Tobacco control regulations: Combating the world´s leading preventable cause of death

Tobacco remains the leading preventable cause of death in the world today and accounts for around 12% of all adult deaths worldwide (more than 7 million people)[1]. Its effects are far-reaching and has implications along the supply chain: from the land used to grow tobacco instead of food, often in countries where food security is a concern, to the 63% of children of tobacco-growing families involved in child labour, to the environmental effects of smoke expelled into the air, the bystander and the smoker´s health[2]. This howtoregulate article focuses on tobacco control regulation and regulation for the emerging tobacco alternative electronic cigarettes.

I. International and supranational regulatory framework

A. World Health Organisation (WHO)

1. The World Health Organisation Framework Convention on Tobacco Control (FCTC) is a treaty to address the health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke worldwide. The treaty is evidence-based and reaffirms the right of all people to the highest standard of health. The FCTC provides a framework for tobacco control measures to be implemented by its Parties at the national, regional and international levels. The treaty also provides for international cooperation to support tobacco controls, including scientific, technical and legal cooperation and information sharing. The FCTC entered into force in February 2005 and as of July 2017 there are 181 Parties.

2. The FCTC obliges Parties to implement demand reduction strategies as well as address supply issues. The core demand reduction provision of the FCTC are contained in Articles 6-14 and include price and tax measures to reduce the demand for tobacco, and non-price measures, such as:

- **Protection from exposure to tobacco smoke**;
- Regulation of the **contents of tobacco products**;
- Regulation of **tobacco product disclosures**;
- **Packaging and labelling** of tobacco products;
- **Education, communication, training and public awareness**;
- Tobacco **advertising, promotion and sponsorship**; and
- Demand reduction measures concerning tobacco dependence and cessation.

The core supply reduction provisions of the FCTC are contained in Articles 15-17:

- **Illicit trade** in tobacco products;
- **Sales to and by minors**; and
- Provision of support for economically viable alternative activities.

The treaty also includes liability provisions at Article 19 encouraging Parties to consider legislative action to deal with criminal and civil liability, including compensation. Mechanisms for scientific and technical cooperation and exchange of information are set out in Articles 20-22.

3. An important feature of the FCTC is cooperation in the development of proposed measures, procedures and guidelines for the implementation of the treaty, which the Conference of the Parties (COP) have adopted in the form of guidelines for implementation of key treaty provisions. There are currently eight adopted guidelines covering the following Articles of the FCTC:

- Article 5.3: Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry[3];
- Article 6: Price and tax measures to reduce the demand for tobacco[4];
- Article 8: Protection from exposure to tobacco smoke[5];
- Articles 9 and 10: Regulation of the contents of tobacco products and regulation of tobacco product disclosures[6];
- Article 11: Packaging and labelling of tobacco products[7];
- Article 12: Education, communication, training and public awareness[8];
- Article 13: Tobacco advertising, promotion and sponsorship[9]; and
- Article 14: Demand reduction measures concerning tobacco dependence and cessation[10].

The COP also has policy options and recommendations for implementation of Articles 17 and 18 concerning economically sustainable alternatives to tobacco growing[11].

4. Currently, there are no adopted guidelines for Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), colloquially known as electronic cigarettes (e-cigarettes). E-cigarettes are battery operated devices that heat a liquid (called 'e-liquid') to produce a vapour that users inhale. Although the composition of this liquid varies, it typically contains a range of chemicals, including solvents and flavouring agents, and may or may not contain nicotine. E-cigarettes have evolved as a product group since first entering the market, with products now ranging from early 'first generation' devices that resemble cigarettes, to second and third generation devices that enable users to modify characteristics of the device, such as adjusting the voltage[12].

5. The WHO report concerning ENDS/ENNDS states that scientific evidence on which inferences could be drawn about regulating ENDS/ENNDS is not yet equal to the body of evidence about tobacco products on which the FCTC and the adopted guidelines are based[13]. The WHO ENDS/ENNDS report notes also that:

> *If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement. This would only be the case if the recruitment of minors and non-smokers into the nicotine-dependent population is no higher than it is for smoking, and eventually decreases to zero. Whether ENDS/ENNDS can do this job is still a subject of debate between those who want their use to be swiftly encouraged and endorsed on the basis of available evidence, and others who urge caution given the existing scientific uncertainties as well as the performance variability of products and the diversity of user behaviour.*

The COP 6 invited Parties to consider applying a range of regulatory measures for ENDS/ENNDS with the following objectives:

- **Prevent the initiation of ENDS/ENNDS by non-smokers and youth** with special attention to vulnerable groups. Although the debate about whether the use of ENDS/ENNDS is a gateway to smoking is unresolved, preventing this eventuality requires making the initiation and persistence of smoking as difficult as possible.
- **Minimise as far as possible potential health risks to ENDS/ENNDS users** and protect non-users from **exposure to their emissions**.
- **Prevention of unproven health claims** being made about ENDS/ENNDS.
- **Protect tobacco control activities from all commercial and other vested interests** related to ENDS/ENNDS, including interests of the tobacco industry.

