WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

SECRETARIAT

Best practices in the implementation of WHO FCTC Article 10 (Regulation of tobacco product disclosures)

Report commissioned by the Convention Secretariat

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1. Introduction

The implementation of Article 10 of the WHO FCTC requires Parties to request manufacturers and importers of tobacco products to disclose to government authorities and the public information on the contents and emissions of tobacco products, including toxic constituents[1]. The Article 10 is an extension to the requirements of Article 9 of the WHO FCTC, which calls upon Parties to test, measure and regulate the contents of tobacco products. The purpose of testing and disclosing product information is to give regulators sufficient information to take action and inform the public about the harmful effects of tobacco use. The Conference of the Parties (COP) adopted partial guidelines for implementation of Articles 9 and 10 in 2010, which were further amended in 2012[2].

An increasing number of Parties have reported progress on their implementation of Article 10 of the WHO FCTC in the 2014 reporting cycle. The available information and Parties' experiences on disclosure of content and emissions now allow for a better analysis and dissemination of advanced practices. The focus of this report is directed at identifying, analyzing, documenting and disseminating best practices of Article 10 of the WHO FCTC. Such practices will further guide and assist in the comprehensive implementation of the WHO FCTC.

2. Methodology

In assessing the status of Parties' implementation of the WHO FCTC, the Secretariat uses four indicators to determine the attained progress in their obligations under Article 10. These four indicators are the following:

1. disclosure of information to government authorities about the contents of tobacco products required;
2. disclosure of information to government authorities about the emissions of tobacco products required;
3. public disclosure of the contents of tobacco products required; and
4. public disclosure of the emissions of tobacco products required.

The 2014 Global Progress Report on Implementation of the WHO FCTC utilized, on a pilot basis, a simple scoring system to assess implementation status by country. Each of the four indicators, when implemented, received a score of 1; therefore, the total possible scores for Parties in fulfilling their obligations for Article 10 were 4 points. Based on the 2014 Global Progress Report, Parties who have advanced in their achievements in the implementation of Article 10 with a total score of 4 points were considered for inclusion in this review; however, careful attention was also accorded to the geographical distribution and economic development status based on the World Bank classification. Consequently, twelve Parties are selected to participate in this review. Those parties are as follows:

- Kenya and Nigeria (African region);
- Brazil, Canada and Uruguay (region of the Americas);

[1] [2] Partial guidelines for implementation of Articles 9 and 10 (Regulations of the contents of tobacco products and regulation of tobacco product disclosures), adopted by the Conference of the Parties at its fourth session (decision FCTC/COP4(10)) with amendments adopted at the fifth session (decision FCTC/COP5(6)), available at: http://www.who.int/fctc/treaty_instruments/adopted/article_9and10/en/

- Saudi Arabia (Eastern Mediterranean);
- the European Union and Turkey (European region);
- Thailand[3] (South-East Asia); and
- Australia, Cook Islands and Kiribati (Western Pacific).

This paper involved the review and critical assessment of available documents that primarily describe the tobacco control legislation and regulation. As a basis, Parties' implementation reports were reviewed and additional questions were posed to Parties that were selected for inclusion in this report. Upon completion of this supplementary questionnaire, in-depth interviews were arranged with key individuals from the respective Parties.

3. Findings

A) The process of developing relevant legislation and policies

All the participating Parties in this review, except for Australia, have in place regulations that align with Article 10 of the WHO FCTC. Australia in 2000 departed from the prevailing practices and instituted a voluntary agreement with the tobacco companies to disclose information on the ingredients, constituents, and emissions in tobacco products. This agreement can be renewed after three years of implementation. Presently, this voluntary agreement has become an unofficial permanent agreement in Australia.

Although this voluntary agreement does not have any legal obligations, three tobacco companies in Australia with the largest market shares fully complied with the terms set out in the agreement. More importantly, the information on the contents and emissions disclosed has been used to further regulate the tobacco products as to the scientific evidence on the extent of their toxicity become more available[4].

Presently, Australia considers developing legally binding regulations in line with Article 10 of the WHO FCTC, but it is in an exploratory stage[5]. The process towards regulations requires conducting a regulation impact assessment, where a cost-benefit analysis may be necessary to provide the government with an economic perspective in determining whether benefits to public well-being outweigh the costs to the government and consumers. Subsequently, Australia charts its road map in a methodical and strategic manner in order to mobilize support from the decision makers and public, as well as being equipped with scientific information to respond to potential disputes from the tobacco industry.

