European Tobacco Products Directive (TPD): current impact and future steps

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Abstract

Efforts to reduce the toll of tobacco-related morbidity and mortality in the European Union are spearheaded by the Tobacco Products Directive (TPD), a legal act implemented during 2016–2021, with the overall aim to reduce tobacco consumption by 2% in Europe. Within this time frame, several core tobacco control measures were implemented, the impact of which is outlined within this manuscript. Key successful legislative actions implemented in this time frame led to greater availability of information and further regulation of additivés, the banning of mentholated cigarettes, enhanced pictorial package warnings and a regulatory framework for e-cigarettes. While repeated cross-sectional data indicated a 12.5% relative reduction in smoking prevalence after implementation of the TPD, the differential regulation of cigarettes and roll-your-own tobacco compared with other products, such as cigarillos, e-cigarettes and heated tobacco products, may have also led to product displacement. Moreover, as the TPD could not keep up with the ever-changing nicotine product landscape, further adaptations may be needed.

Tobacco use within the European Union Member States (EU MS) has a significant impact on health and on the provision of healthcare, and poses an additional burden to economies within the Eurozone, many of which are already under substantial economic constraints due to austerity measures of the previous decade and the current impact of the COVID-19 pandemic. Efforts to reduce the toll of tobacco-related morbidity and mortality in the EU are spearheaded by the Tobacco Products Directive (TPD), a legal act that was designed to meet the obligations of the EU under the WHO Framework Convention for Tobacco Control (FCTC). These two instruments, the TPD and the FCTC, provide EU MS with a framework of actions and goals that aims to protect human health and potentially reduce tobacco consumption, monitor tobacco product evolution and reduce demand for tobacco products across the EU. Although significantly modified during the negotiation phase, the central legislative framework of the TPD provided substantial leverage for the implementation of tobacco control measures across countries, as collectively, the regulations proposed in the TPD could not have been achieved at the national level alone, within which industry interference and political willingness may hamper national tobacco control efforts.

The TPD transposed into EU MS legislation and implemented during 2016–2021, aiming to reduce tobacco consumption by 2% within this time frame. Although a low threshold to pass in the short term, the long-term impact of the TPD was expected to be high due to the long-term effects that tobacco control policies have on youth. Within this time frame, tobacco control policies outlined in the TPD were gradually implemented across the 27 EU MS (and the UK at that time), supported by central policy actions, European projects (such as the Joint Action on Tobacco Control) and by EU MS regulators’ efforts. In light of the actions performed to date, both centrally and across the 27 EU MS, this manuscript aims to provide a short overview of the actions performed, targets that have been met and areas that warrant future effort in light of the ever-changing tobacco product landscape in Europe.

Increasing the evidence base on tobacco product constituents and additives

Over the past years, we have witnessed an evolutionary maelstrom that led to the development and proliferation of new brands of existing cigarettes, e-cigarettes and heated tobacco products (HTPs), products that further perpetuate the complexity of the taxonomy, understanding and effective regulation of tobacco products and their constituents.

To support the monitoring of tobacco product design and constituents and within the context of the TPD, the European Commission migrated from a decentralised paper/CD submission process to a centralised online submission portal, the European Union Common Entry Gate (EU-CEG). The EU-CEG is an information portal through which the tobacco industry is mandated to submit the complete chemical composition and product design information for each product it wishes to market in the EU MS, which is required to make aspects of this information publicly available. Indeed, EU-CEG may be the first application of Big Data to tobacco control. It is a living database of over 220 000 product versions submitted across the 27 EU MS. Each submission contains quantitative information on product design, constituents and emissions, and multiple PDFs with qualitative data.

The EU-CEG, while highly complex and challenging to use in day-to-day regulatory work at the EU MS level, is an exceptional monitoring tool as it may allow EU MS to swiftly respond to product evolutions or upcoming ‘outbreaks’ of newly evolved tobacco products or ‘variants of interest’ across the EU MS markets as they emerge. The need for such a fast turnaround and assessment of new ‘variants of interest’ is especially evident in light of the swift expansion of JUUL in the USA and the launch and proliferation of HTPs. However, for its maximum potential to be reached, the issue of
ensuring sustainable staff capacity working on tobacco control in
the EU MS would need to be addressed.

