

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

COMPARISON ACROSS JURISDICTIONS



World Health
Organization

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

**COMPARISON ACROSS
JURISDICTIONS**



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

ISBN 978-92-4-002036-8 (electronic version)

ISBN 978-92-4-002037-5 (print version)

© World Health Organization 2021

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

Suggested citation. Litigation relevant to regulation of novel and emerging nicotine and tobacco products: comparison across jurisdictions. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Design and layout by Lushomo

Contents

Executive summary	iv
Introduction and scope	1
Scope and methodology.	4
1. Product characteristics and disclosures.	5
Classification hurdles under existing laws	5
Prohibition and proportionality	8
Flavour bans	10
2. Health claims and advertising, promotion, and sponsorship	13
Misleading conduct and false claims	13
Restrictions on advertising, promotion and sponsorship.	14
Conclusion	17

Acknowledgements

The report was drafted by Benn McGrady and Kritika Khanijo from the Public Health Law and Policies Unit (LAW), Health Promotion Department. At various stages of preparation, the report benefited from comments, discussions and inputs from the No Tobacco Unit (TFI), WHO: Ranti Fayokun, Sarah Galbraith-Emami, and Vinayak Prasad.

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 <ul style="list-style-type: none">• Classification hurdles under existing laws• Prohibition and proportionality• Flavour bans	2 HEALTH CLAIMS AND ADVERTISING, PROMOTION, AND SPONSORSHIP <ul style="list-style-type: none">• 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](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](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.
- e 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;
 - iv. Regulating the need for manufacturers to disclose product content to government;
 - v. Regulating appropriate labelling of devices and e-liquids;
 - vi. Requiring manufacturers to monitor and report adverse effects; and
 - vii. Providing for the removal of products that do not comply with regulations.
- 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 / child resistant packaging for e-liquids and leak-proof containers for devices and e-liquids and (b) limiting the nicotine concentration and total nicotine amount in devices and e-liquids.

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

Prevention of unproven health claims being made about ENDS/ENNDS.

- a Prohibiting implicit or explicit claims about the effectiveness of ENDS/ENNDS as smoking cessation aids unless a specialized governmental agency has approved them;
- b Prohibiting implicit or explicit claims that ENDS/ENNDS are innocuous or that ENDS are not addictive; and
- c Prohibiting implicit or explicit claims about the comparative safety or addictiveness of ENDS/ENNDS with respect to any product unless these have been approved by a specialized governmental agency.

Protect tobacco control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry.

- a Raising awareness about potential industry interference with Parties' tobacco control policies;
- b Establishing measures to limit interactions with the industry and to ensure transparency in those interactions that do take place;
- c Rejecting partnerships with the industry;
- d Taking measures to prevent conflicts of interest for government officials and employees;
- e Requiring that information provided by the industry be transparent and accurate;
- f Banning activities described as "socially responsible" by the industry, including but not limited to activities described as "corporate social responsibility";
- g Refusing to give preferential treatment to industry; and
- h Treating State-owned industry in the same way as any other industry.

Some WHO Member States regulating ENDS have been challenged in international and domestic legal proceedings. With a view to capture this experience, this paper sets out a comparative analysis of litigation concerning novel and emerging nicotine and tobacco product regulation. The experience with regulation of cigarettes shows that tobacco companies make similar arguments across different jurisdictions and that comparative analysis of those arguments can help

regulators anticipate litigation and address the risks associated with such litigation. Accordingly, this paper is intended to assist Member States to achieve a high level of health protection in the context of ENDS and HTPs through a discussion on the legal challenges arising globally, arguments advanced therein, and reasoning of the courts to enable policymakers to design regulatory approaches that also withstand legal scrutiny.

Scope and methodology

Rellevant judicial decisions and administrative proceedings (together referred to as cases) have been identified primarily through the Tobacco Control Laws database (<https://www.tobaccocontrolaws.org/litigation>) and LexisNexis. A handful of cases not in the database, but known to the authors through engagement with Member States, have also been included in this paper.

As of 10 November 2020, the Tobacco Control Laws database contains 1065 cases dating back to 1968. Accordingly, the scope of the review and analysis is limited to novel and emerging nicotine and tobacco products, in order to focus on contemporary issues in product regulation, rather than on legal challenges to tobacco control more generally. Product regulation can be a broad concept, encompassing regulation of the manufacture, presentation and content of products, to reduce demand, supply or to improve safety. Recognizing the breadth of this concept, the analysis is focused primarily on the regulation of ENDS and HTPs, including how these products might be classified under existing laws or new legislation to be introduced by Member States, and the extent to which such regulation is coherent with approaches to other novel and emerging nicotine or tobacco products. In this regard, 89 cases between 2008-2020 were identified as relevant.

Another limitation on the scope of this paper is that challenges to generally applicable tobacco control laws, or to general packaging and labelling laws, are excluded in the absence of an argument with broader implications for product regulation. Although this approach necessarily involves some element of editorial discretion, it enables identification of common arguments or issues that can be taken into account in the legislative or regulatory process.

Finally, in many instances official English language translations of court decisions are not available. However, Google Translate was used, where necessary, to review decisions in other languages, especially in the absence of unofficial translations. This limits the detail of the discussion on specific cases.

These categories of cases are described in more detail below with the final caveat that the description is focused more on the arguments raised and types of challenges brought rather than on the legal analysis offered by the courts. This approach assumes that the conclusions drawn by the courts in the cases mentioned below are often particular to the jurisdictions in question, but that lessons can be drawn from commonalities found in the arguments raised.



The scope of the review and analysis is limited to novel and emerging nicotine and tobacco products, in order to focus on contemporary issues in product regulation.

1

Product characteristics and disclosures

Litigation in the context of product characteristics and disclosures primarily concerns prohibition of product categories and measures prescribing the form that a product must or may take. This includes claims challenging the following:

- a** classification of ENDS and other products as drugs;
- b** classification of smokeless tobacco products as food;
- c** prohibitions (whether legislated or the result of administrative decision-making) on constitutional grounds; and
- d** prohibition of flavoured ENDS and non-nicotine flavourings.

Together, these cases highlight how both ENDS and HTP manufacturers use litigation in attempting to fall between regulatory regimes, effectively evading regulation either as tobacco products or other regulated goods. Where the cases go beyond product classification, questions of regulatory authority and interpretation of statutory definitions, they foreshadow some of the arguments that governments can expect once ENDS or HTPs are subjected to tobacco control or other laws and regulations. In this respect, a series of claims relating to the prohibition of snus in the 2014 EU Tobacco Products Directive⁹ shows the types of constitutional law arguments that might be invoked in challenges. One striking aspect of these cases is how arguments about the relative harmfulness of different product categories are deployed in challenging the proportionality of product prohibitions.

Classification hurdles under existing laws

In many countries, ENDS and HTPs have entered the market in the absence of specific legal or regulatory regimes to govern them, leaving governments to apply existing laws, amend existing laws, or permit the products to fall within legislative or regulatory gaps. In a number of countries, litigation has arisen with economic operators challenging how either ENDS or HTPs have been classified under existing laws.

