LITIGATION RELEVANT TO REGULATION OF NOVEL AND EMERGING NICOTINE AND TOBACCO PRODUCTS

COMPARISON ACROSS JURISDICTIONS

World Health Organization

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Litigation relevant to regulation of novel and emerging nicotine and tobacco products: comparison across jurisdictions

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Executive summary

Novel and emerging tobacco products have presented a number of challenges for regulators, including the risk that regulation may lead to litigation. This paper analyses litigation concerning tobacco product regulation across jurisdictions, with the aim of highlighting the legal arguments advanced and the reasoning of courts relevant to novel and emerging nicotine and tobacco products.

Two broad categories of litigation can be identified. The first concerns measures addressing product characteristics and disclosures. This group of cases concerns legal challenges against measures which prescribe the form that a product may or may not take, including, classification of these products under national legislation, proportionality of product prohibitions, and flavour bans. The second category of cases concerns health claims and advertising, promotion and sponsorship. These concern application of laws to different products, including enforcement actions concerning misleading conduct and restrictions on advertising, promotion, and sponsorship.

Key findings

The key findings for the purposes of regulation of novel and emerging nicotine and tobacco products are as follows:

1. **manufacturers of e-cigarettes and heated tobacco products attempt to avoid products being regulated, so as to effectively fall within regulatory or legislative gaps;**
2. **manufacturers can be expected to deploy arguments concerning the relative risk of different product categories, and the need for coherent regulation along a continuum of risk;**
3. **not all courts are receptive to arguments about relative risk, either because regulations are justified by reference to absolute risk or because the concept of relative risk is judged at the population level and taking into account factors beyond relative toxicity;**
4. **technological advances employed for the manufacture of novel and emerging nicotine and tobacco products will raise questions of whether a product falls within the ambit and scope of the national legislation of the country;**
5. **there are relatively few cases addressing misleading marketing of novel and emerging products, or enforcing restrictions on advertising, promotion and sponsorship, but important cases have been decided, including on how social media posts may constitute advertising and on whether advertising of a heated tobacco product device also constitutes advertising of a tobacco product.**

Together, the cases described offer governments an idea of the legal arguments that have been used in attempts to evade or minimize regulation, as well as how courts have addressed those arguments. For ease of access, those cases are also summarized briefly in the Case Summaries document.[i]

Two broad categories of tobacco product litigation:

1 PRODUCT CHARACTERISTICS AND DISCLOSURES

- Classification hurdles under existing laws
- Prohibition and proportionality
- Flavour bans

2 HEALTH CLAIMS AND ADVERTISING, PROMOTION, AND SPONSORSHIP

- Misleading conduct and false claims
- Restrictions on advertising, promotion and sponsorship

i World Health Organization, Litigation relevant to regulation of novel and emerging nicotine and tobacco products: case summaries, (2021), (https://apps.who.int/iris/bitstream/handle/10665/340842/9789240024182-eng.pdf).

Introduction and scope

In recent years, regulation of novel and emerging nicotine and tobacco products has taken on increased importance in the context of tobacco control. The emergence of products such as heated tobacco products (HTPs) and electronic nicotine delivery systems (ENDS) and their market growth has raised questions about how they should be regulated and how that regulation might affect comprehensive tobacco control. WHO has previously published its position on regulation of these products, but has not addressed legal issues, such as how those regulations are being challenged in different jurisdictions.

HTPs produce aerosols containing nicotine and toxic chemicals when tobacco is heated or when a device containing tobacco is activated.[1] HTPs contain tobacco and are tobacco products and therefore subject to the provisions of the WHO Framework Convention on Tobacco Control (WHO FCTC).[2] Consequently, Parties to the Convention are legally obliged to implement measures including regulating product contents and disclosures (Articles 9 and 10), banning or restricting advertising, promotion and sponsorship (Article 13) and regulating labelling (Article 11).

ENDS are devices that heat a liquid solution to create an aerosol that is inhaled by the user.[3] ENDS is an all-encompassing term for multiple product categories: e-cigarettes, vapes, vape pens, e-cigars, e-hookahs, and e-pipes.[4] There are other electronic, non-nicotine delivery systems (ENNDS), which do not contain nicotine.[5] For the purposes of this report, ENDS, includes ENNDS unless otherwise specified.