Other participating Parties in this study implemented Article 10 in conjunction with Article 9, which deals with product regulation, where they are included as provisions within the national tobacco control legislation. The broad national tobacco control legislation prescribes an overarching legislative framework, and each provision in the legislation may require developing specific detailed regulation in a separate by-law at a later stage after the parliamentary approval of the national tobacco control legislation.

[3] Thailand received a score 2 in the 2014 Global Progress Report, WHO FCTC, but was selected due to the accessibility of information and represent the South-East Asia region.
[4] Information from the Australian Government representative through phone interview, 2015.
[5] At the time of the writing of this report. Information from the Australian Government representative through phone interview, 2015.

In order to create a more autonomous and independent system of operation, which includes the development and revision of regulations that align with Articles 9 and 10 of the WHO FCTC without a parliamentary or ministerial approval, Nigeria, Turkey, and Brazil instituted a legally independent body to regulate the provisions prescribed in these articles. Nigeria established the Standard Organization of Nigeria to regulate the processes along the supply chain of all products manufactured, distributed and consumed in Nigeria, including tobacco products under the Standard Organization of Nigeria Act, 2015[6]. In the same way, Turkey created an administrative and financial autonomous body, Tobacco and Alcohol Market Authority (TAPDK) in 2007, to regulate, supervise, and control of alcohol beverages, methanol, and tobacco products. Similarly, Brazil established The National Health Surveillance Survey Agency (Agência Nacional de Vigilância Sanitária, ANVISA) in 1999 as an autonomous regulatory agency overseeing the production and marketing of products that require sanitary control, including tobacco products[7].

The remaining Parties in this review, Canada, Cook Islands, Kenya, Kiribati, Saudi Arabia, Thailand and Uruguay, develop regulations to comply with the Article 10 within their respective legislative and administrative systems at the Ministry of Health. While Kiribati only recently drafted its first tobacco control legislation in 2013 and is awaiting its approval by the Parliament, other participating Parties (Cook Islands, Saudi Arabia and Thailand) are revising their tobacco control legislation including Article 10 provisions, to be in line with the partial guideline adopted at COP6 and expected to come into force within 2016. Meanwhile, Kenya and Uruguay are awaiting the pending outcomes of the tobacco industry lawsuits.

B) Policies/measures which require manufacturers and importers of tobacco products to disclose/report to government authorities information about the ingredients and emissions of tobacco products

The measure that requires the disclosure of relevant information from the tobacco product manufacturers and importers provides important evidence for government authorities, as this evidence allows them to develop and implement effective policies, regulations and various tobacco control activities.

Pursuant to Article 10 of the WHO FCTC, this information also includes the ingredients and emissions of the tobacco products, manufacturers and importers of tobacco products company information, as well as their market information and sales volumes. The knowledge gained from these disclosures contributes to both the surveillance and monitoring of tobacco product contents and emissions, market trends, and assessment of tobacco industry claims[8].

All of the participating Parties require manufacturers and importers of tobacco products to disclose information to government authorities regarding tobacco products ingredients[9] and emissions[10]. However, the range of the compounds mandated to be reported varies from all

[6] According to the Federal Republic of Nigeria Official Gazette, No. 91, Volume 102, 23rd June, 2015.
[7] From the website of the Brazilian Health Surveillance Agency.
[8] Partial guidelines for implementation of Articles 9 and 10 (Regulations of the contents of tobacco products and regulation of tobacco product disclosures), adopted by the Conference of the Parties at its fourth session (decision FCTC/COP4(10)) with amendments adopted at the fifth session (decision FCTC/COP5(6)), available at: http://www.who.int/fctc/treaty_instruments/article_9and10/en/

[9] Decision FCTC/COP5(6), "Ingredients" include tobacco, components (e.g. paper, filter), including materials used to manufacture those components, additives, processing aids, residual substances found in tobacco (following storage and processing), and substances that migrate from the packaging material into the product (contaminants are not part of the ingredients).
[10]Decision FCTC/COP5(6), "Emissions" are substances that are released when the tobacco product is used as intended. For example, in the case of cigarettes and other combusted products, emissions are the substances found in the smoke. In the case of

ingredients and emissions to a limited list of major substances, such as, the ingredients of tar and nicotine, to emission compounds such as carbon monoxide. Additionally, almost all Parties in this study (Brazil, Canada, EU, Kenya, Kiribati, Nigeria, Turkey and Uruguay) require the disclosure of tobacco ingredients that include type(s) of tobacco leaves, percentage of reconstituted tobacco used, and percentage of expanded tobacco used, as well as design features[11].