The WHO ENDS/ENNDS report outlined a number of useful regulatory measures, which have been reproduced at the end of this article for ease of reference. This howtoregulate article will give examples of national reference regulation for ENDS/ENNDS, as well as those jurisdictions that have opted to ban the importation, sale and distribution of ENDS/ENNDS.

6. Connected to the FCTC is the Protocol to Eliminate Illicit Trade in Tobacco Products, which aims to eliminate all forms of illicit trade in tobacco products. It provides tools for preventing illicit trade by securing the supply chain, including by establishing an international tracking and tracing system, by countering illicit trade through dissuasive law enforcement measures and a suite of measures to enable international cooperation. The Protocol was adopted on 12 November 2012 and it requires 6 more parties before it enters into force.

B. European Union (EU)

7. The EU is a Party to the FCTC and implements its obligations therein through the Tobacco Products Directive (the Directive). The Directive aims to improve the functioning of the EU internal market for tobacco and related products, while ensuring a high level of health protection for European citizens. The Directive regulates the manufacture, presentation and sale of tobacco and related products, such as: cigarettes, roll-your-own tobacco, pipe tobacco, cigars, cigarillos, smokeless tobacco, e-cigarettes, and herbal products for smoking. The Directive regulates the

following:

- characterising flavours: prohibited in cigarettes and roll-your-own tobacco.
- the ingredients used in tobacco products: EU countries to receive ingredient reports.
- packaging:
  - combined (picture, text and information on how to stop) health warnings must cover 65% of the front and back of cigarette and roll-your-own tobacco packages;
  - minimum dimensions for warnings and prohibits small packages for certain tobacco products; and
  - bans promotional and misleading elements on tobacco products, e-cigarettes and herbal products for smoking .
- illicit trade of tobacco products: EU-wide tracking and tracing.
- internet sales: allows EU countries to prohibit internet sales of tobacco and related products.
- E-cigarettes (WHO uses ENDS/ENNDS): sets out safety, quality and notification requirements.
- novel tobacco products: before placement on the market manufacturers and importers are obliged to notify EU countries.

8. Article 20 of the Tobacco Products Directive (2014/40/EU) concerns the rules for e-cigarettes sold as consumer products in the EU. However, where therapeutic claims are made or products contain over 20 mg/ml of nicotine, such products will require medicine authorisation under Directive 2001/83/EC. The Directive lays down the following rules for e-cigarettes:

- safety and quality requirements around maximum nicotine concentration and volume for cartridges, child-resistant and tamper evident, ingredients must be high purity and should deliver the same amount of nicotine when puffed at the same strength and duration;
- manufacturers and importers must notify all products they place on the EU market through a standardised electronic format;
- packaging and labelling rules advising consumers of the nicotine contents and should not be used by non-smokers are mandatory, a list of ingredients contained in the product, and information about the product´s nicotine, and a leaflet with instructions for use and information on adverse effects, addictiveness and toxicity;
- promotional elements are not allowed on packaging, and cross-border advertising and promotion of e-cigarettes is prohibited; and
- monitoring and reporting requirements for manufacturers and importers, EU countries and the Commission.

II. National regulations

Using the FCTC and its associated guidelines national reference regulations will be presented to highlight some best practices from jurisdictions that have implemented tobacco control measures.

A. **Protection** of public tobacco control health policies **from vested interests against control**

1. This regulatory guideline of the FCTC recognises the “need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts”[14]. The World Health Assembly has also warned states that “the tobacco industry has operated for years with the express intention of subverting the role of governments and of WHO in implementing public health policies to combat the tobacco epidemic”[15].

2. Gabon´s tobacco control law Loi 006-2013 (mesures en faveur de la lutte antitabac) contains a good example of a stand alone provision for the protection of its tobacco control policies in Chapter 7 Measures to Protect Tobacco Control Policies from Business Interests and Other Interests:

> *Article 33*
> *The State's relations with the tobacco industry must be guided by the following principles:*
> - ***tobacco products are lethal****;*

- *any report by the State and / or its representatives to the tobacco industry and to those who promote its interests* ***must be transparent and justified****; and*
- *the tobacco industry, and with those who promote its interests,* ***must act responsibly and transparently****.*

Article 34
Any direct or indirect partnership, any agreement that is impossible to apply or of an obligatory nature concluded with the tobacco industry and with those promoting its interests, is null and void.
Article 35
No public subsidy or incentive may be granted or granted for the cultivation, production or processing of tobacco or tobacco products.