Before these cases are described, it is also worth noting that there are two ongoing international legal processes that could affect product classification under domestic laws. First, the Secretariat of the WHO FCTC has been requested to report back to the Ninth session of the Conference of the Parties (COP) to the WHO FCTC on appropriate classification of HTPs to support regulatory efforts and define new product categories.¹⁰ This decision also recognized HTPs as tobacco products under the WHO FCTC, but did not equate them with a single type of tobacco product, such as cigarettes or any other type of tobacco product.¹¹ It is reasonable to expect that some Parties to the Convention may use guidance from the COP in classifying HTPs under existing domestic tobacco control laws. For example, classification by the COP may affect application of tobacco control laws where different product categories are subject to different laws on tax or labelling.

Secondly, the World Customs Organization is facilitating revision of the Harmonized System Code to create new customs codes for novel nicotine and tobacco products, including HTPs and ENDS. Amendments to chapter 24 of the HS Code will create a new heading 24.04 for products intended for inhalation without combustion

9 Official Journal of the European Union, Directive 2014/40/EU, April 3, 2014, (https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf, accessed 3 August 2020)

10 FCTC/COP8(22), n (2)

11 *ibid*, para 3 (b)

and sub-headings for those containing tobacco (2404.11), such as HTPs, and those containing nicotine (2404.12), such as ENDS. Other nicotine products, such as nicotine replacement therapies, will also be included in chapter 24, but under separate sub-headings. Amendments to the HS Code will be reflected in domestic customs codes no later than January 2022.¹² This may affect application of domestic tobacco tax laws, such as where those laws define taxable goods and/or applicable rates by reference to customs codes.

In the context of ongoing classification processes, it is worth examining legal disputes that have arisen to date.

One example of a classification case is *New Zealand Ministry of Health v Philip Morris (New Zealand) Ltd.*¹³ This case concerned an enforcement action by the New Zealand government against Philip Morris concerning sale of 'Heets', to be used in an HTP device. Under the Smoke Free Environment Act (1990) it was prohibited to, among other things, import or sell any product labelled or otherwise described as suitable for chewing, or for any other oral use (other than smoking). The government alleged that Heets constituted a tobacco product for oral use other than smoking as it was not ignited but heated and that importation and sale were, therefore, prohibited. Philip Morris argued that oral use was intended to refer to chewing tobacco and similar products taken orally, and that 'Heets' did not fall within the scope of the definition (Rather than argue that the products were prepared for smoking, the company argued that they fell within a legislative gap). The Court agreed with Philip Morris, concluding that the legislative intent was to prohibit products used for chewing or similar activities. In February 2020, a bill was introduced to amend the Smoke Free Environment Act (1990) in order to bring the provisions of the Act up to date and ensure that all regulated products were covered within its ambit. A definition for heated tobacco products was included through the amendment: 'a smokeless tobacco product that has a device that uses or facilitates the use of heat to aerosolise nicotine from tobacco leaf directly'.¹⁴ The Amendment Bill received royal assent on 11 August, 2020.

In Israel, while the government was developing legislation to govern ENDS, a company applied for permission

“ This paper is intended to assist Member States to achieve a high level of health protection in the context of ENDS and HTPs through a discussion on the legal challenges arising globally.

to import and market an e-cigarette. The government rejected the request on grounds that the efficacy and safety of the product were not proven, and that import was thereby inconsistent with the Pharmacists Ordinance. This led to *E-Cig Ltd. v Ministry of Health*¹⁵, in which the decision was challenged on grounds that e-cigarettes are recreational products rather than pharmaceuticals. The court agreed, holding that there was no basis in the Ordinance for the decision to apply to e-cigarettes.

In December 2018, the Israeli legislature passed a new law governing both tobacco products and ENDS. JUUL Labs challenged provisions of the new legislation that stipulated restrictions on advertising of ENDS and application of tobacco plain packaging to ENDS. A similar challenge was brought by the Tel Aviv Chamber of Commerce (Chamber). The main argument advanced by the Chamber was that vaping products are less harmful than tobacco smoking products and should encourage regular smokers to switch to vaping. Accordingly, prohibitions and restrictions on the advertising of vaping products violate the freedom of occupation of the Members of the Chamber. JUUL Labs withdrew its petition days before the hearing, followed by a withdrawal by the Chamber.¹⁶

The ENDS classification disputes in India ended in December 2019 with the enactment of legislation to prohibit the production, manufacture, import, export, transportation, sale, distribution, advertisement, and promotion of electronic cigarettes.¹⁷ The law includes a broad definition of electronic cigarettes that includes

12 World Customs Organization, 'The new 2022 Edition of the Harmonized System has been accepted', January 8, 2020, (<http://www.wcoomd.org/en/media/newsroom/2020/january/the-new-2022-edition-of-the-harmonized-system-has-been-accepted.aspx>, accessed 4 August 2020)

13 District Court at Wellington, *Ministry of Health v Phillip Morris (New Zealand) Limited*, [2018] NZDC 4478, (https://www.tobaccocontrol.org/files/live/litigation/2632/NZ_New%20Zealand%20MOH%20v.%20PMI.pdf, accessed 27 June 2019)

14 New Zealand Legislation, Smoke free Environment and Regulated Products (Vaping) Amendment Bill: Section 2, (<http://legislation.govt.nz/bill/government/2020/0222/latest/LMS313857.html>, accessed 13 August 2020)

15 The Israel Supreme Court, *E-Cig Ltd. v Ministry of Health*, [2014] HCJ 6665/12, (https://www.tobaccocontrol.org/files/live/litigation/2217/IL_E-Cig%20Ltd.%20v.%20Ministry%20of%20Heal.pdf, accessed 27 June 2019)

16 The Israel Supreme Court, *Tel Aviv Chamber of Commerce v Israeli Knesset & Ors.*, [2019] HC 4657/19 and HC 1532/19, (https://www.tobaccocontrol.org/files/live/litigation/2711/IL_The%20Tel%20Aviv%20Chamber%20of%20Commer.pdf, accessed 15 May 2020)

17 Ministry of Law and Justice, No. 342 of 2019, (http://www.prsindia.org/sites/default/files/bill_files/Prohibition%20of%20Electronic%20Cigarettes%20Ordinance%2C%202019.pdf, accessed 17 July 2020)

ENDS, HTPs, and other similar devices.¹⁸ In the process of passing this legislation, India defended a few legal challenges concerning the classification of ENDS. At the beginning of the policy process, the Ministry of Health and Family Welfare issued an advisory which stipulated that ENDS and HTPs should not, among other things, be traded or advertised except where approved under the Drugs and Cosmetics Act 1940. This was challenged by an importer in *M/s Focus Brands v Directorate of Health Services and Ors.* The High Court of Delhi stayed operation of the advisory on the basis that these products do not fall within the definition of drugs under the Act of 1940.¹⁹ Following the advisory issued by the Ministry of Health and Family Welfare, 12 states in India undertook steps to ban the use of ENDS: Punjab & Haryana, Maharashtra, Karnataka, Kerala, Bihar, Uttar Pradesh, Jammu & Kashmir, Himachal Pradesh, Tamil Nadu, Puducherry, and Jharkhand.²⁰ Thereafter, in September 2019, the Central Government promulgated an ordinance.²¹ Two writ petitions were filed against the Ordinance claiming that it infringed the right of the user to choose a less harmful alternative (i.e. ENDS) to combustible cigarettes.²² The claims were dismissed on the ground that the Ordinance passed the scrutiny of both the Houses, to become an Act of Parliament. In the circumstances, nothing remained for adjudication in the writ petitions.²³

The Indian ENDS classification cases have similarities with a number of Indian cases concerning the smokeless tobacco products gutka, pan masala, and zarda. In this context, 23 states and 5 union territories have prohibited these products under the food law. A number of claims have challenged the classification of these products as food, leading to a series of pending claims before the Supreme Court of India in *Central Arecanut Co. & Ors. v Union of India*.²⁴ The Ministry of Health & Family Welfare brought to the notice of the Supreme Court that the manufacturers in order to circumvent the ban were selling pan masala (without tobacco) along with flavoured chewing tobacco in separate sachets. The central question is whether powers under India's food law extend to the separate packages of tobacco.