The level of details of disclosure regarding both tobacco products ingredients and emissions varies among Parties in this study. Some Parties stipulate all tobacco ingredients and emissions must be reported. On the other hand, some Parties require the identification of specific compounds to be included in reports. For example, Canada calls for the manufacturers of tobacco products to report information on all ingredients, i.e., some 26 constituents, and emissions from both mainstream and side-stream, comprising 40 compounds[12]. Similarly, Brazil identifies 28 ingredients, 49 compounds from mainstream emission and 48 compounds from side-stream emissions to be included in reports[13].

In addition to the disclosure of the said ingredients and emissions, some Parties require additional reports, in order to develop and implement effective policies and measures on product regulations. Among the 12 Parties in this study, Canada, the EU, Kenya and Turkey require toxicological data including health and addictive effects on each ingredient in both burnt and unburnt form.

Moreover, the EU Tobacco Products Directive 2014/40/EU (TPD) broadens the scope requesting manufacturers to state their reasons for the inclusion of each ingredient in the tobacco products. Canada, on the other hand, requests the submission of manufacturers' research activities related to the development of new consumer tobacco products, information on advertisement, sponsorships, accessories that displays a consumer tobacco product-related brand element, and a non-tobacco product, other than an accessory that displays a consumer tobacco product-related brand element including detail descriptions and related costs for each province in Canada that these activities occur[14].

In order to expand reporting obligations by the manufacturers of tobacco products, the EU TPD contains a specific provision to address additives used in the manufacturing of tobacco products. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[15], established by the EU Commission, developed a priority list of additives in 2016.

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smokeless tobacco products for oral use, emissions are the substances released during the process of chewing or sucking, and in the case of nasal use, refer to substances released by particles during the process of snuffing.

[11] Decision FCTC/COP5(6), "Design feature" means a characteristic of the design of a tobacco product that has an immediate causal link with the testing and measuring of its contents and emissions. For example, ventilation holes around cigarette filters decrease machine-measured yields of nicotine by diluting mainstream smoke.

"Design feature" means a characteristic of the design of a tobacco product that has an immediate causal link with the testing and measuring of its contents and emissions. For example, ventilation holes around cigarette filters decrease machine-measured yields of nicotine by diluting mainstream smoke.

[12]Tobacco Reporting Regulations, SOR/2000-273. (Last amended on December 15, 2015). Retrieved from http://laws.justice.gc.ca/PDF/SOR-2000-273.pdf

[13] Brazil: Resolution – RDC No. 90, of December 27, 2007. Retrieved from http://www.tobaccocontrollaws.org/files/live/Brazil/Brazil%20-%20RDC%20No.%2090.pdf

[14] Tobacco Reporting Regulations, SOR/2000-273. (Last amended on December 15, 2015). Retrieved from http://laws.justice.gc.ca/PDF/SOR-2000-273.pdf

[15] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) commissioned by the European Commission to develop a priority list of additives based on the following criteria: (a) contribution to the toxicity or addictiveness of the products concerned / increases the toxicity or addictiveness of any of the products concerned to a significant or measurable degree; (b) Resulting in a characterising flavour; (c) Facilitating inhalation or nicotine uptake; (d) Leading to the formation of substances that have CMR properties / increasing the CMR properties in any of the products concerned (cigarettes/RYO) to a significant or measurable degree; in which the Commission published the committee findings on 25 January, 2016. The priority list of additives can be found in this report. Retrieved from http://ec.europa.eu/dgs/health_food-

The manufacturers and importers of cigarettes and roll-your-own tobacco are required to conduct comprehensive studies on the additives in the tobacco products that are on the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) priority list and take into account emissions resulting from the combustion process of the concerned additives. The comprehensive studies must examine whether each additive:

- contributes to the toxicity or addictiveness;
- results in characterizing flavor;
- facilitates inhalation of nicotine uptake;
- leads to the formation of substances that have carcinogenic, mutagenic, or toxic for reproduction (CMR) properties; or
- interacts with other ingredients in the tobacco products[16].