Preliminary analysis of EU-CEG data for tobacco produc-
tests has indicated that among 12 EU MS, and within almost
40 000 tobacco product types submitted, priority additives were
identifiable more than 90 000 times—indicating the extensive
appearance of these additives within tobacco products on the
EU market.20 Similarly, the EU tracking and tracing system also
opened the window for the use of Big Data in tobacco control as
it allows for the tracking of every legal cigarette pack in the EU
from the moment of production or import, up to the dispatch to
the retail store. It is the only system in the world, which works
across borders. However, as access to the data is restricted, its
use by researchers, although promising, is still limited.13

**Banning menthol and other characterising flavours**

Although nicotine and its pharmacological effects are central to
sustaining tobacco product use, they are insufficient to support
product acceptance.14 15 Sensory stimuli attributable to flavours
are particularly critical to product acceptance, reducing subjective
measures of cravings and withdrawal, even in the absence of
nicotine. A primary example of such an additive is menthol.
Menthol is 1 of the 15 priority additives for tobacco products
that were subject to further evaluation within the TPD,16 based
on the data that these additives may (1) contribute to toxic,
addictive or carcinogenic, mutagenic or reprotoxic properties
of cigarettes and roll-your-own (RYO) tobacco, (2) may result
in a characterising flavour, or (3) may facilitate inhalation or
nicotine uptake. Within the course of the TPD, supporting infor-
mation on these additives was requested from the industry, and
the extensive data were assessed by an independent panel, the
conclusions of which are expected to contribute to the regula-
tion of tobacco product ingredients at the EU level.17

The banning of a ‘mentholated’ characterising flavour is hence
a key aspect of the success of the TPD. From May 2016, the
TPD prohibited cigarettes and RYO tobacco with characterising
flavours (a flavour other than that of tobacco) from being placed
on the market, with a 4-year phase-out period for products
with a characterising menthol flavour (May 2020).18 This ban
has significant implications. 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 packaging.19 Similarly, youth aged 15–24 years were
more likely than the older participants to report initial smoking
because of menthol flavour (adjusted OR (aOR)=2.4) or a
specific sweet, fruity or spicy flavour (aOR=2.6).19 While the
tobacco industry has extensively researched the role of flavours
in product acceptance in the context of product development
and evolution, the assessment of flavours for regulatory purposes
in tobacco control is still in its infancy.20 Consumers’ percep-
tion of flavour attributes is driven by specific concentrations of
individual flavour compounds, which form a composite odour,
the way cigarettes are perceived by a consumer. Even though
the consumer perceives these aroma constructs, the perception,
recognition and identification of flavours in the human nose
occur at the level of the individual chemical compounds. Simi-
larly, the flavour and odour of tobacco, both before and during
burning, comprise numerous individual flavour attributes. Each
of these unique attributes arises from the impact of individual
chemical compounds on the human olfactory system. Based on
these principles, the TPD prohibits tobacco and RYO tobacco
from conveying a characterising flavour by applying principles of
sensory science to tobacco control, a significant step in tobacco
product regulation—with substantial applications also for other
jurisdictions across the globe.21 22

**The introduction of more prominent warning labels and the
path towards plain packaging**

Harmonising labelling and packaging rules was another crit-
ical success of the TPD. It homogenised packaging across the
internal market and set the legal framework for several EU MS
to pursue plain packaging. The TPD, at minimum, required
larger, combined text and graphic warning labels on packaging,
covering 65% of the front and the back of cigarette and RYO
tobacco packs, effectively prohibiting smaller packages and
included a ban on promotional and misleading elements on
tobacco products and their packaging. This was an essential
improvement of labelling measures compared with the previous
Directive 2001/37/EC, which had only more minor text-only
warnings.23 Assessments of these warnings among adult smokers
in six EU MS (Germany, Greece, Hungary, Poland, Romania,
Spain) reported that these had increased salience, in that they
noticed the warning labels more often with over half of the
smokers. Furthermore, one-third of quitters noticed at least
one of the five TPD-related packet changes, while around one-
quarter of all respondents saw changes to health warnings, stan-
dardised openings, minimum packet unit size and the removal
of Tar, Nicotine and CO (TNCO) information on packaging.24 25

Eight EU MS (including at that time the UK) went beyond
the TPD’s minimum labelling provisions and introduced plain
packaging for tobacco products,26 leading to the development
of a regional evidence base in support of plain packaging. Based
on evidence from EU MS, plain packaging along with picto-
rial warnings appear to increase awareness of tobacco-related
diseases, making warnings more salient and supporting reduc-
tions in smoking.27–29 More recent evidence also indicates that
about half of the EU population supports the adoption of plain
packaging, however with significant cross-country differences
(ranging from 72% in Ireland and the UK, 66% in Belgium to
28% in Portugal).30

On the contrary, while introducing pictorial warning labels
across the EU for cigarettes and RYO, other products regulated
under the TPD such as smokeless tobacco, waterpipe tobacco,
HTPs and e-cigarettes were mandated to have text-only warn-
ings, which was a significant improvement from the status quo.