3. The Philippines Civil Service Commission promotes its Joint Memorandum Circular on "Protection of the Bureaucracy Against Tobacco Industry Interference" national, regional and local government levels and contains an online form to complain about violations.

4. National lobbying regulations can serve as a useful measure of transparency as to the activities of lobbyists connected with the tobacco industry. According to a report developed by Transparency International, Access Info Europe, Sunlight Foundation and Open Knowledge 20 countries worldwide had specific lobbying regulations[16]. Chile´s lobbying law Regula El Lobby Y Las Gestiones Que Representen Intereses Particulares Ante Las Autoridades Y Funcionarios establishes a public register (http://www.infolobby.cl) where authorities **must disclose information on meetings and individuals/lobbyists who attended those meetings**. The subjects of disclosure are arranged by active (paid lobbyists and unpaid interest managers) and passive (ministers, vice ministers, heads of departments, regional directors of public service, mayors and governors, regional ministerial secretaries and ambassadors, and other public individuals and entities). **Canada and the UK have also established public online registries of all lobbying** activities, and Canada has a useful Lobbyists´Code of Conduct[17]. In our howtoregulate article Countering unfair lobbying we list some recommendations that might help officials to defend the common interest against disproportionate lobbying.

B. **Price and tax measures** to reduce the demand for tobacco

5. The WHO recommends that tobacco excise taxes account for at least 70% of the retail prices for tobacco products[18]. **Australia will increase the excise on tobacco products by 12.5% each year** from 2017 until 2020, at which point it will make up 69% of the price of a pack of cigarettes (AU$45)[19]. Some of the additional revenue generated by this excise increase will be used to increase policing against illegal importation of tobacco products and fund legal proceedings to defend Australia´s plain packaging laws[20].

6. While Australia has opted to regulate tobacco excise increases slowly each year, the **Philippines** adopted Republic Act No. 10351 "the Sin Tax Reform Law" in 2012 **to simplify the excise tax structure of "sin products" such as tobacco, which increased by up to 820%**[21]. The revenue from the "sin tax" will fund the universal health care programme and fund programmes to encourage alternative production and livelihoods for tobacco farmers[22].

C. **Protection from exposure** to tobacco smoke

7. The FCTC guidelines for implementation of Article 8 Protection from exposure to tobacco smoke contains principles on which regulation should be based and definitions that should be clear. The Bermuda Tobacco Control Act 2015 provides a good example of a simple approach to protection from exposure to tobacco smoke in 3 short sections. Part 2 of Bermuda´s Tobacco Control Act 2015 provides:

Prohibition on smoking in certain areas
3 (1) ***No person shall smoke a cigarette product or tobacco product in any enclosed public place, enclosed workplace or public conveyance, including but not limited to any place listed in Schedule 1*** *Part 1.*

(2) No person shall smoke a cigarette product or tobacco product on the parts of buildings and land ancillary to the places listed in Schedule 1 Part 2.
Offence and penalty under Part 2
4 Any person who contravenes section 3 commits an offence and is liable on summary conviction to a fine of $1,000.

8. New Zealand´s Smoke-free Environments Act 1990 Part 1 Smoke-free workplaces and public areas provides a **more detailed treatment for protection from exposure to tobacco smoke, particularly around workplaces where children frequent**. The purpose of this detailed treatment by New Zealand is to:

prevent the detrimental effect of other people's smoking on the health of people in workplaces, or in certain public enclosed areas, who do not smoke or do not wish to smoke there; and to prevent young people who are being taught or cared for in registered schools or early childhood education and care centres from being influenced by seeing other people smoke there; and to prevent the detrimental effect of other people's smoking on the health of young people who are being taught or cared for in registered schools or early childhood education and care centres.

New Zealand´s legislation provides for the appointment of enforcement officers and their powers (Section 14) and contains a mechanism for complaints of contravention of any provision of Part 1 to the Director-General of Health (Section 15-16). Fines are imposed for contraventions of Part 1 ranging from NZ$400 for an individual up to NZ$4,000 for a body corporate (Section 17A).

9. All states in Australia, except for one, have implemented **legislation to protect children from tobacco smoke in cars by empowering police officers and/or tobacco control officers to issue a range of on the spot fines** starting from AU$75 to AU$250. The South Australian Tobacco Products Regulation Act 1997 provides at Section 48:

48—Smoking in motor vehicle if child present
(1) A person must not smoke in a motor vehicle if a child is also present in the motor vehicle. Maximum penalty: $200. Expiation fee: $75.
(2) In proceedings for an offence against this section an allegation in the complaint that a child was present in a motor vehicle at a specified time will be accepted as proved in the absence of proof to the contrary.
(3) In this section—
child means a person under 16 years of age;
motor vehicle has the same meaning as in the Motor Vehicles Act 1959.

