

Worldwide news and comment

EUROPEAN UNION

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EU considers flavour ban for heated tobacco products

The European Commission has announced that it will consider a flavour ban for heated tobacco products (HTPs) for all 27 Member States of the European Union. Tobacco products, including HTPs with a characterising flavour or containing flavourings in any of their components would be prohibited. The announcement stated that the substantial increase in HTP consumption in many Member States warrants this intervention.

At European Union level, between 2018 and 2020 there was an increase of over 2000% in sales volumes of HTPs, and as of 2020, HTPs accounted for approximately 3.51% of the tobacco market.

Flavour additives, including menthol are already prohibited for conventional cigarettes in the EU but not for HTPs and some other tobacco products such as cigarillos. Research evidence suggests that flavourings and additives such as menthol appeal to young people and are erroneously perceived as less harmful.

The European Council will now consider the EU proposal. If approved, Member States are likely to be given many months to implement a ban.

NORTH AMERICA

Canada publishes proposed regulations to require a health warning directly on every cigarette

On 10 June 2022, Canada announced proposed regulations for its third round of picture warnings, together with a requirement for a health warning to appear on every cigarette, a world first. The draft regulations were subject to a 75-day consultation period, which ended on 25 August 2022. Final regulations are expected to be adopted in the first half of 2023, with the new warnings for cigarette packages and sticks to be implemented 180 days later at the manufacturer level, and 270 days later at the retail level.

For the warnings on each cigarette, there will be two sets of 6 bilingual text warnings with black text on a white background, with the sets changed after 24 months. The



Proposed Health-related messages - Cigarettes.

warning will appear on the tipping paper (paper that wraps over the filter) portion of the cigarette (see Figure), and will apply to cigarettes, cigars with a filter, and filtered cigarette tubes sold without tobacco. The on-cigarette warning featured at the announcement states “Poison in every puff”. Having a black on white warning will disrupt the manufacturer practice of having a fake cork appearance or off-amber type colour appearing on the filter for many brands. Canada already bans brand names, logos and colours from appearing on the cigarette.

Dr. Carolyn Bennett, Minister of Mental Health and Addictions and Associate Minister of Health, made the announcement at a news conference also attended by health organisation representatives. She noted, among other points, that warnings on each cigarette “will help ensure that these essential messages reach people, including the youth who often access cigarettes one at a time in social situations, sidestepping the information printed on a package.”

Wire stories by Associated Press and Reuters resulted in the Canadian announcement receiving widespread international media coverage.

The proposed Canadian requirements also include, for cigarettes, two new sets of 14 exterior picture-based warnings, two sets of 13 interior picture-based messages that are more cessation focused, and two sets of 6 text-only toxicity messages in black, red and yellow to cover a full lateral package side. The interior messages will have enhanced visibility as the upper slide flap will be increased in size (see Figure). The 75% size requirement for the package front and back will be unchanged, however Canada’s unique slide and shell package requirement increases the surface area for external warnings compared with a flip top package. The new health warnings complement Canada’s requirements for plain packaging.

This round of warning requirements had previously been the subject of a general Health Canada consultation on tobacco warnings for packages and on cigarettes, but without any draft regulations, initiated in October 2018. A consultation summary by the Canadian Department of Health indicated that 141 submissions were received in response to the consultation, with tobacco manufacturers opposed to on-cigarette warnings, and health organisations in support.

Finalisation and implementation of the Canadian requirement for a warning on every cigarette – supported by a compelling evidence base including an increasing number of studies in multiple countries – will undoubtedly prompt other countries to do the same.

Mockup of proposed new health warnings for cigarette packages and the cigarette itself released by the Canadian Department of Health.

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USA

Heat on Juul as FDA moves to remove products from market

In June 2022 the U.S. Food and Drug Administration (FDA) ordered Juul Labs (which is partly-owned by Altria Group who have a 35% stake in the company) to remove its e-cigarette devices as well as its tobacco and menthol flavoured cartridges from the market. However, products remained on sale after Juul filed an emergency temporary hold through the federal appeals court, which ruled that the company can continue to sell its e-cigarettes while it appeals the ban.

Following a review of Juul’s premarket tobacco product applications (PMTAs), the FDA determined these PMTAs did not

provide sufficient evidence to demonstrate that the marketing of these products would be appropriate for the protection of public health.

The FDA had concerns about insufficient and conflicting data in Juul's PMTAs, including data on genotoxicity and potentially harmful chemicals leaching from their e-liquid pods. Therefore, the FDA was unable to complete a full toxicological risk assessment of the products,

FDA Commissioner Robert M. Califf, M.D. stated "Today's action is further progress on the FDA's commitment to ensuring that all e-cigarette and electronic nicotine delivery system products currently being marketed to consumers meet our public health standards...The agency has dedicated significant resources to review products from the companies that account for most of the U.S. market. We recognise these make up a significant part of the available products and many have played a disproportionate role in the rise in youth vaping."