**Regulating e-cigarettes and novel tobacco products**

The TPD brought forward regulatory requirements for several
design and packaging parameters of e-cigarettes, including but
not limited to: maximum nicotine concentrations at 20 mg/mL,
a maximum volume of 2 mL for refillable e-cigarette tanks, child-
resistant refill containers and the regulation/notification of the
constituents of e-liquids to regulators, via EU-CEG. Implemen-
tation of child-resistant caps, tamper-proof vials and maximum
refill volumes reached high levels of compliance in pre–post
product studies31—an area of significant public health relevance
due to the impact of unintentional exposures among younger
children in Europe32; however, variations in the declared versus
measured nicotine contents were identified, indicating the need
to ensure quality control in the manufacturing processes.33 34

Under the TPD, e-cigarettes were further required to implement
text-only warning messages and include a leaflet containing
instructions for use and contraindications.35 Among smokers
and recent quitters who used cigarettes, reported noticing and
reading leaflets included in the packaging of e-cigarettes

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increased significantly from before versus after implementation of the TPD.

On the contrary to e-cigarettes which had already emerged before the TPD, HTPs had not launched during the drafting of the legislation, leading to them being covered under a more general blanket of ‘novel tobacco products’. As, however, their use has expanded over the years, predominantly among youth, more comprehensive regulation may be needed. HTPs, although required to have their ingredients and emissions reported to regulators via the EU-CEG, they were exempted from the ban on characterising flavours. Furthermore, an ambiguous clause in the TPD allowed them to self-categorise themselves as either a smokeless tobacco product or a tobacco product for smoking. Naturally, manufacturers opted for the latter (defining the products as ‘smokeless’), and hence HTPs were mandated to carry the smaller (30% coverage) text-only warning labels and were not subject to stricter packaging requirements.

Despite the above, changes are likely expected to the regulation of novel tobacco products in the future as the TPD assessment report indicated that there had been problems with the TPD maintaining its relevance with novel and innovative products due to the pace at which new products have developed, especially taking into account that the provisions of the TPD were drafted before e-cigarettes and HTPs appeared in strength on the EU market.

**The overall impact of the TPD**

While a causal inference cannot be attributed solely to the implementation of the TPD, repeated cross-sectional data have indicated that smoking prevalence among those aged 15+ years fell from 26% in 2014 to 23% in 2020—an absolute 3% reduction in prevalence and a 12.5% relative reduction following TPD implementation, significantly higher than the target goal. Despite this notable drop in prevalence, the differential regulation of cigarettes and RYO tobacco compared with other smoked products (ie, cigarillos) and other products, such as e-cigarettes and HTPs, created inconsistencies concerning packaging, labelling, and flavouring and may have led to product displacement rather than a reduction in consumption, particularly among youth. Cohort study research has indicated that the implementation of the TPD had altered smoking behaviour through changes in consumption patterns but may also have led to product switching or displacement, which may partially explain some of the differences in prevalence for specific product categories.

**Next steps in Europe**

The 2021 Europe’s Beating Cancer Plan notes that tobacco control is placed at the centre of disease prevention efforts, with the overarching goal to create a ‘tobacco-free generation’—where less than 5% of the population uses tobacco—by 2040, compared with around 25% today. To achieve this long-term goal, and essentially tobacco endgame in Europe, the EU has the opportunity to use devices for change, including the potential revisions to the current TPD, revisions to the Tobacco Advertising Directive (as advertising was not a core component of the TPD), modifications to the EU Tax Directive and the recently introduced EU Green Deal’s Single-Use Plastics directive, all of which will further influence both product innovation and impact population use. The future for tobacco control in Europe is ambitious—it remains to be seen how this momentum will be best used so as to achieve the maximum benefit to the health of the European population.

**What this paper adds**

- The Tobacco Products Directive (TPD) set the stage for the implementation of stricter EU wide tobacco control policies.
- The TPD increased consumer and regulator information on tobacco product additives, banned characterising flavours, regulated e-cigarettes, implemented graphic warning labels and set the stage for the implementation of plain packaging in certain European Countries.
- Although heated tobacco products were included in the TPD before their market expansion, the changing product landscape may have caused issues with the TPD maintaining its relevance with innovative and novel products - for which changes are most likely expected.
- Although product switching or displacement may partially explain some of the differences in measured prevalence in the EU, the TPD has surpassed its initial projected goals and facilitated harmonised tobacco control measures across the EU.

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**Competing interests** CIV is the head of the Technical Group of Sensory and Chemical Assessors that assists the Independent Advisory Panel (IAP) by carrying out the practical sensory and chemical assessments of tobacco products and provides input to IAP on the methodology to be used for the technical assessment of these products.

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