D. Regulation of the **contents of tobacco products and tobacco product disclosures**

10. The objective of the FCTC guideline for regulation of the contents and tobacco product disclosures is to contribute to reducing tobacco-attributable disease and premature death by reducing the attractiveness of tobaccos products, reducing their addictiveness (or dependence liability) or reducing their overall toxicity. Given the significant public health implications of smoking tobacco a strict regulatory regime and enforcement is required to be effective.

11. The first country to implement a nationwide cigarette safety standard was Canada in 2005. It´s Tobacco Reporting Regulations requires tobacco manufacturers and importers to provide Health Canada with annual reports which include their sales data, manufacturing information, tobacco product ingredients, toxic constituents, toxic emissions, research activities and promotional activities (Sections 6-13). **Canadian manufacturers and importers must provide Health Canada with information about their tobacco products and, where applicable, their emissions** (Part 3). In addition to information on sales, ingredients, manufacturing procedures, promotional activities and research activities, they must report on over 20 constituents and 40 emissions. Every fiscal year Health Canada releases an Annual Report on Compliance and Enforcement Activities (Tobacco Control), which provides information about:

- the number of tobacco samples collected and analysed for compliance with ingredients and additives regulations, and the percentage of non-compliance found;
- the number of tobacco retailers inspected for compliance with the regulations, and the most

frequently found infraction type; and
- the number of reports analysed from tobacco manufacturers and importers for completeness of information provided in line with the reporting regulations, and number of letters of deficiency sent for missing information.

This Annual Report on Compliance also includes litigation, and interestingly Canada´s tobacco control legislation has been challenged by members of the tobacco industry for most of the period since 1988, it lists the current cases before the courts. This underscores the importance of a strict tobacco control regime.

12. **Brazil regulates the maximum allowable limits for tar, nicotine and carbon monoxide inhaled in the primary stream or main smoke** (Article 4 of Resolução da Diretoria Colegiada-RDC No.14 2012 in Portuguese). Brazil has also prohibited the use of most additives (as listed in Chapter 4 of the RDC 14/2012) in all tobacco products as a way to reduce the attractiveness of tobacco products, with a view to reducing the initiation of new smokers.

13. The **US bans cigarettes containing certain characterising flavours** through its Family Smoking Prevention and Tobacco Control Act to reduce the number of children who want to smoke due to the attractiveness of flavoured cigarettes. Section 907 of the Act provides that:

> *Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.*[23]

The **US also plans to begin a public dialogue about lowering nicotine levels** in combustible cigarettes to non-addictive levels through achievable product standards[24].

14. In **South Korea cigarettes must pass a Test for Certificate of Fire-Prevention Performance before being placed on the market** according to the recently amended Tobacco Business Act (amended by Presidential Decree No. 26659 No 2015). The test measures the function of the cigarette to extinguish by itself before it is burnt out, if it is left alone without being smoked after being lighted (Article 4.2).

E. **Packaging and labelling** of tobacco products

15. On 1 December 2012 Australia became the first jurisdiction in the world to i**ntroduce plain packaging for all tobacco products sold, offered for sale, or otherwise supplied in Australia**. The objectives of tobacco plain packaging as set out in the Tobacco Plain Packaging Act 2011 are to improve public health by discouraging people from using tobacco products, encouraging people to give up using tobacco products, discouraging relapse of tobacco use and reducing exposure to tobacco smoke. Tobacco plain packaging contributes to these objectives by **regulating the retail packaging and appearance of tobacco products** in order to:

- **reduce the appeal** of tobacco products to consumers;
- increase the **effectiveness of health warnings**; and
- **reduce the ability of the retail packaging of tobacco products to mislead consumers** about the harmful effects of smoking or using tobacco products.

16. Chapter 2, Part 2, Division 1 contains very precise requirements for retail packaging of tobacco products covering inter alia:

- physical features of retail packaging (Section 18), including the dimensions of the pack, the cardboard used, the lining used etc.,
- colour and finish (Section 19), must have a matt finish, be one colour (not applicable to the health warnings or the text concerning the brand,
- prohibition on trade marks and marks generally appearing on the retail packaging (Section

20),
- wrappers (Section 22) must be transparent, and
- retail packaging not to produce noise or scent (Section 24).

The Tobacco Plain Packaging Regulations 2011 provides that the packaging must be the colour known as Pantone 448C (Section 2.2.1). Pantone 448C can be described as `drab dark brown´, and was selected after market research determined it was the least attractive colour[25]. Britain, Ireland and France also have regulations for plain packaging for tobaccos products using this same colour, and Singapore[26] intends to implement similar regulations soon.