Similarly, Turkey established a scientific committee to develop a list of substances found in tobacco products and their emissions from a thorough scientific review. One of the approval criteria for allowing the tobacco manufacturers to market any particular tobacco product involves verifying whether the disclosed ingredients and emissions are found on the Tobacco and Alcohol Market Authority (TAPDK) "positive list"[17]. Information for each substance on TAPDK "positive list" includes its registration with the Turkey Food and Drug Administration (FDA), the EU commission, or its inclusion in the tobacco products marketed in other countries.

Most of the Parties in this study require the disclosure of information to be submitted annually and at the time of modification for tobacco products. However, Canada and Uruguay impose a shorter quarterly reporting period for some provisions of their tobacco control regulations, while Thailand mandates a longer reporting period of every 3 years. Moreover, most Parties apply the reporting requirements for each tobacco product type and each brand within a brand family in either the total quantity and/or maximum quantity for each ingredient and emission compound. This disclosure of information on the ingredients and emissions of tobacco products for each brand should provide the government authorities the ability to monitor the trends in tobacco compositions and changes in the market that may occur over time and afford Parties with evidence to consider more stringent tobacco product regulations.

The disclosure of general company information, including the name, street address and contact information of the principal place of business of each manufacturing and importing facility forms part of the reporting regulations for all Parties in this study. Additionally, most of these Parties, except Brazil and Australia, require disclosure of sale volume's information in units of tobacco products, for example, the number of cigarettes or cigars and the weight of roll-your-own tobacco cigarettes. However, in the case of the EU, the Tobacco Products Directives further impose a submission of internal and external market research on various consumer groups, particularly the younger age group and current smokers. These reports are inclusive of market surveys when introducing new products[18]. Market information affords Parties the ability to conduct comparative analysis between various brands of tobacco products, in order to determine and monitor tobacco consumption patterns and to assist in identifying regulatory needs and priorities.

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safety/dyna/enews/enews.cfm?al_id=1662 and
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_051.pdf

[16] Article 6, Tobacco Products Directive 2014/40/EU of the European Parliament and of the Council, April 3, 2014.

[17] Term used by TAPDK staff through face to face interview, 2016.

[18] Tobacco Products Directive 2014/40/EU of the European Parliament and of the Council, April 3, 2014.

C) Measures requiring public disclosure of information about the toxic constituents and of the tobacco products and their emissions

Pursuant to the adopted partial guidelines of Article 9 and 10 at the fifth session of the COP, Parties are recommended to make available information about the toxic constituents and emissions of tobacco products and other information that have been disclosed to the government authorities publicly available[19]. Disclosing the information about the toxicity of the tobacco products may contribute to raising awareness among the general public, to be better informed in protecting their own health. In this case, public includes not only the public at large but members of the civil society, academic institutions, and nongovernment organizations who play an important role in tobacco control nationally and internationally.

Effective measures to communicate the toxicity of tobacco products may take various forms, including mass media, health education, campaigns and training programs in line with Article 12 of the WHO FCTC, as well as packaging and labelling of tobacco products in line with Article 11. Each Party has the obligations to adopt appropriate means to disseminate the information within its national context and legislations with the goal to protect the health of its citizens.

Parties participating in this study capitalize on various mass media channels, such as radio and television, in addition to newspaper in the dissemination of public information regarding toxic constituents of tobacco products and their emissions. However, some Parties adopt other measures, such as health education campaigns and training programs.

In the EU, sixteen European countries collaboratively implement a more strategic approach to increase public access to information regarding additives in tobacco products and their health effects. This approach utilize through the Public Information Tobacco Control (PITOC) project funded by the EU to support the implementation of EU tobacco products legislation, Directive 2001/37/EC.

The main goal of the PITOC project is to produce scientifically sound documents on 14 additives with the highest health hazards in addition to the highest amounts used in tobacco products[20]. Two European institutions, namely German Cancer Research Center (DKFZ), in Heidelberg, and the National Institute for Public Health and Environment (RIVM), Bilthoven, in the Netherlands, develop a comprehensive report. This report consists of 14 factsheets aimed at policy makers, journalists, civil society, nongovernmental organizations, and the public at large.

Additionally, the websites launched in 2012 contain factsheets with the general information on the additives and for each of the 14 additives, information on its general usage, its use by the tobacco industry, and its harmful health effects. There are separate websites aimed specifically for professionals and the public at large[21].