In the context of ENDS, where they are not prohibited, WHO has recommended that Member States regulate the products as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health. WHO has recommended that Member States pursue the following general regulatory objectives:

General regulatory objectives

a **impeding ENDS promotion to and uptake by non-smokers, pregnant women and youth;**

b **minimizing potential health risks to ENDS users and non-users;**

c **prohibiting unproven health claims from being made about ENDS; and**

d **protecting existing tobacco-control efforts from commercial and other vested interests of the tobacco industry.[6]**

WHO has also recommended that in order to achieve these objectives, Member States that have not banned the importation, sale, and distribution of ENDS/ENNDS should consider a list of non-exhaustive regulatory options set out in Box 1.[7] [8]

1 World Health Organization (WHO), Heated Tobacco Products: Information Sheet, March 2020, WHO/HEP/HPR/2020.2, 52 (https://www.who.int/publications/i/item/WHO-HEP-HPR-2020.2, accessed 3 August 2020)
2 Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC), Novel and emerging tobacco products. Eight session, FCTC/COP8(22), 6 October, 2018, (https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8(22).pdf, accessed 1 July 2020)
3 World Health Organization (WHO), Report on the Global Tobacco Epidemic, [2019], 56, (https://apps.who.int/iris/bitstream/handle/10665/326043/9789241516204-eng.pdf, accessed 3 August 2020)
4 *ibid*, 56
5 *ibid*, 56
6 Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC), Electronic nicotine delivery systems: Report by WHO, Sixth session, FCTC/COP/6/10 Rev.1, September 1, 2014, para 36 (http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1, accessed 15 November 2019); COP WHO FCTC, Electronic nicotine delivery systems and electronic non-nicotine delivery systems: Decision, Sixth session, FCTC/COP6(9), October 18, 2014, para 2-3 (https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6(9)-en.pdf, accessed 4 July 2020)
7 FCTC/COP/6/10 Rev.1, para 39-53
8 See COP WHO FCTC, Electronic nicotine delivery systems: Report by WHO, Seventh session, FCTC/COP/7/11. August 2016, para 28-32 (https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf, accessed 4 August, 2020); COP WHO FCTC, Electronic nicotine delivery systems and electronic non-nicotine delivery systems: Decision, Seventh session, FCTC/COP7(9), November 12, 2016, (https://www.who.int/fctc/cop/cop7/FCTC_COP7_9_EN.pdf?ua=1, accessed 4 August 2020)

Box 1. Regulatory options for Member States that have not banned ENDS/ENNDS

Prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups.

a Banning the sale and distribution of ENDS/ENNDS to minors;

b Banning the possession of ENDS/ENNDS by minors;

c Banning or restricting advertising, promotion and sponsorship of ENDS/ENNDS (see FCTC/COP/6/10 Rev.1 discussed below);

d Taxing ENDS/ENNDS at a level that makes the devices and e-liquids unaffordable to minors in order to deter its use in this age group. In parallel, combustible tobacco products should be taxed at a higher level than ENDS/ENNDS to deter initiation and reduce regression to smoking;

e Banning or restricting the use of flavours that appeal to minors;

f Regulating places, density and channels of sales; and

g Taking measures to combat illicit trade in ENDS/ENNDS.

Minimize as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions.

a To minimize health risks to users:

i. Testing heated and inhaled flavourants used in the e-liquids for safety, and banning or restricting the amount of those found to be of serious toxicological concern such as diacetyl, acetyl propionyl, cinnamaldehydes or benzaldehyde;
ii. Requiring the use of ingredients that are not a risk to health and are, when allowed, of the highest purity;
iii. Regulating electrical and fire safety standards of ENDS/ENNDS devices;

b To minimize health risks to non-users:

i. Prohibiting by law the use of ENDS/ENNDS in indoor spaces or at least where smoking is not permitted;
ii. Requiring health warnings about potential health risks deriving from their use. Health warnings may additionally inform the public about the addictive nature of nicotine in ENDS; and
iii. Reducing the risk of accidental acute nicotine intoxication by (a) requiring tamper evident /