F. **Education, communication, training and public awareness**

17. The WHO best practice in education, communication, training and public awareness campaigns should include better research around audiences, pre-testing of messages used and messages tailored for particular groups, particularly high risk groups such as children, indigenous groups and the poor. In this section of the howtoregulate article we provide examples of how education, communication, training and public awareness has been used with good results.

18. Hungary´s approach to tobacco control education and communication programmes primarily targeted young people and adults to prevent smoking and help quit: Available in English at: http://www.dohanyzasvisszaszoritasa.hu/eng/megelozes_es_leszokas_segites.html. The Hungarian strategy includes a smoking prevention programme in kindergartens with **the aim of influencing children´s attitudes towards the negative effects of smoking, which in turn influenced smoking parents to begin the smoking cessation journey**. The programme has been introduced in more than 1600 kindergartens and the results of evaluation have been good[27]. It also includes an interactive computer game for 5 to 10 years old kids.

19. South Korea has developed “web dramas” (a series of scripted videos featuring famous K-pop singers). An example of a web drama and the story lines used can be found here. Korea reports that youth smoking rate has been the lowest in 10 years following these targeted web dramas that appeal to young people[28].

20. Turkey is a good example of a country that after signing the FCTC in 2005 and implementing the legislative reforms required to meet its obligations in the treaty, experienced a dramatic decrease in smoking prevalence[29]. The whole-of-government education, communication, training and public awareness strategy was focused on children and young people. The Ministry of Health, together with a Turkish youth NGO organised several events across the country on WHO World No-Tobacco Day and created a Tobacco Free Youth Week[30]. Through the use of participatory training sessions and social media communications targeting 15-25 year olds, the goal of the campaign was to help young people learn for themselves the effects and impact of smoking on their lives and to adopt healthy behaviours. The campaign also worked in tandem with the Ministry of Health´s smoking cessation campaign, which targeted 13,500 young people through the wide use of communication tools and anti-tobacco mass media campaigns.

G. Tobacco **advertising, promotion and sponsorship**

21. Togo´s Decree No. 2012-72/PR Concerning the prohibition of advertising, promotion and sponsorship of tobacco and its derivative products in Togo is a good example of a simple stand-alone legislation. Article 2 defines advertising, promotion and sponsorship broadly to include the usual types of activities such as commercial communications, direct and indirect sponsorship of any event (theatre, sports, includes films too) and any form of cross-border advertising. In terms of promotional activities Article 8 also **prohibits sponsorship for tobacco and its derivatives**:
- in certain premises such as cafes, clubs or places of entertainment, in exchange for the construction or **renovation of the premises to promote tobacco products, or the use or awnings or umbrellas**; and
- any other kind of contribution, regardless of whether the financial support is or is not publicised.

22. Singapore´s Tobacco (Control of Advertisements and Sale) Act is more detailed and generally all advertising of tobacco products is banned, even **the list of prices is regulated by a prescribed description** [Section 3(1A)]. **"Advertisement" is defined broadly and includes any kind of transmission for aural or visual reception, which encompasses the internet**. Therefore, advertising via internet communications is prohibited. "Published electronically" is defined to include any internet advertisement that originates in Singapore, or that originates elsewhere but is published by a "Singapore-connected person" and is accessible by people in Singapore. Singapore also prohibits all loyalty programmes "under which a gift or other benefit may be obtained by a purchaser of tobacco products on the basis of the amount or type of those products purchased, whether or not the programme extends to the purchase of other goods or services"[31]. The enforcement officers have broad powers also to enter premises and seize advertisements, products, vending machines and documents (Section 26).

H. **Supply and demand** measures

23. The EU is the leading authority for traceability of cigarettes regulation, noting its desire to prevent the movement of cheaper-priced cigarettes to jurisdictions that have higher-priced cigarettes due to different excise regimes or other public health reasons. Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU (TPD) provide for **EU-wide systems of traceability and security features for tobacco products to address the issue of illicit trade**. Under the EU traceability system:

- All unit **packets of tobacco products will be required to be marked with a unique identifier**;
- Relevant economic operators involved in tobacco trade will be required to **record the movements of these packets throughout the supply chain** and transmit the related information to an independent provider (data storage contracts to be approved by the Commission); and
- The **data will then be made accessible to the authorities of EU countries** and to the Commission for enforcement purposes.

This enables the movement of legal tobacco products to be tracked and traced by public authorities to determine when a product was diverted into the illicit market. Although the implementing and delegated acts to lay down the technical details necessary for the systems of traceability and security features for tobacco products to become fully operation has not yet been approved by the European Parliament and Council, it expected to be adopted soon. The Commission Implementing Regulation on traceability for tobacco products sets out the process for generating and issuing unique identifiers, the period of validity, how packets are to be marked and identifier codes for economic operators, facilities and machines.