[19] Partial guidelines for implementation of Articles 9 & 10, Regulations of the contents of tobacco products and regulation of tobacco product disclosures, adopted by the Conference of the Parties at its fourth session (decision FCTC/COP4(10)) with amendments adopted at the fifth session (decision FCTC/COP5(6)), Retrieved from http://www.who.int/fctc/treaty_instruments/article_9and10/en/

[20] Commission Staff Working Document: Implementation of the Second Programme of Community Action in the Field of Health in 2012, Retrieved from http://ec.europa.eu/health/programme/docs/second_healthprogramme_implementation_2012_en.pdf

[21] https://www.rivm.nl/en/Topics/T/Tobacco

D) Public disclosure of constituents and emissions of the tobacco products in the context of Article 11 of the WHO FCTC

The use of packaging and labelling of tobacco products to communicate health consequences and addictiveness posed by tobacco consumption and tobacco smoke is another effective dissemination channel. Pursuant to adopted guidelines for implementation of Article 11 of the WHO FCTC, Parties are encouraged to place on each packet and package of tobacco products, health warnings and messages, including pictorial health warnings, and information on relevant ingredients and emissions of tobacco products[22].

The implementation guidelines further recommend the use of both text and pictorial images, which provide a better graphic imprint of the harmful effects of tobacco products. The WHO FCTC Convention Secretariat compiles and maintains a database of pictorial health warnings and messages on its website[23] to be shared and accessible by all Parties to the Convention. The addition of pictorial images also accommodates the literacy-challenged segment of the population. The 2014 Global Progress Report indicated that more than half of the Parties implemented pictorial health warnings on the packaging of tobacco products.

All Parties in this study adhere to the recommended contents for the health warnings and messages prescribed in the adopted guidelines. These guidelines include, but are not limited to, the addictiveness, advice on cessation, adverse economic and social outcomes, and health impacts on significant others, as well as the placement location, size/percentages of space, colours, and rotational schemes of multiple health warnings and messages.

Some Parties implement the minimum recommendations as prescribed in the implementation guidelines, in particular the size of health warnings and messages where the guidelines specify to be not less than 30% of the display area but preferably more than 50%; other Parties, however, impose more stringent obligations. For example, Brazil requires pictorial health warnings at 100% of the display area of the front or the back, followed by Thailand at 85% of both sides, Uruguay at 80%, Kiribati at 70%, and Turkey at 65% of both front and back. Australia, on the other hand, takes a more stringent approach by adopting plain packaging to prevent the tobacco company from establishing brand images of their tobacco products and highlights the health warnings and messages on the packages.

The main goal of displaying health warnings and messages on tobacco products packages is to raise awareness of harmful effects from tobacco products among the public at large. The acquisition of knowledge from these important sources of information empowers the public to make informed choices. The effectiveness of the health warnings and messages depends on how well they are communicated to the intended audience. For example, Canada evaluated the health warnings on their packaging of tobacco products eighteen months after the introduction of these health warnings. The results of the survey indicated the messages are viewed among smokers as useful in being aware of the health impact of smoking, encourage them to smoke less, and compel them to try to

[22] Guidelines for Implementation of Article 11 of WHO FCTC on Packaging and Labelling of Tobacco Products. adopted by the Conference of the Parties at its third session in November 2008 (decision FCTC/COP3(10))., Retrieved from http://www.who.int/fctc/guidelines/adopted/article_11/en/

[23] WHO FCTC Health Warnings Database, Retrieved from http://www.who.int/tobacco/healthwarningsdatabase/en/

quit. Lastly, the survey revealed that Canadian public supports the tobacco regulations requiring the tobacco products manufacturers and importers to display health warnings and messages on cigarette packages[24].

It is well accepted that the use of descriptors, such as "low tar", "light", "ultra-light" or "mild" to denote a particular tobacco product is less harmful than another provides a misleading and deceptive labelling, and more importantly, an impression of a lower toxicity of the tobacco product. All Parties participating in this study prohibit the use of these terms on the packaging and labelling of tobacco products marketed in their respective countries, which complies with the adopted guidelines on Article 10 of the WHO FCTC. Although disclosing information on the toxic ingredients and emissions of tobacco products to the public is important, the aforementioned guidelines discourage Parties from displaying numerical quantities of harmful ingredients and emissions on the tobacco products packages.