Acting Director of the FDA's Centre for Tobacco Products Michele Mital, said, "As with all manufacturers, Juul had the opportunity to provide evidence demonstrating that the marketing of their products meets these standards. However, the company did not provide that evidence and instead left us with significant questions. Without the data needed to determine relevant health risks, the FDA is issuing these marketing denial orders"

In 2021 Superior Court Judge Orlando Hudson found that Juul had ignored court orders and destroyed documents as part of a case examining unfair and deceptive practices that targeted young people in the U.S. state of North Carolina. Juul agreed to pay North Carolina US\$40 million over a 6 year period.

E-cigarette use has significantly increased among teenagers in the U.S. after Juul launched in 2015, and the FDA declared an epidemic of vaping among teenagers in 2018. "The evidence is clear that Juul's high-dose nicotine products caused the youth e-cigarette epidemic," said Matthew Myers from the Campaign for Tobacco-Free Kids.

Recent research indicates that approximately 5.22 million (34%) of high school students and 1.34 million middle school students reported ever-using a tobacco product, including e-cigarettes, in 2021.

Plans to reduce nicotine to non-addictive levels in cigarettes

In June 2022 the U.S. Federal Government announced that it plans to develop a proposed product standard which would establish a maximum nicotine level for

cigarettes. The aim of this product standard would be to reduce nicotine in cigarettes and other combustible tobacco products and to consequently reduce use among youth, and subsequent addiction and death.

In 2009, the FDA was given authority to regulate tobacco products through the adoption of the Family Smoking Prevention and Tobacco Control Act. This Act gives the FDA authority to regulate tobacco products, including lowering nicotine levels. Nicotine levels can be reduced by using different tobacco leaf blends or through the use of different types of papers or filters.

"Making cigarettes and other combusted tobacco products minimally addictive or non-addictive would help save lives. The U.S. Surgeon General has reported that 87% of adult smokers start smoking before age 18, and about two-thirds of adult daily smokers began smoking daily by 18 years of age. Lowering nicotine levels to minimally addictive or non-addictive levels would decrease the likelihood that future generations of young people become addicted to cigarettes and help more currently addicted smokers to quit," said FDA Commissioner Robert M. Califf, M.D.

Tobacco use is the leading cause of preventable disease and death in the U.S. with approximately 480 000 premature deaths from smoking-related diseases each year. Tobacco use is also the number one cause of preventable death among African Americans, causing approximately 45 000 deaths each year. Tobacco use also costs the U.S. around \$300 billion per year in direct healthcare and lost productivity costs.

In 2018, the FDA published a study estimating that by the year 2100, a nicotine product standard could result in more than 33 million fewer regular smokers, a smoking rate of only 1.4% (the current smoking rate is 12.5%), and more than 8 million fewer deaths from tobacco-related illnesses in the U.S.

CENTRAL AMERICA

Mexico bans sales of e-cigarettes and heated tobacco products

To mark World No Tobacco Day on the 31 May 2022, the President of Mexico, Manuel López Obrador, announced that sales of e-cigarettes and heated tobacco products were to be prohibited with immediate effect.

The decree states "The circulation and commercialization within the Republic, whatever their origin, of Electronic Nicotine Administration Systems, Similar Systems without Nicotine, Alternative Nicotine Consumption Systems, electronic cigarettes,

and vaporising devices with similar uses, as well as the solutions and mixtures used in said systems is prohibited."

Imports of devices were banned back in 2021 but sales of remaining stock were previously permitted.

One of the reasons stated for the current total ban is the potential appeal of flavourings to children and young adults.

Sales of e-cigarettes are also banned in many other countries, such as Argentina, India, Gambia, Hong Kong, and Singapore (where possession of a vaping device is also a crime). Conversely, countries such as England, and New Zealand have recommended that e-cigarettes be used as smoking cessation devices in order to meet smoke-free targets (smokefree equating to <5% smoking prevalence).

AFRICA

While global smoking rates decline, Africa is an opportunity for tobacco companies to grow their business

The seventh edition of the global Tobacco Atlas was published on 18th May 2022.

For the first time ever, global smoking prevalence has declined. But there is little room for complacency. There are still 1.3 billion smokers worldwide, which means much more tobacco related illness and deaths to come. Also, while many countries are seeing significant declines in smoking prevalence, 63 countries out of the 135 surveyed have reported increases in smoking prevalence in 13–15 year olds. In addition, in Africa, where typically, smoking prevalence has been low, smoking is on the rise. According to the Tobacco Atlas the rise in the latter is in no small part due to the tobacco industry's aggressive marketing practices on the continent and an increase in the affordability of tobacco products. Such increases in prevalence will undoubtedly increase tobacco related disease, suffering, and death.

The Atlas emphasises the importance of countries implementing evidence-based tobacco control measures, namely, tobacco tax increases, marketing restrictions and counter messaging such as plain packaging and pictorial health warnings, as well as anti-smoking mass media campaigns. While impactful in their own right, these policies are likely to have the most impact when implemented together.

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Tob Control 2022;**31**:595–596.
doi:10.1136/tc-2022-057659