24. The tobacco industry also has an obvious interest in combating the illicit trade of tobacco products and has established a Digital Coding and Tracking Association, which aims to provide all stakeholders with the tools, information and capacity needed to really tackle illicit trade. The Association states there is no "silver bullet" or one technology system alone that can completely tackle smuggling, counterfeiting or tax evasion[32]. Nevertheless, the Association does advocate its members to use product tracking and tracing, authentication and digital volume verification technologies.

25. Effective tobacco control must also look at measures to prevent people from taking up smoking and noting that many current smokers started smoking before they were 19 years old, supply to minors should be a regulatory focus. Most of the Parties to the FCTC prohibit sales of tobacco products by minors and some even prohibit tobacco sales by minors. Singapore passed a law in November 2017 increasing the **legal minimum age of 18 to purchase tobacco products** in the Tobacco (Control of Advertisements and Sale) (Amendment) Bill. Starting 1 January 2019 the new legal minimum age to purchase tobacco products in **Singapore will be 19, which will subsequently be raised one year at a time until it is set at 21 in 2021**. The Australian state of Tasmania is also considering increasing the minimum legal age in Tasmania from 18 to 21. The UK Children and Families Act 2014 makes it an offence for an adult to buy tobacco or electronic cigarettes for anyone under 18 (proxy purchasing). The UK also operates **a negative licensing**

scheme for tobacco retailers, which allows Magistrates to impose orders banning sales of tobacco products for up to a year, for persistent flouting of the age of sale law.

I. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)

1. The regulatory landscape for ENDS/ENNDS (e-cigarettes) is mixed and inconsistent around the world. This reflects the nascent scientific research of the effects of e-cigarettes on health but also the multitude of mixtures and variants of e-cigarette liquids on the market, and unknown health affects of dual use (smoking and e-cigarette), including prevalence. As explained above at Part I, paragraph 4, the WHO FCTC does not have an adopted guideline on e-cigarettes because scientific evidence on which inferences could be drawn about regulating e-cigarettes is not yet available. However, the WHO has made some recommendations for Parties to the FCTC to consider and its report `A systematic review of health effects of electronic cigarettes´ has drawn some useful conclusions to consider, both of which are reproduced at Annex A at the end of this article. This section of the article will look at how states have approached the regulation of e-cigarettes which can be arranged according to those that classify e-cigarettes as a poison (A); medical therapy (B); as part of the tobacco control regime (C); unregulated or mixed regulation; and prohibited (D).

A. E-cigarettes **regulated as a poison**
2. Both Australia and Hong Kong do not have specific regulation concerning e-cigarettes, however, both are in the process of developing specific e-cigarette regulations[33]. In Australia **every form of nicotine, except for replacement therapies for smoking cessation and cigarettes, are classed as a poison** and the Therapeutic Goods Administration (TGA) regulates those seeking to sell any such poisons listed on Schedule 6 (Poison) and Schedule 7 (Dangerous Poison)[34]. Nicotine is currently classed as a Schedule 7 poison and sellers must register with the TGA. In 2017, an applicant made a submission to the TGA to exempt nicotine from Schedule 7 at concentrations of 3.6% or less for self-administration with an e-cigarette for `tobacco harm reduction´ purposes. The TGA´s Expert Panel decided that the current scheduling of nicotine remains appropriate and their decision provides a useful summary of the regulation of nicotine. In the Australian state of Victoria, non-nicotine e-cigarettes may be sold in retail stores so long as the manufacturers do not make `therapeutic claims´, for example claiming to help people quit smoking. Most of Australia´s states treat non-nicotine e-cigarettes like tobacco for the purposes of no smoking areas, sales to children and restrictions on advertising and promotion of e-cigarette products[35]. Australian states, Western Australia and South Australia, prohibit the sale of products that are designed to resemble tobacco products, meaning that it will be against the law to sell many non-nicotine e-cigarettes.

3. Hong Kong´s Pharmacy and Poisons Ordinance (Cap 138) states that any e-cigarettes with nicotine are categorised as pharmaceutical products and must be registered with the Pharmacy and Poisons Board of Hong Kong before sale or distribution. Hong Kong´s Smoking (Public Health) Ordinance includes e-cigarettes as smoking and is therefore prohibited from use in no-smoking areas.