Studies have shown that the public at large lacks the comprehension to interpret the meanings of numerical values or the amounts of ingredients/constituents and emissions found in tobacco products. More critically, comparison of numerical concentrations of toxic compounds across brands may potentially lead to a false impression of the degree of harmful effects of these substances. In agreement with Article 10, most Parties in this study prohibit disseminating quantitative values of ingredients and emission in tobacco products on the packaging. Instead, these Parties have adopted textual information messages in disclosing the toxicity of ingredients and emissions of tobacco products.

Most of the textual information messages provide the consumers with general statements about the composition of toxic compounds in the total number, presence of specific compounds, and/or a general qualitative account of the toxic substances. For example, Brazil imposes on the cigarette packages the following information text messages: "This product contains more than 4,700 toxic substances, and nicotine that causes physical or mental dependence", and "There are no safe levels for consumption of these substances"[25].

Canada's regulations, on the other hand, stipulate a total of six information messages to be placed on all cigarettes and little cigars packages. These information messages are:

- "Tobacco smoke contains more than 60 chemicals that can cause cancer";
- "Tobacco smoke contains hydrogen cyanide which is a poisonous gas";
- "Tobacco smoke contains benzene which is a chemical that causes cancer"; and
- "Tobacco smoke contains fine particles that damage respiratory system"[26].

The Cook Islands and Kiribati require similar statements on the packaging of tobacco products: "Smoking exposes you to more than 40 harmful chemicals. These chemicals damage blood vessels, body cells and the immune system. QUIT NOW to reduce your risk of chronic illness or premature death." More textual information messages may be found on the Convention Secretariat health warnings database[27].

[24] Best Practices in Tobacco Control: Regulation of Tobacco Control Report, Canada, 2005. Retrieved from http://www.who.int/tobacco/global_interaction/tobreg/Canada%20Best%20Practice%20Final_For%20Printing.pdf?ua=1

[25] Brazil: Resolution – RDC No. 335, of November 21, 2003. Retrieved from http://www.tobaccocontrollaws.org/files/live/Brazil/Brazil%20-%20RDC%20No.%20335.pdf

[26] Tobacco Products Labelling Regulations (Cigarettes and Little Cigars), SOR/2011-177. Retrieved from http://laws.justice.gc.ca/PDF/SOR-2011-177.pdf

[27] WHO FCTC Health Warnings Database, Retrieved from http://www.who.int/tobacco/healthwarningsdatabase/en/

E) Tobacco industry challenges related to measures under Article 10 of the WHO FCTC

The tobacco industry continues to challenge Parties to the WHO FCTC from developing effective legislation, regulations and measures to fulfill their obligations to the Convention. Some of these challenges aim towards the entire tobacco control legislation in general, while some focus on specific articles of the Convention, including Article 10. The tobacco industry uses various legal channels and other means to deter and intimidate Parties from developing and implementing their tobacco control legislations.

Kenya, Uruguay and the EU recently revised their tobacco control legislation with Parliamentary approval but unable to come into force, pending the outcomes of the litigation brought by the tobacco industry. Similarly, Thailand's revised tobacco control legislation faces obstacles and challenges instigated by the tobacco industry through front groups, intense lobbying and other means. The landmark case of Australia's implementation of plain packaging after the positive ruling by the Australia court now faces challenges at the international arena, the WTO. Occurrences of legal challenges by the tobacco industry have become a certainty and endless, since the WHO FCTC threatens their market shares and the subsequent profits.

However, Parties' progress against the legal challenges of the tobacco industry is gaining ground. This transpires despite the tobacco industry relentless attempt to undermine Parties' determination to strengthen their tobacco control efforts. Most recently, the EU Tobacco Products Directives 2014, preliminary opinion of the European Court of Justice (ECJ) Advocate General Kokott on the current legal challenges by several tobacco companies indicate that the EU TPD 2014 is valid and lawfully adopted, "in particular the extensive standardization of packaging, the future EU-wide prohibition on menthol cigarettes and the special rules for e-cigarettes"[28]. If the final rulings of the ECJ are in line with Advocate General Kokott opinion, this will set a legal example for others Parties to follow in strengthening their tobacco control efforts, and in particular, adopting the plain packaging provision prescribed in Article 10.