A similar question was raised in the context of ban on the sale of food flavourings in specialized tobacco shops in Finland, discussed in the flavour ban sub-section below.

Prior to the 2014 European Union Tobacco Products Directive (EU TPD), the Netherlands also faced challenges with respect to classification of ENDS. In 2007, the government provisionally classified ENDS as a medicine and issued a provisional enforcement policy that would permit importation without market authorization, but would not permit advertising or promotion. This provisional policy was first upheld in *X v The Netherlands*²⁵ where the court concluded that because nicotine had a stimulating and calming effect it could be classified as a medicine. Subsequently, a decision of the Minister of Health, Welfare and Sport to formally classify ENDS as medicines under the Medicines Act was challenged in *United Tobacco Vapor Group Inc. v The Netherlands*.²⁶ At first instance, the District Court of The Hague ruled against the government, finding that it should have first demonstrated the pharmacological effects of ENDS before classifying them as medicines under the Act. On appeal, The Hague Court of Appeal²⁷ also found against the government, concluding that ENDS do not constitute a medicine under the Medicines Act and that application of the Act in this way created obstacles to free movement of ENDS within the EU that were not proportionate to the protection of public health.

In Canada before the amendment of the Tobacco Act in 2018, which broadened its scope to include vaping products, Health Canada's authority to regulate electronic cigarettes as a 'scheduled drug' under the Food and Drugs Act was in question in *Zen Cigarette Inc. v Health Canada*.²⁸ It was contended by Health Canada that as Zen Cigarette's website claimed that electronic cigarettes may assist with tobacco cessation, it qualified as a drug under provisions of the Food and Drugs Act.²⁹ The Court held that the evidence established that Zen promoted electronic cigarettes for the treatment of nicotine addiction and thus qualified as a drug under Section 2(a) of the Act.

18 *ibid*, Section 3(d)

19 The High Court of Delhi, *M/s Focus Brands v Directorate of Health Services and Ors.* [2019] Writ Petition (Civil) 2688/2019, (http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=60136&yr=2019, accessed 3 May 2019)

20 Live Mint, '12 states ban e-cigarettes, health ministry urges all to follow', Neetu Chandra Sharma, March 13, 2019, (<https://www.livemint.com/news/india/12-states-ban-e-cigarettes-health-ministry-urges-all-to-follow-1552447122172.html>, accessed 2 September 2019)

21 Ministry of Law and Justice, No. 14 of 2019, (https://www.prsindia.org/sites/default/files/bill_files/Prohibition%20of%20Electronic%20Cigarettes%20Ordinance%2C%202019.pdf, accessed 17 July 2020)

22 The High Court of Calcutta, *Plume Vapour Private Ltd. & Anr. v Union of India & Ors. and M/s Woke Vapors Pvt. Ltd. v Union of India & Ors.*, [2019] A.S.T 40 and 41, (https://www.calcuttahirhighcourt.gov.in/Order-Judgment-PDF/A/AST_40_2019_26092019_O_239.pdf, accessed 3 October 2019)

23 *ibid*, (https://www.calcuttahirhighcourt.gov.in/Order-Judgment-PDF/A/AST_40_2019_12122019_O_239.pdf, accessed 15 May 2020)

24 The Supreme Court of India, *Central Arecanut Co. & Ors. v Union of India*, [2010] Transfer Case (Civil) No. 1, (https://www.tobaccocontrollaws.org/files/live/litigation/2620/IN_Central%20Arecanut%20Marketing%20Com.pdf, accessed 30 June 2019)

25 The District Court of Hague, *X [Company selling e-cigarettes] v The Netherlands*, [2008] Case No: KG 08-136, (https://www.tobaccocontrollaws.org/files/live/litigation/2126/NL_X%20%5BCompany%20selling%20e-cigarette.pdf, accessed 1 July 2019)

26 The District Court of Hague, *United Tobacco Vapor Group Inc. v The Netherlands*, [2012] Case No.: 414117-KG ZA 12-209, (https://www.tobaccocontrollaws.org/files/live/litigation/2128/NL_United%20Tobacco%20Vapor%20Group%20Inc.pdf, accessed 22 July 2019)

27 The Hague Court of Appeal, *The Netherlands v United Tobacco Vapor Group*, [2012] Case No.: 200.105.395-01, (https://www.tobaccocontrollaws.org/files/live/litigation/2130/NL_The%20Netherlands%20v.%20United%20Toba.pdf, accessed 21 July 2019)

28 2012 FC 1465

29 Section 2(a): the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;

In many respects, these classification cases are similar to the experience in the United States of America (US) with *Smoking Everywhere Inc. & Ors. v FDA*³⁰ and *Sottera, Inc. v FDA*³¹, in which the courts examined whether FDA's authority to regulate electronic cigarettes stemmed from the Federal Food, Drug and Cosmetic Act (FDCA) or the Family Smoking Prevention and Tobacco Control Act (Tobacco Act). Distributors of electronic cigarettes (plaintiffs before the District Court) argued that electronic cigarettes were a functional equivalent of traditional cigarettes and should be regulated under the Tobacco Act. On the other hand, FDA argued that the promotional materials of the electronic cigarettes suggested that e-cigarettes provided a 'healthier way' to obtain effects of nicotine and intended to alleviate nicotine withdrawal symptoms and should be regulated as a drug-device combination under the FDCA. It was held that e-cigarettes could not be brought under the scope of the FDCA merely because they delivered nicotine, doing so would dismantle the regulatory wall erected by Congress between tobacco products and drug-device combinations.

These cases were followed by a subsequent challenge to the deeming of e-cigarettes (Deeming Rule) as tobacco products in *Nicopure Labs LLC v FDA*.³² The short question in this case was whether the FDA exceeded its authority in applying the Deeming Rule to open-ended devices sold without any liquid and e-liquids that did not contain nicotine. The Court concluded that FDA acted within the scope of its statutory authority by regulating e-liquids as a 'component' of refillable electronic nicotine delivery systems. It was observed that given the proliferation of ENDS, subjecting these products to a premarket review would ensure that fewer harmful or addictive products entered the market.

The US cases also foreshadowed the situation in Israel where legal challenges arose in the context of administrative action to regulate ENDS as drugs, and then subsequently when ENDS are regulated as tobacco products. In this sense, the challenges pursue the common goal of delaying regulation and ensuring that ENDS fall through regulatory gaps between the legal regimes governing tobacco and drugs.

Prohibition and proportionality

Outside of the context where governments have made decisions concerning how to classify products under existing laws, a number of cases have arisen in which product prohibitions have been challenged. Typically, these challenges have included arguments that prohibition is not proportionate to the policy objective in light of the health risks posed by a specific product category.