C. E-cigarettes **regulated as part of the tobacco control regime**
4. Whether nicotine e-cigarettes in the US should be regulated as tobacco, a drug or a medicinal product has been the subject of many court cases. Since 2016 the issue has now been settled and the US Food and Drug Administration (FDA) f**inalised a rule extending tobacco control authority to cover nicotine e-cigarettes known as "covered tobacco product"**. Nicotine e-cigarettes cannot be sold to minors below the age of 18[36]. FDA regulations cover the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS, including components and parts of ENDS but excluding accessories[37]. From August 2018 all nicotine e-cigarettes manufactured, packaged, put to sale, offered to sale, distributed, or imported for sale or distribution within the US require a warning label statement: "WARNING: This product contains nicotine. Nicotine is an addictive chemical"[38]. This required warning statement must also meet certain requirements, with respect to font, text, size, placement and formatting of the warning

statement on the package labels[39]. Non-nicotine e-cigarettes are not required to have a label. Currently, the US are investigating regulations for non-addictive nicotine levels (see here https://www.fda.gov/TobaccoProducts/NewsEvents/ucm600955.htm).

D. E-cigarettes regulated as **prohibited**
5. Singapore has the world´s toughest regulation for e-cigarettes as a recent amendment to the Tobacco (Control of Advertisements and Sale) Act **makes it illegal to buy, use and own imitation tobacco products, such as e-cigarettes, the penalty on conviction is a fine not exceeding SG$2,000**[40]. Previously, it was prohibited to import, distribute, sale or offer for sale any e-cigarette but as of February 2018 so too is possession.

6. In Brazil **the sale, importation and advertising of any kind of electronic cigarette is prohibited**. The Brazilian health and sanitation federal agency, Anvisa, found the current health safety assessments for e-cigarettes insufficient for commercial approval eligibility.

7. Turkey also bans e-cigarettes which is covered as a "tobacco product" regardless of its contents under Law No. 4207 on the Prevention and Control of hazards to Tobacco Products[41]. There are no licensed e-cigarettes in Turkey and they are prohibited from distribution in Turkey too.

III. What we missed

1. Noting the array of tobacco control measures and the variety of economic operators from tobacco manufacturers, to e-liquid mixing shops, to the corner shop selling cigarettes, it is important that enforcement powers are robust. State policing efforts around enforcement of non-smoking regulations, toxicity of ingredients and emissions of e-cigarettes, sales to minors and advertising prohibitions in retail shops requires vigilant surveillance, and state authorities need to have appropriate enforcement powers. Our Handbook: How To Regulate?, outlines the pros and cons of general enforcement powers or explicit and detailed inspection and enforcement powers. Where general enforcement powers are provided for in the regulation, it should also explicitly mention the most far reaching measures such as take-down of advertising or on the spot fines. In jurisdictions which require extremely precise and delimited empowerments, regulators might appreciate studying Singapore´s Air Navigation Act 2014 which contains comprehensive empowerment at Division 2 and 3. It is worth also looking at Part IV of Singapore´s Tobacco (Control of Advertisements and Sale) for the enforcement powers relating to e-cigarette possession (it is illegal to buy, use and own e-cigarettes). Another good example to look at are the enforcement powers of the police and tobacco control officers enforcing no smoking in cars, particularly cars with children[42]. Our howtoregulate article "Regulating Research and Technology Risks: Part II - Technology Risks" also contains information about empowerments in relation to identified risks at paragraph 10.

2. Policing of tobacco control measures can also include "citizen enforcers" and private, but public utility organisations. Many of the jurisdiction´s examined in this howtoregulate article had some form of online complaint mechanism for "citizen enforcers" to report non-compliance with tobacco control regulations. See the examples of Brazil (http://portal.anvisa.gov.br/denuncias) and the US (https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/ucm377563.htm). To encourage more "citizen enforcers" it could be an incentive to offer to the "citizen enforcers" part of the proceeds of the fine collected for non-compliance. Although many of the tobacco control agencies had online complaint forms for non-compliance, there were no whistle-blowing mechanisms. Noting the legal resources of the tobacco industry and their strong interest in keeping tobacco control regulations to a minimum it would be useful to promote whistle-blowing mechanisms, particularly to employees in the tobacco industry and their partners. For more information about whistle-blowing schemes see our howtoregulate article Whistleblowers: protection, incentives and reporting channels as a safeguard to the public interest.

3. Policing by private, but public utility organisations, for example small retailers associations (many cigarettes are purchased from small shops such as 24/7 or petrol stations) or unions (in terms of workplace smoking) or NGOs, such anti-smoking NGOs. In the case of small retailers

associations it might be appropriate to require them to report on compliance of its small retailers members on tobacco control measures around the display of cigarettes, advertising of brands, pricing lists and sales to minors.

4. In addition to the enforcement powers contained in our Handbook: How To Regulate? it is also recommended that regulators consult the part concerning measures dealing with rogue operators at page 78 for ideas on how to manage mobile e-liquid mixing shops and e-cigarette manufacturers.