Protecting trade secrets is the tobacco industry's main argument in disputing the provisions prescribed in Article 10, particularly, the disclosure of the information related to the ingredients and emissions to the public. Some Parties in this study, particularly the EU and Turkey, specify in its reporting regulations to take account trade secrets when making the information publicly available. However, the EU TPD also requires the tobacco manufactures and importers to identify what they consider trade secrets in their reports. Moreover, the EU TPD further classifies the information that does not constitute to be confidential and of trade secrets; this includes the following:

> "(a) for all tobacco products, inclusion and quantity of additives other than flavorings;
>
> (b) for all tobacco products, inclusion and quantity of ingredients other than additives used in quantities above 0.5% of the total tobacco product unit weight;
>
> (c) for cigarettes and roll-your-own tobacco, inclusion and quantity of individual flavorings used in quantities above 0.1% of the total tobacco product unit weight;

[28] Court of Justice of the European Union, Advocate General Kokott considers the new EU tobacco directive of 2014 to be valid, Press Release No. 154/15, Retrieved from http://curia.europa.eu/jcms/upload/docs/application/pdf/2015-12/cp150154en.pdf

(d) for pipe tobacco, cigars, cigarillos, smokeless tobacco products and all other tobacco products inclusion and quantity of individual flavorings used in quantities above 0.5% of the total tobacco product unit weight;

(e) studies on toxicity, addictiveness or attractiveness not linked to specific brands; where those studies are linked to specific brands, the explicit and implicit references to the brand shall be removed and the redacted version shall be accessible."[29]

5. Summary

There is no such thing as "one size fits all"

The review of Parties' experiences included in this study provides examples of good practices in approaching implementation of Article 10 of the WHO FCTC. These best practice models may prove effective within each Party context, timing and circumstances; when considering adopting interventions following these best practices, Parties need to take into consideration their own country context.

There is a need to be able to react quickly

The development and implementation of tobacco products reporting regulations require a legislative process that is fluid, with limited bureaucratic administrative systems. This fluidity is needed in order to respond quickly to the proliferation of information on tobacco product contents and emissions. Parties with an effective and efficient regulatory process can establish an autonomous body outside the health ministry, and a mechanism that does not require parliamentary or ministerial approval in the development and revision of tobacco products reporting regulations, so as to keep pace with the appearance of new tobacco brands and products, as well as with the development of the WHO FCTC Articles 9 and 10 partial guidelines that continues to advance and evolve over time.

Similar to the concept of a "one-stop shop", the administratively and financially independent units in Brazil, Nigeria and Turkey that oversee the tobacco product reporting regulations have the decision-making authority to update regulations as necessary, as well as to implement the regulations. In contrast, Parties that adhere to the national legislative process and system within the health ministry might face long and cumbersome procedures that may involve either parliamentary or ministerial approval for even minor revisions of the regulations. This might result in long delays and gives the opportunity for intense lobbying from the tobacco industry.

Clear and detailed prescriptions

Developing clear detailed regulations on disclosure of information to the government authorities and the public would prevent any misinterpretation of regulations. It will also result in an effective implementation and enforcement of provisions and will also assist the judiciary in making appropriate legal judgments in any legal challenges initiated by the tobacco industry.

Canada developed and applies three separate regulations that stipulate thoroughly crafted provisions within each regulation. These regulations are (1) Tobacco Products Information

[29] Notification Detail, Draft Commission Implementing Decision establishing a format for the submission and making available of information on ingredients and emissions of tobacco products and on sales volumes, 5 August 2015.

Regulations, requiring information placed on tobacco products other than cigarettes and little cigars; (2) Tobacco Products Labeling Regulations (Cigarettes and Little Cigars), requiring information placed on cigarettes and little cigars; and (3) Tobacco Reporting Regulations, involving reporting of contents and emissions of tobacco products to the government authority and the public. These regulations became a blueprint for both the government authorities to regulate, and the tobacco products manufacturers and importers to comply within the scope of the laws.

Information for surveillance of toxic substances in the market

Regulations that impose reporting of amounts of specific toxic contents and emissions help government authorities in gathering information for the purposes of surveillance and monitoring of toxic substances, in analyzing the trends in changing the concentration of such substances, and these all will eventually help governments in further regulating the contents and emissions of tobacco products available on the market. Canada and Brazil require the disclosure of over 20 substances. In the European Union, a priority list of additives has been developed by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[30], taking into account the health hazards related to the use of the respective additives and their concentration in the tobacco product itself. Parties may wish to consider adopting such lists as part of their regulations on tobacco products disclosures.