For example, numerous challenges arose following implementation of the 2014 EU TPD. The EU TPD required EU Member States to impose requirements on e-cigarettes, including maximum nicotine limits, child-proof packaging, health warnings and a product registration system.³³ The validity of these aspects of the EU TPD were challenged in the United Kingdom by an e-cigarette manufacturer in *Pillbox v Secretary of State for Health*.³⁴ The company challenged these rules on a number of grounds under EU law, including with respect to proportionality and equal treatment. The company also invoked the European Charter of Fundamental Rights, arguing that the requirements impinged the right to conduct a business and the right to property with respect to intellectual property rights. The High Court of England and Wales referred the matter to the European Court of Justice (ECJ), which ultimately upheld the EU TPD.

In considering the question of equal treatment the ECJ highlighted that e-cigarettes have different characteristics to tobacco products, are used to consume nicotine and that their risks to human health are not clear.³⁵ Accordingly, they were viewed as being in a different situation to tobacco products, such that different treatment was justified. The ECJ did not engage in a detailed examination of the relative risks posed by the different product categories.

On the question of proportionality, the company had argued that e-cigarettes are less harmful to health than tobacco products and that in this context the regulations imposed were not proportionate. In examining the issue, the court stressed the high standard of proof, which required the company

30 United States District Court, *Smoking Everywhere Inc. v FDA*, [2010] 680 F.Supp. 2d 62 (Columbia), (https://www.tobaccocontrolaws.org/files/live/litigation/1493/US_Smoking%20Everywhere%20v.%20Food%20and.pdf, accessed 25 July 2019)

31 United States Court of Appeals, *Sottera, Inc. v FDA*, [2010] 627 F.3d 891 (Columbia), (https://www.tobaccocontrolaws.org/files/live/litigation/1032/US_Sottera%20v.%20Food%20%26%20Drug%20Adminis.pdf, accessed 27 June 2019)

32 United States District Court, *Nicopure Labs, LLC v Food and Drug Administration*, [2017] F.Supp.3d (Columbia), (https://www.tobaccocontrolaws.org/files/live/litigation/2558/US_Nicopure%20Labs%20LLC%20v.%20Food%20and.pdf, accessed 1 July 2019)

33 See, Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014, (https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf, accessed 27 July 2019)

34 Court of Justice of the European Union, *Pillbox 38 (UK) Ltd. v Secretary of State for Health*, [2016] Case C-477/14, (https://www.tobaccocontrolaws.org/files/live/litigation/2458/EU_Pillbox%2038%20%28UK%29%20Ltd.%20v.%20Secret.pdf, accessed 27 June 2019)

35 *ibid.*, para 41

to show that the requirements were manifestly inappropriate, emphasized that the EU legislature has a broad discretion and also relied on the precautionary principle.³⁶ In light of mixed evidence on the risks posed by e-cigarettes the ECJ held that application of the requirements was proportional and justified. Having found that the requirements were proportionate, the ECJ also rejected the arguments relating to freedom to conduct a business. Separately, the court concluded that intellectual property rights were not affected.

The requirements imposed on e-cigarettes under the EU TPD can be contrasted with snus, which EU Member States, with the exception of Sweden, are required to prohibit. This led the company Swedish Match to challenge the ban and also led to claims in Switzerland and Norway, which are not EU Member States.

In Case C-151/17 *Swedish Match*, challenged the EU TPD ban on snus despite the fact it had been found valid in an earlier case (C-210/03) concerning the 2001 EU TPD.³⁷ The 2017 challenge was presented in light of new evidence on the relative harmfulness of snus from Sweden and Norway, as well as the introduction of ENDS, such as e-cigarettes, and novel tobacco products into the EU.

Swedish Match argued that the prohibition on snus violates the principle of equal treatment, which requires that comparable situations must not be treated differently unless objectively justified. The company argued that this principle was violated because other smokeless products, cigarettes, ENDS and novel tobacco products are permitted on the market. The European Court of Justice (ECJ) rejected this argument, concluding that the:

- evidence suggests snus would be attractive to young people and has considerable potential for market expansion, thereby justifying different treatment from cigarettes and smokeless products;
- objective characteristics of ENDS differ from tobacco products, justifying different treatment; and
- effects of novel tobacco products on health could not be observed when the EU TPD was adopted, whereas the effects of snus had been scientifically substantiated.

“ Product prohibition challenges have typically included arguments that prohibition is not proportionate to the policy objective in light of the health risks posed by a specific product category.”

Swedish Match also argued that the obligation to prohibit snus is invalid as it violates the principle of proportionality. The ECJ rejected this argument, concluding that the prohibition was not manifestly inappropriate. The Court noted the relevance of the precautionary principle and based its conclusion partly on the risk that the attractiveness of snus to young people might create a gateway effect. Having rejected the argument concerning equal treatment, the court also rejected the argument that the different treatment of other products showed the prohibition on snus to be disproportionate.

In *GmbH v. Customs Inspectorate Basel*³⁸ similar arguments were made concerning a national level ban on snus in Switzerland, which has both ENDS and HTPs in its market. The Swiss courts were called upon to determine the constitutionality of an import ban implemented through an ordinance prohibiting tobacco products for oral use. The court considered the legislative basis for the Ordinance under the Foodstuff and Utility Articles Act and held that the Act only provided a basis to ban goods that endangered health in unexpected ways, whereas the health hazards of tobacco were well known. The court found that it need not consider arguments concerning proportionality or the public interest.

The Court also touched on the arguments concerning relative risk and stated that it was arbitrary and illegal (in the context of constitutionally guaranteed economic freedoms) to prohibit snus when more dangerous products like cigarettes were not prohibited. The Court reasoned that even in the European Union, the ban on snus did not apply to Sweden. Thus, it was unclear why a ban on snus would be required in Switzerland, for which EU law is not binding.

³⁶ *ibid*, para 51-55

³⁷ Court of Justice of the European Union (CJEU), *Swedish Match AB v Secretary of State for Health*, [2018] Case C-151/17, (<http://curia.europa.eu/juris/document/document.jsf?text=&docid=207969&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=16669669>, accessed 14 September 2020)

³⁸ Federal Court of Switzerland, *GmbH v Customs Inspectorate Basel*, [2019] 2C_718/2018, (https://www.bger.ch/ext/eurospider/live/de/php/aza/http/index.php?highlight_docid=aza%3A%2F%2Faza://27-05-2019-2C_718-2018&lang=de&zoom=&type=show_document, accessed 27 June 2019)

Finally, in *Swedish Match v The Ministry of Health & Care Services*³⁹ the company challenged the legality of tobacco plain packaging to snus in Norway. The Norwegian regulations on plain packaging apply to cigarettes, roll-your-own tobacco and snus. They do not apply to cigars or ENDS, even though the regulatory power exists for the Minister to extend plain packaging to those product categories. Plain packaging was also introduced simultaneously to the lifting of a prohibition on ENDS in order for Norway to implement provisions of the 2014 EU TPD (under Norway's European Free Trade Area commitments to the EU).

Swedish Match challenged the plain packaging regulation on grounds that it was not proportionate. The company argued that there was no factual basis for extending the regulations to snus as the evidence underpinning plain packaging was specific primarily to cigarettes. Norway relied on an expert report in arguing that snus was particularly attractive to youth and that rates of snus use were increasing among youth. Swedish Match also sought to compare snus to cigarettes, as a 'reduced harm' product, and ENDS, for which there is less evidence of relative risk.