This article was written by Valerie Thomas, on behalf of the Regulatory Institute, Brussels and Lisbon.

Links

World Health Organisation, http://www.who.int/tobacco/industry/product_regulation/BackgroundPapersENDS3_4November-.pdf
World Health Organisation, Global Progress Report on implementation of the WHO Framework Convention on Tobacco Control http://www.who.int/fctc/reporting/2016_global_progress_report.pdf?ua=1
Australian National Health and Medical Research Council, CEO Statement: Electronic Cigarettes https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf
Australian Council on Smoking Health https://www.acosh.org/law-policy/.
Action on Smoking and Health http://ash.org.uk/home/
Tobacco Control Laws https://www.tobaccocontrollaws.org/

Annex A
WHO Report on Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)

The following is a non-exhaustive list of options that Parties might consider in accordance with their national law, in order to achieve the ENDS/ENNDS objectives set out in the COP 6 decision on ENDS/ENNDS.

Objective: prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups.
Although the debate about whether the use of ENDS/ENNDS is a gateway to smoking is unresolved, preventing this eventuality requires making the initiation and persistence of smoking as difficult as possible. Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options:
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);
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.

Objective: minimise as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions.
a. Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options 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. Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options to minimise 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.

Objective: prevention of unproven health claims being made about ENDS/ENNDS.
Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options:
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 specialised governmental agency.

Objective: protect tobacco control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry.
Parties, including those that have banned the importation, sale, and distribution of ENDS/ENNDS, may consider the following options:
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

<u>WHO Report `A systematic review of health effects of electronic cigarettes´</u>

These are the conclusions drawn from this report:

1. Even though no firm conclusions can be drawn on the safety of e-cigarettes there is an increasing body of evidence indicating harm.
2. Due to the many methodological problems, the many studies with severe conflicts of interest, the inconsistencies and contradictions in results, the relatively few highquality studies, the rapidly changing designs of the product and the lack of longterm follow-up, it seems very premature to perform calculations for how harmful vaping is compared with smoking, and much is still left to

subjective interpretation.
3. It is not meaningful to speak of risk of vaping of e-cigarettes as risk of one product, as the risk seems to depend not only on the brand and batch, but also on, for example, the preferred flavour, the heating of the e-cigarette, the vaporizer, how dirty or worn the e-cigarette is, the method of vaping, and factors still unknown.
4. In a simple product-to-product comparison most e-cigarettes are probably less, and some products may even be much less, harmful than conventional cigarettes, but as the large majority of e-cigarette users continue to smoke, the health risks of dual use must be taken into account in assessment of the harm of vaping.
5. We have almost no evidence on the health effects of dual use of e-cigarettes and conventional cigarettes.
6. For ex-smokers and never smokers, use of e-cigarettes will increase the risk of harm on health.
7. Negative health effects should be expected from the pulmonary system but adverse effects from (for example) the cardiovascular system and a carcinogenic effect cannot be ruled out either.
8. E-cigarettes are highly addictive and there is insufficient evidence on the safety of long-term use of nicotine.
9. Comparing risk of vaping with the risk of (for example) drinking coffee is misleading.
10. Systematic high-quality research is urgently needed, especially on health effects of dual use.

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4 http://www.who.int/fctc/treaty_instruments/Guidelines_Article_6_English.pdf?ua=1.
5 http://www.who.int/fctc/treaty_instruments/adopted/Guidelines_Article_8_English.pdf?ua=1.
6 http://www.who.int/fctc/treaty_instruments/guidelines_articles_9_10_2017_english.pdf?ua=1.
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9 http://www.who.int/fctc/treaty_instruments/adopted/Guidelines_Article_13_English.pdf?ua=1.
10 http://www.who.int/fctc/treaty_instruments/adopted/Guidelines_Article_14_English.pdf?ua=1.
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13 WHO Report p. 4 http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1.
14 WHO Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control "on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry", p. 1, http://www.who.int/fctc/treaty_instruments/Guidelines_Article_5_3_English.pdf?ua=1.
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29 Global Adult Tobacco Surveillance System, there is a 13.4% relative decrease on tobacco use, http://gatsatlas.org/pdf/mobile/index.html#p=90.
30 http://partnerships.ifpma.org/partnership/tobacco-free-youth-campaign
31 Section 9A of the Tobacco (Control of Advertisements and Sale) Act.
32 http://www.dcta-global.com/our-mission.html.
33 Australia has a Parliamentary Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia, which concluded public hearings in October 2017, https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes. Hong Kong announced in December 2017 that it will strengthen the regulatory framework for e-cigarettes and will report to the Legislative Council on the issue within the legislative year http://www.news.gov.hk/en/categories/health/html/2017/12/20171201_112737.shtml.
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