In addition, requiring the tobacco products manufacturers and importers to submit toxicological data, comprehensive studies, and research on all substances contained in the tobacco products, including additives, the justification for the use of each ingredient, and any market research on new products, would provide the government authorities with a solid knowledge base. This can also be conducive to a better understanding of the toxicity and health risks attached to the tobacco products available in the market. In-depth comprehension of the content of tobacco products may lead to a more effective regulation and equips regulators with scientific evidence that might be necessary in responding to legal challenges from the tobacco industry.

Disclosure of content information to the public

An informed general public is critical to tobacco control efforts and disclosing the information about the toxicity of the tobacco products to the public leads to an increase in awareness regarding the health risks associated with smoking. Communication channels used should be specific to the social and cultural context of the target audience. Although the accessibility to telecommunication has increased exponentially in the past few years, placing health warnings and messages on the package of tobacco products remains to be highly effective. Studies have substantiated that most smokers view tobacco product packaging and labelling as an important source of health impact information, encouraging them to smoke less and compelling them to quit.

[30] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) commissioned by the European Commission to develop a priority list of additives based on the following criteria: (a) contribution to the toxicity or addictiveness of the products concerned / increases the toxicity or addictiveness of any of the products concerned to a significant or measurable degree; (b) Resulting in a characterising flavour; (c) Facilitating inhalation or nicotine uptake; (d) Leading to the formation of substances that have CMR properties / increasing the CMR properties in any of the products concerned (cigarettes/RYO) to a significant or measurable degree; in which the Commission published the committee findings on 25 January 2916. The priority list of additives can be found in this report. Retrieved from http://ec.europa.eu/dgs/health_food-safety/dyna/enews/enews.cfm?al_id=1662 and http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_051.pdf

Intimidating tactics of the tobacco industry

Parties continue to face legal challenges by the tobacco industry and claims on the impingements of their intellectual property rights seem to dominate their law suit threats related partly or fully to implementation of Article 10 of the WHO FCTC. Disclosing the contents of the tobacco products may appear to hinder the tobacco industry trade secrets and the industry uses this argument to intimidate government authorities from disclosing the information to the public. One effective approach to respond to the tobacco industry accusation involves a screening system by government authorities to assess whether what is reported by the tobacco industry may be trade secret or not. The European Union's Tobacco Products Directives goes further to define what is not considered to be trade secret in its reporting regulations, thereby, oblige the tobacco products manufacturers and importers to comply with those regulations.

The judicial branch in some Parties lack experience and knowledge in the complexity of the tobacco industry's tactics, as well as on how implementation of the WHO FCTC should be protected from tactics of the tobacco industry. However, many Parties have successfully educated the judiciary system by raising awareness on tobacco industry tactics to undermine tobacco control measures and what are the main counterarguments used in other courts in Parties that have already successfully protected their policies. Lessons learned from the court rulings can be instructive to Parties that face similar challenges.

The benefit of scientific evidence and implementation research

Regulations and policies supported with solid scientific evidence may gain more easily the support of the public and the legislators, thus ensuring speedy and smooth parliamentary approval. In the presence of solid evidence any attempts by the tobacco industry to prevent or weaken the adoption of regulations through false claims and legal challenges will have less impact. Conducting a pre- and post-regulation impact assessment has proven to be an effective strategy in adopting and implementing appropriate policies. Implementing a pre-adoption impact assessment that considers the health, social, economic and other impact of the planned measures is important to garner public support for the regulation and provide proof for the value of the regulations. A post-implementation study on the impact of the regulation may produce additional evidence of its effectiveness on curtailing the smoking rates, changing smoking behaviour and increase awareness of the health risks associated with smoking. Such rigorous research provides the scientific background for Parties' adoption and implementation of tobacco control regulations, including on contents and emissions of tobacco products and content disclosures.

In conclusion, this review of best practices in the implementation of Article 10 of the WHO FCTC reveals that such good practices grounded on solid scientific evidence and proven by implementation research indeed exist. Sharing of expertise, knowledge and information, as well as collaboration between the Parties to document and exchange such experience, may assist Parties in strengthening their own tobacco control regulations on tobacco contents, emissions and their disclosures. The WHO FCTC is an effective and powerful instrument, and a united effort among Parties plays a significant role in advancing the comprehensive implementation of the Convention.

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