In considering the proportionality argument, the Oslo County Court and then Court of Appeal both recognized that a margin of appreciation needs to be afforded to the state on questions of health. The courts focused primarily on the appropriateness of imposing plain packaging on snus, rather than on the relative treatment of ENDS. Nonetheless, the differential treatment of ENDS was considered justifiable by reference to the differences between the product categories and differences in the evidence base concerning youth use.

Viewing these cases together, it is apparent that courts applying EU law are reluctant to engage in arguments concerning the justification for treating product categories differently. Rather, they are inclined to focus more narrowly on whether the regulations in question are proportionate to the risks posed by the products in question and to afford a broad margin of appreciation to the EU parliament and regulators.

Some of these cases point to broader issues likely to arise in future challenges, including:

- a **the relative regulatory treatment of one product compared to other products and how this is justified;**
- b **questions of the relative harmfulness of different product categories; and**
- c **the potential for a challenge to the regulatory treatment of one product category to open up questions concerning regulation of all tobacco and nicotine products that may push governments towards adopting a 'continuum of risk' approach to regulation.**

This final point, concerning regulation based on a continuum of risk, is also borne out in a Mexican case in which a provision designed to prevent so-called brand-stretching was considered. In *Neri, José Armando Contreras v. Mexico*⁴⁰, the Federal Commission for the Protection against Sanitary Risks (Cofepris) imposed a fine on a merchant offering electronic cigarettes in a commercial establishment. The fine found its basis in the General Law on Tobacco Control, which prohibited, among other things, the sale of objects containing the brand elements of tobacco products or any design or symbol identifying the object with tobacco products. The merchant argued that this fine amounted to unequal treatment before the law because it was permissible to sell tobacco products. The court sought to balance the interests underpinning the right to health with the right to conduct a business and found against Cofepris, concluding that applying the tobacco control law in this way was excessive.

Flavour bans

In Finland, Section 24 of the Tobacco Act states that nicotine-containing liquids intended for use in electronic cigarettes, may only be sold or supplied to consumers if the liquid does not have characteristics or contain additives that are prohibited in tobacco products.⁴¹ Section 25 of the Act extends this requirement to nicotine-free liquids intended for vaporization as well. Municipalities in Finland prohibited the sale of flavouring liquids (including food flavourings) to be sold in vape shops. This prohibition has been challenged by owners of specialized vape shops as violative of the freedom of movement under Article 24 of the EU TPD and the principle of proportionality.⁴² The Administrative Court of Turku,

39 Oslo County Court, *Swedish Match v The Ministry of Health & Care Services*, [2017] Case No. 17-110415TVI-OBYF, (https://www.domstol.no/globalassets/upload/obyf/internett/aktuelt/kjennelser/17-110415tvi_swedish-match-ab.pdf, accessed 9 July 2018)

40 Supreme Court of Justice of the Nation (Mexico), *Neri, José Armando Contreras v Mexico*, [2015] Revision 513/2015, (https://www.tobaccocontrolaws.org/files/live/litigation/2642/MX_Neri%2C%20Jos%C3%A9%20Armando%20Contreras%20.pdf, accessed 27 June 2019)

41 The Finland Tobacco Act (No. 549/2016), (https://www.tobaccocontrolaws.org/files/live/Finland/Finland%20-%20Tobacco%20Act%20%28No.%20549_2016%29.pdf, accessed on 18 May 2020)

42 SKA Liquids: ITA Finland Administrative Court, 19/0482/1, [2019]; Striker Finland Oy: Decision of the Administrative Court of Turku, 19/0345/1, [2019]; and Salon Höjry Oy: Decision of the Administrative Court of Turku, 20/0056/1, [2020]

in *Salon Höyry Oy* held that permissibility of sale of liquid food flavour concentrates was to be assessed based on the conditions and context of supply of the products. In a specialty e-cigarette shop, liquid food flavour concentrates were suitable for vaporization in connection with the main product of the specialty shop as its flavour and the prohibition by the Construction and Environment Board of Salo was upheld. On the other hand, a similar prohibition stipulated by the City of Kotka Environmental Board was annulled by the Supreme Administrative Court on the ground that Finland's Ministry of Employment and Economy failed to notify the EU Commission with the final text of the Tobacco Act.⁴³ Section 25 of the Tobacco Act, which prohibits characterizing flavor or aroma for nicotine-free liquids intended for vaporisation is a technical regulation which had not been notified to the Commission in accordance with Article 5 (3) of the Technical Regulations Directive (2015/1535 / EU). Thus, it was held by the Supreme Administrative Court that section 25 of the Tobacco Act was not applicable to SKA Liquids Oy. However, the court did not rule on the question raised by the manufacturer, i.e. whether the prohibited liquids were intended for vaporization in e-cigarettes and whether the municipality had the right to issue the prohibition under the Tobacco Act.

During the EVALI (e-cigarette or vaping product use-associated lung injury) outbreak in the US, eight states: Massachusetts, Michigan, Montana, New York, Oregon, Rhode Island, Utah, and Washington, promulgated emergency regulations to ban the sale of flavoured e-cigarettes.⁴⁴ The emergency regulations in New York carved an exception for e-liquids that are tobacco flavoured, menthol, or flavourless, Massachusetts enacted a broader ban that applied to all nicotine-vaping products, and Rhode Island excluded tobacco flavoured and unflavoured vaping products.⁴⁵ The emergency regulations were challenged by a vapor association alleging that the Health Councils' in each of the States' overstepped their authority in enacting the emergency regulations.⁴⁶ On the exception for tobacco flavour and menthol in New York, it was observed by the Court that the emergency regulation carves out an exception without any evidence that these flavours have been eliminated from the list of substances shown to trigger the spate of pulmonary diseases in New York.⁴⁷ Accordingly, it was held that the emergency

“ The Court observed that the emergency regulations carved out an exception for tobacco flavour and menthol without any evidence that these flavours were eliminated from the list of substances shown to trigger the spate of pulmonary diseases in New York.

regulation in New York was a statement of public policy and not the product of biomedical research and an order for preliminary injunction was granted. On the other hand, the Superior Court of Rhode Island deferred to the Department of Health's assessment of the emergent nature of the 'vaping' crisis and the necessity to enact emergency regulations.⁴⁸

A precursor to the prohibition of flavoured ENDS can be observed in a dispute before the World Trade Organization (WTO) concerning the prohibition of flavoured cigarettes.

In *US – Clove Cigarettes*, Indonesia brought a claim before the WTO against the United States concerning a law that prohibits cigarettes containing a constituent that is a characterizing flavour of tobacco or tobacco smoke, other than menthol or tobacco.⁴⁹ Among other things, Indonesia argued that the:

- law is discriminatory because it treats clove cigarettes (primarily produced in Indonesia) less favourably than like menthol cigarettes (primarily of United States origin), in violation of Article 2.1 of the TBT Agreement; and
- prohibition is not necessary to achieve a legitimate objective, such as protection of human life or health, and that accordingly, the measure results in violation of Article 2.2 of the TBT Agreement.

