettes

Such ban could ensure the adequate implementation, monitoring, and enforcement of member states' tobacco control and fiscal policies. The TPD allows member states to prohibit cross-border distance sales of tobacco products to consumers. However, the risks are recognised in the TPD Recital (33). More than half of EU member states banned cross-border distance sales of tobacco and/or related products to consumers, while other member state impose registration requirements. There is insufficient monitoring and enforcement of cross-border distance sales restrictions or bans under the TPD. Age verification systems have proven to be ineffective, vary between member states and are poorly enforced. Therefore, 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.

6. To include a reference to the FCTC Article 5.3 (protecting public health policy from tobacco industry interference) in the TPD in addition to the existing reference in Recital (7) of the TPD

Article 5.3 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.' 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. However, the obligation under 5.3 is not appropriately fulfilled at EU level. A reference to both, member states and the EU's, obligations under 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.



7. To eliminate TPD Article 7(12) which exempts tobacco products other than cigarettes and roll-your-own tobacco from the ban on characterising flavours

As confirmed by the European Court of Justice in its 2016 judgment, 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. More than 90% of smokers in the EU reported the cigarette flavour as the most decisive parameter related to their brand choice, rated higher than the importance of price or packaging¹³. Similarly, youth aged 15–24 years were more likely than the older participants to report initial smoking because of menthol flavour or a specific sweet, fruity or spicy flavour¹³. Therefore, as stated in the Court’s judgment and 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 to effectively protecting public health.

8. To maintain the ban on tobacco products for oral use (‘snus’) at EU market and to introduce a distinct definition for ‘snus’ and ‘chewing tobacco’.

A more clear and distinct definition for ‘snus’ and ‘chewing tobacco’ is needed as there are interpretation issues on the delimitation between those products which led to placing on the EU market of snus-type products. Subsequently, this led to a legal action when the Bavarian Court of Justice banned¹⁴ a product sold under the category of ‘chewing bag’ which has similarities to Swedish snus.

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