43 Supreme Administrative Court, *SKA Liquids*, KHO: 2020:77, (<https://www.kho.fi/fi/index/paatokset/vuosikirjapaatokset/1592891459008.html>, accessed 3 November 2020)

44 See Campaign for Tobacco-Free Kids, States & Localities that have restricted the sale of flavoured tobacco products, May 8, 2020, (<https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>, accessed 21 May 2020)

45 Supreme Court of New York, *Matter of Vapor Tech. Assn. v Cuomo*, [2020] 118 N.Y.S. 3d 397; Superior Court of Rhode Island, *Vapor Tech Association v Raimondo*, [2019] C.A. No. PC-2019-10370; Superior Court of Massachusetts, *Vapor Tech Association v Baker*, [2019] WL 6050041

46 *ibid*

47 Supreme Court of New York, *Matter of Vapor Tech. Assn. v Cuomo*, [2020] 118 N.Y.S. 3d 402

48 Superior Court of Rhode Island, *Vapor Tech Association v Raimondo*, [2019] C.A. No. PC-2019-10370

49 World Trade Organization, *Request for the establishment of a panel by Indonesia-United States- Measures affecting the production and sale of clove cigarettes*, [2010] WT/DS406/1

With respect to non-discrimination, the United States argued that the measure is non-discriminatory and that the law draws a distinction between clove cigarettes and menthol cigarettes on health grounds (rather than based on the origin of the products). More specifically, the US argued that clove cigarettes are a niche product that is used disproportionately by youth, whereas menthol cigarettes are attractive to youth and adult smokers in similar proportions and are smoked by tens of millions of adults in the United States on a regular basis. The United States had also argued that a regulatory distinction was drawn between clove and menthol cigarettes because the extent of menthol consumption in the United States means that prohibiting menthol could create significant risks of illicit trade as well as problems for the United States health system (given the addictive character of nicotine).

The WTO panel found that the US law discriminated against cigarettes produced in Indonesia in favour of cigarettes produced in the US.⁵⁰ In upholding the Panel Report, the Appellate Body found that the law fell heaviest on imported products and was not based solely on a legitimate regulatory distinction between the two product classes. In the latter respect, the Appellate Body emphasized that clove and menthol each mask the harshness of tobacco and that clove and menthol cigarettes are each attractive to youth.⁵¹

The Panel also rejected Indonesia's argument that the prohibition of clove flavoured cigarettes was more trade restrictive than necessary under Article 2.2 of the TBT Agreement. This aspect of the Panel Report was not appealed and subsequent disputes, such as *Australia – Tobacco Plain Packaging*, tend to confirm the scope that WTO Members have for tobacco control under Article 2.2.

In this context, the Appellate Body's approach to non-discrimination, which asks whether different treatment of product categories is based on a legitimate regulatory distinction, embraces a continuum of risk approach to legal analysis. Put differently, WTO Panels may inquire deeply into the relative risks posed by different product categories. In this instance, that inquiry occurred in the context of a discrimination claim, but a similar approach could arise in the context of necessity analysis.

Following the outcome of *US - Clove Cigarettes*, the 2014 EU TPD required a prohibition on flavoured

cigarettes, including menthol. Poland challenged this aspect of the EU TPD arguing, among other things, that the prohibition violated principles of free movement of goods.⁵² The ECJ was therefore called upon to consider the proportionality of the measure. The Court first found that flavoured tobacco products share objective characteristics that make tobacco products more attractive, particularly in the context of initiation. The focus of the analysis then shifted to whether alternatives proposed by Poland were equally suitable. In this respect, the ECJ rejected the argument that stricter age limits, country-by-country bans on import of flavoured products, and specific health warnings were equally suitable and less restrictive measures. In some respects, this analysis is similar to application of the necessity test in the WTO Panel Report in *US - Clove Cigarettes*. In each instance, adjudicators did not find it difficult to justify flavour bans. It was only where they were partial in nature (the exemption for menthol in the US) that continuum of risk arguments gained traction.

Bans on flavours have also been challenged in other countries. The most prominent example of this, concerning a ban on flavours and additives is *Sinditabaco v ANVISA*.⁵³ In this claim, Sinditabaco challenged the authority of ANVISA, the Brazilian regulatory agency, to regulate flavours and additives. The claim delayed implementation of the regulation, but was ultimately unsuccessful. An English translation of the Supreme Court ruling is not available.

Similarly, in Germany a manufacturer sought permission to import and market a cigarette which contained a capsule filled with menthol flavouring in the cigarette filter.⁵⁴ The Office of Consumer Protection and Food Safety rejected this request on the ground that menthol would soften the unpleasant properties of tobacco smoke and thus lead to increased consumption. The manufacturer challenged this decision of the government agency and argued that the product was not a novelty but a further development of menthol cigarettes already being sold. The Court upheld the agency's decision. It was noted that there was information that the cigarette showed greater harmfulness or risk addiction compared to traditional cigarettes, and that the attractiveness of smoking this cigarette was significantly increased with the new capsule technology.

50 World Trade Organization, *Panel Report- United States- Measures affecting the production and sale of clove cigarettes*, [2011] WT/DS406/R

51 World Trade Organization, *Appellate Body Report- United States- Measures affecting the production and sale of clove cigarettes*, [2012] WT/DS406/AB/R

52 Court of Justice of the European Union (CJEU), *Republic of Poland v European Parliament & Council of the European Union*, [2016] Case C-358-14, (https://www.tobaccocontrol.org/files/live/litigation/2456/EU_Republic%20of%20Poland%20v.%20European.pdf, accessed 26 July 2019)

53 Federal Court of the Federal District (Brazil), *Sinditabaco v ANVISA*, [2012] Decision No. 323-B/2012, (https://www.tobaccocontrol.org/files/live/litigation/1098/BR_Sinditabaco%20v.%20ANVISA.pdf, accessed 25 July 2019)

54 Chamber of the Administrative Court (Germany), *Menthol Capsule Case*, [2012] File Number 5A 206/11, (https://www.tobaccocontrol.org/files/live/litigation/2267/DE_Menthol%20Capsule%20Case.pdf, accessed 25 July 2019)

2 Health claims and advertising, promotion, and sponsorship

Where a product category is in the marketplace, governments administer laws and regulations with respect to those products, including by undertaking enforcement actions. Such actions that have led to legal disputes include actions against companies to implement:

- a **laws concerning misleading conduct, including unsubstantiated claims and false claims of endorsement; and**
- b **restrictions on advertising and promotion.**

This second group of cases is distinct from those described above in the sense that the cases reflect administration of laws and rules governing the marketing of ENDS where the products are available in the market (whether legally or not).

“Where a product category is in the marketplace, governments administer laws and regulations with respect to those products, including by undertaking enforcement actions. Such actions have led to legal disputes.”

Misleading conduct and false claims

There is a substantial line of case law concerning misleading conduct and false claims with respect to cigarettes, particularly relating to use of misleading descriptors such as ‘light’ and ‘mild’. In many instances, these cases take their lead from action against major US tobacco companies under the Racketeering Influenced and Corrupt Organization (Act).⁵⁵

Parties to the WHO FCTC also have international legal obligations to prohibit misleading labelling on tobacco products (Article 11.1(a)) and misleading tobacco advertising, promotion and sponsorship (Article 13.4 (a)).

However, despite often being marketed with claims relating to their relative risk to health, or their potential as tobacco cessation devices, there appear to be only a few cases in which governments have challenged ENDS companies concerning misleading conduct.

A number of these cases come from Australia, where the Australian Consumer Law includes a general prohibition on misleading or deceptive conduct by companies, as well as specific prohibitions on misleading representations.⁵⁶ This law was previously used by the Australian Competition and Consumer Commission (ACCC) to extract legally enforceable undertakings by major tobacco companies not to use misleading descriptors with respect to cigarettes.⁵⁷

ENDS are in effect prohibited as nicotine is a proscribed poison in Australia and the ACCC has taken action against a number of companies for misleading conduct, but in the process sought to restrain the

55 United States v. Philip Morris USA Inc., 449 F. Supp. 2d 1 (D.D.C. 2006), aff’d in part & vacated in part 566 F.3d 1095 (D.C. Cir.2009) (per curiam), cert. denied, 561 U.S. ___, 130 S. Ct. 3501 (2010), pp 819 – 864.

56 Australia (Competition and Consumer Act 2010 (Cth), Schedule 2, s 18, (http://classic.austlii.edu.au/au/legis/cth/consol_act/caca2010265/sch2.html, accessed 29 July 2019)

57 See <https://www.accc.gov.au/media-release/accc-resolves-light-and-mild-cigarette-issue-with-bat-and-philip-morris>

“ **Despite often being marketed with claims relating to their relative risk to health, there appear to be only a few cases in which governments have challenged ENDS companies concerning misleading conduct.** ”

companies from selling ENDS. For example, in *ACCC v. The Joystick Company*⁵⁸, the ACCC alleged that the company in question had engaged in misleading or deceptive conduct by representing that e-cigarettes for sale by the company did not contain carcinogens, toxic substances or formaldehyde and for representing that flavours had received the approval of the ACCC. The company and its Director accepted the allegations and made an undertaking that it would not supply e-cigarettes for a period of three years. Similar outcomes were achieved in other cases.⁵⁹

Claims concerning misleading advertising have also been submitted to the United Kingdom (UK) Advertising Standards Authority (ASA), which administers codes of practice concerning how businesses should advertise in the UK. For example, an ASA adjudication on *Nicocigs Ltd.* concerned a website selling e-cigarettes that claimed ‘vapour’ from a particular product was completely harmless and that nicotine was mildly addictive, but harmless.⁶⁰ In the absence of any substantiation for the claims, ASA found them to be misleading under the Code and directed the company to ensure that the claims no longer appeared in their current form. In the ASA adjudication on *Ten Motives Ltd.*⁶¹, it was examined whether claims featured on a leaflet for electronic cigarettes, “healthier smoking alternative” and “you can still enjoy smoking without worrying about the effects on your health” were misleading. The advertisers had not provided any documentation from the Medicines and Healthcare Products Regulatory

Agency (MHRA) to support their claims and they were held to be misleading.

Given the claims with which ENDS are commonly marketed there are relatively few reported cases concerning misleading or false claims. This might be attributable to the absence of general consumer laws concerning misleading conduct, to domestic laws implementing the WHO FCTC provisions typically not applying to ENDS, or to a general enforcement challenge concerning the number of small-scale operations marketing ENDS, including online.

Restrictions on advertising, promotion and sponsorship

At the fifth session of the Conference of the Parties (COP) to the WHO FCTC, a request was made for WHO to examine evidence on the health impacts of ENDS and identify options for their prevention and control. The report prepared by WHO was considered at the sixth session of the COP to the WHO FCTC.⁶² It was recommended that in terms of ENDS advertising, promotion and sponsorship, an appropriate governmental body must be the regulator.⁶³ In the event this was not possible, an outright ban on ENDS advertising, promotion and sponsorship was encouraged rather than the implementation of a voluntary code on ENDS marketing.

58 Federal Court of Australia, *ACCC v. The Joystick Company*, [2017] FCA 397, (https://www.tobaccocontrollaws.org/files/live/litigation/2541/AU_Australian%20Competition%20and%20Con.pdf, (Accessed 5 May 2019)

59 *ACCC v. Social-Lites Pty Ltd.*, [2017] FCA 398, (https://www.tobaccocontrollaws.org/files/live/litigation/2542/AU_Australian%20Competition%20and%20Cn.pdf, accessed 15 July 2019) and *ACCC v Burden*, [2017] FCA 399, (https://www.tobaccocontrollaws.org/files/live/litigation/2542/AU_Australian%20Competition%20and%20Con.pdf, accessed 15 July 2019)

60 ASA Ruling on *Nicocigs Ltd.*, [2013] Complaint Ref: A12-207775, (https://www.tobaccocontrollaws.org/files/live/litigation/1396/GB_ASA%20Adjudication%20on%20Nicocigs%20L.pdf, accessed 27 June 2019)

61 ASA Adjudication on *Ten Motives Ltd.*, [2014] Complaint Ref: A13-250753, (https://www.tobaccocontrollaws.org/files/live/litigation/1714/GB_ASA%20Adjudication%20on%20Ten%20Motive.pdf, accessed 27 June 2019)

62 FCTC/COP/6/10 Rev.1 n (6)

63 *ibid*

It was recommended that advertising, promotion and sponsorship of ENDS and ENDS must, at the minimum:⁶⁴

- a. State clearly whether the product contains nicotine or may be used with nicotine solutions;
- b. Not make them appealing to or target, either explicitly or implicitly, non-smokers or non-nicotine users, and must therefore indicate that ENDS are not suitable for use by people who do not currently consume tobacco products;
- c. Not make them appealing to or target, either explicitly or implicitly, minors, including through the selection of media, location or the context in which they appear or through imagery that promotes sexual or sporting prowess;
- d. Never promote ENDS for non-smokers, and their use should not be portrayed as a desirable activity in its own right;
- e. Encourage smoking cessation and provide a quit line number if one exists;
- f. Contain nothing that could reasonably be expected to promote the use of tobacco products, such as:
 - i. the appearance or/and use of tobacco products;
 - ii. the use of any brand name, design, colour, emblem, trademark, logo or trade insignia or any other distinctive feature that might be associated by the audience with a tobacco product;
- g. not contain health or medicinal claims, unless the product is licensed for those purposes by the appropriate regulatory agency. Electronic cigarettes and other nicotine-containing products should be presented only as an alternative to tobacco, and should include warnings that dual use will not substantially reduce the dangers of smoking;
- h. not undermine any tobacco-control measure, including by not promoting the use of ENDS in places where smoking is banned;
- i. include factual information about product ingredients other than nicotine and in a way that does not distort evidence of risks;
- iii. the use of the words e-cigarette, electronic cigarette, or any other descriptor that might reasonably be expected to create confusion with the promotion of cigarettes and other combustible tobacco products;
- iv. showing ENDS products in ways that could reasonably be expected to promote tobacco products, including images of tobacco-like products;
- j. not link these products with gambling, alcohol, illicit drugs or with activities or locations in which using them would be unsafe or unwise.

In this respect, the UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code)⁶⁵ and the UK Code of Broadcast Advertising (BCAP Code)⁶⁶, incorporates several WHO recommendations and sets out a number of rules concerning marketing of e-cigarettes. The UK ASA has also been called upon to adjudicate a substantial number of complaints concerning the compliance of electronic cigarette advertising with the CAP and BCAP Code. Complaints have concerned whether advertising is irresponsible, targets children, indirectly promotes tobacco products, targets non-smokers or sexualizes electronic cigarettes. For example, a television

advertisement showed a man handing a woman an electronic cigarette, followed by on-screen text that stated "CHOICE", "FLAVOUR" and then "FREEDOM", and ended with the couple in vapour-like clouds.⁶⁷ In this adjudication, the ASA observed that even though it was clear that the product featured was an electronic cigarette, a strong association with traditional tobacco was created through the advertisement. It was held that the advertisement indirectly promoted the use of tobacco products and breached the CAP Code. In another television advertisement for KiK electronic cigarettes, a man claimed that he used to smoke normal cigarettes but after he quit, he tried electronic

⁶⁴ *ibid*

⁶⁵ See <https://www.asa.org.uk/uploads/assets/uploaded/11ef66e3-3638-4573-a867097d631c7c15.pdf>

⁶⁶ See <https://www.asa.org.uk/uploads/assets/846f25eb-f474-47c1-ab3ff571e3db5910/BCAP-Code-full.pdf>

⁶⁷ ASA Ruling on Mirage Cigarettes Ltd., [2015] Complaint Ref: A15-292291, (https://www.tobaccocontrollaws.org/files/live/litigation/2360/GB_ASA%20Adjudication%20on%20Mirage%20Cig.pdf, accessed 27 June 2019)

cigarettes and preferred them.⁶⁸ The question before the ASA was whether the advertisement breached the Code as it would encourage non-smokers and particularly former smokers to try electronic cigarettes. It was held that the advertisement was irresponsible and breached the BCAP Code. The company was directed not to encourage ex-smokers or non-nicotine users to use e-cigarettes.

Engagements on social media by Vype electronic cigarettes were also examined by the UK ASA.⁶⁹ Vype submitted before the ASA that the use of product-focused hashtags on Instagram, as well as broader hashtags, only allowed information about Vype to reach users actively seeking it or users seeking information around vaping in general. ASA observed that content on an Instagram page was not similar to content on a marketers' website, as there were mechanisms on social media to push content to consumers. In any case, the advertisements contained content that went beyond factual information about the product. BAT was directed not to publish marketing communications with the direct or indirect effect of promoting nicotine-containing e-cigarettes and their components which were not licensed as medicines.⁷⁰

The lawfulness of commercial communications on social media pages was examined by a court in Rome. The National Council of Consumers and Users (Association) filed a petition before the court for an injunction to revoke the advertising campaign promoted by two electronic cigarette manufacturers.⁷¹ The Association argued that Article 21 of the national decree (Legislative Decree No. 6 of 12 January 2016) prohibited all forms of advertising and/or sponsorship of electronic cigarettes. After a perusal of all the provisions of the national decree and the EU TPD, the court held that in view of the restrictive approach to the advertising of electronic cigarettes and liquid refill containers taken in the EU TPD, the argument of the manufacturers that commercial communications on its social media pages be excluded from the scope of information society services was untenable. With respect to user-generated content, it was held that though the e-cigarette manufacturers could not

be held responsible for it, they could not republish or promote through links such posts or images on their own social media channels. Accordingly, the manufacturers were directed to cease all commercial communications aimed at promoting the sale of electronic cigarettes and refill cartridges and remove all unlawful content from their websites and social media pages.

To circumvent Spain's advertising law, Philip Morris argued that advertisement of its heat-not-burn device, IQOS was not prohibited as it was not a tobacco product. A lawsuit was filed against Philip Morris alleging that it illegally advertised IQOS along with 'Heets'.⁷² The Court directed Philip Morris to cease its campaigning of these products. It was held that in the field of tobacco, if the purpose or effect of the communication was direct or indirect promotion of a tobacco product, then it was violative of the law. The isolated advertising of the IQOS device had no other purpose than the use of tobacco and would be caught within the ambit of the national legislation (Law 28/2005).⁷³

The consumer authority in Colombia also examined whether prohibition on promotion of tobacco products applied to the Philip Morris product IQOS.⁷⁴ The Directorate of Consumer Protection Investigations under the Superintendence of Industry and Commerce initiated an investigation concerning marketing of IQOS after a complaint was received that a picnic festival in 2017 was sponsored by IQOS. Philip Morris Colombia was directed to share information about advertising and marketing plans of IQOS in Colombia. The Ministry of Health and Social Protection submitted that the IQOS devices irrespective of the power source are covered by tobacco control legislation of the country. Further, the Ministry had demanded compliance with labelling and packaging requirements for *Heets*, but not the IQOS device. It was observed by the Directorate that in spite of the authority to investigate infractions of the tobacco law (No. 1335 of 2009) and apply sanctions, the prohibition with respect to advertising, promotion and sponsorship do not apply to the IQOS device, as it is not a tobacco product or a derivative.

68 ASA Adjudication on Vape Nation Ltd., [2014] Complaint Ref: A14-284845, (https://www.tobaccocontrollaws.org/files/live/litigation/2167/GB_ASA%20Adjudication%20on%20Vape%20Natio.pdf, accessed 27 June 2019)

69 ASA Ruling on British American Tobacco UK Ltd., [2019], (https://www.tobaccocontrollaws.org/files/live/litigation/2710/GB_ASA%20Ruling%20on%20British%20American.pdf, accessed 27 January 2020)

70 *ibid*

71 Court of Rome, Civil action n. 57714/2019, XVII Civil Division, (https://www.tobaccocontrollaws.org/files/live/litigation/2706/IT_National%20Council%20of%20Consumers%20.pdf, accessed 27 January 2020)

72 Commercial Court of Madrid, *Altadis v. Philip Morris*, [2018] Roj: SJM M 1157/2019 - ECLI: ES:JMM:2019:1157

73 Spain] Law 28/2005]Health measures regarding smoking and its sales regulation, supply, use and advertising of tobacco products, (https://www.tobaccocontrollaws.org/files/live/Spain/Spain%20-%20Law%2028_2005.pdf, accessed 18 December 2019)

74 The Directorate of Consumer Protection Investigations of the Superintendence of Industry and Commerce (Colombia), *Dir. of SIC v Coltabaco S.A.S et al.*, [2019] No. 17-82520-58-0, (<https://www.tobaccocontrollaws.org/litigation/decisions/co-20191227-sic-decision-on-iqos-marketing>, accessed 8 July 2020)

Conclusion

The analysis above highlights a number of important observations in the context of regulating novel and emerging nicotine and tobacco products, including:

- 1** **ENDS and HTP manufacturers attempt to avoid products being regulated so as to 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 must be**

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 of the national legislation of the country;**
- 5** **there are relatively few cases addressing misleading marketing of ENDS, 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 an HTP device also constitutes advertising of a tobacco product.**

Without doubt, other lessons might also be drawn from the broader body of case law concerning tobacco control. For example, cases challenging application of packaging and labelling measures or advertising restrictions to other tobacco products will also be relevant to application of the same or similar measures to ENDS or HTPs. In this respect, the conclusions above are drawn from a sub-set of over 1000 judicial

decisions and are focused narrowly on contemporary issues in product regulation. The present paper is relevant for countries to analyze the arguments presented, and conclusions drawn in different jurisdictions in the attempt to assist regulation of novel and emerging nicotine and tobacco products in line with country-specific public health goals.



World Health
Organization

