

# Implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control

# Positive experiences, best practices and factors that impede implementation

**Report commissioned by the Convention Secretariat** 

November 2019 (updated March 2020)

# Contents

I.	Background1
П.	Methodology1
III.	Findings and analyses2
S	tatus of implementation of Articles 9 and 102
E	Barriers and challenges for implementation3
	Availability of technical resources
	Financial barriers4
	Policy prioritization and communication4
	Other tobacco products
	Tobacco industry interference5
E	xamples of implementation of Articles 9 and 105
	Tobacco industry interference
E	xamples of successful international cooperation initiatives
F	easibility of establishing a global knowledge hub for Articles 9 and 10
IV.	Key observations
	Comprehensive set of measures to implement Articles 9 and 10
	Access and capacity-building9
	International cooperation9
	Scientific evidence and information10
	Advocacy
S	ources of information11
A	Annex 1: Questions of the ad hoc questionnaire12

# Acronyms and abbreviations

COP	Conference of the Parties
ENDS	Electronic nicotine delivery system
ENNDS	Electronic non-nicotine delivery system
EU	European Union
EU-CEG	European Union Common Entry Gate System
FCTC	Framework Convention on Tobacco Control
HTP	Heated tobacco product
NGO	Nongovernmental organization
РАНО	Pan American Health Organization
SDG	Sustainable Development Goal
TobLabNet	(WHO) Laboratory Network
TobReg	(WHO) Study Group on Tobacco Product Regulation
TPD	(European) Tobacco Products Directive
UN	United Nations
WHO	World Health Organization

# I. Background

The Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC), at its eighth session (COP8), taking note of the analysis provided by the Secretariat of the WHO FCTC (Convention Secretariat) in the *2018 Global Progress Report on Implementation of the Convention*,<sup>1</sup> recognized thatParties are facing challenges in implementing Articles 9 and 10 of the WHO FCTC. Subsequently, the COP adopted decision FCTC/COP8(21).<sup>2</sup> In this decision, the COP requested the Convention Secretariat "to establish, in accordance with guidance from the Bureau, an expert group to examine the reasons for low implementation of Articles 9 and 10 of the Convention, and related partial guidelines" for implementation. The COP decision mandated the Expert Group to analyse the factors that impede the implementation of Articles 9 and 10 and to identify positive experiences and best practices from Parties for addressing these barriers. The Convention Secretariat commissioned this report in response to that decision.

The Convention Secretariat organized a meeting of the Expert Group established through decision FCTC/COP8(21) on 21–22 November 2019 in Bilthoven, Netherlands, and this report served as a background paper to facilitate the discussions at that meeting.

Tobacco product regulation is an essential part of a comprehensive tobacco control strategy, as reflected in the obligations under the WHO FCTC. Effective regulation of tobacco product contents, design and emissions can significantly reduce the demand for and use of tobacco, and the resulting burden of disease. Articles 9 and 10 of the WHO FCTC complement other WHO FCTC articles, allowing for a comprehensive and effective implementation of the treaty. These articles also contribute to keeping the tobacco industry accountable in terms of both contents and disclosures.

Parties may use Articles 9 and 10 and the related partial guidelines<sup>3</sup> to require manufacturers and importers to display information about constituents and emissions on tobacco packaging and not to include information on additives (such as flavourings or energizing additives) that may constitute a means of promotion. This would complement the implementation of Article 13. The regulation of contents (e.g. flavours), in order to make tobacco products less appealing to minors, also contributes to the implementation of Article 16. While implementing Article 12, Parties could include messages about the constituents and emissions of tobacco products in education, communication training, and public awareness measures in order to educate the public on the addictiveness of tobacco as well as on the harms of tobacco and second-hand smoke. In this way, low or no implementation of Articles 9 and 10 has an impact on several other provisions of the WHO FCTC. Consequently it is imperative to understand the reasons behind unsatisfactory execution of these articles.

The focus of this report is to analyse and document the barriers that impede implementation of Articles 9 and 10 and to identify good practices in addressing those barriers to implementation.

# II. Methodology

(https://www.who.int/fctc/treaty\_instruments/guidelines\_articles\_9\_10\_2017\_english.pdf?ua=1, accessed 29 July 2020).

<sup>&</sup>lt;sup>1</sup>2018 Global progress report on implementation of the WHO Framework Convention on Tobacco Control. Geneva: World Health Organization; 2018 (<u>https://www.who.int/fctc/reporting/WHO-FCTC-</u> 2018 global progress report.pdf, accessed 29 July 2020).

<sup>&</sup>lt;sup>2</sup> Decision FCTC/COP8(21). Implementation of Articles 9 and 10 of the WHO FCTC (Regulation of contents and disclosure of tobacco products, including water pipe, smokeless tobacco and heated tobacco products). Conference of the Parties to the WHO Framework Convention on Tobacco Control, Eighth session Geneva, Switzerland, 1–6 October 2018 (https://www.who.int/fctc/cop/sessions/cop8/FCTC\_COP8(21).pdf?ua=1, accessed 29 July 2020).

<sup>&</sup>lt;sup>3</sup> Partial guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (Regulation 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)) and at the seventh session (decision FCTC/COP7(14))

Preparation of this report involved a multi-pronged approach to gather information. The preliminary stage involved extensive desk research. There was an exhaustive review of the information provided through the WHO FCTC reporting instrument, including its core and voluntary questionnaires. As part of this process, the reports submitted by the Parties to the WHO FCTC in the 2018 reporting cycle were re-analysed with special focus on understanding the challenges Parties faced in implementing Articles 9 and 10.

In parallel, a new set of questions was developed as part of the preparation of this document in order to seek Parties' opinions and perspectives on the major barriers they face when implementing Articles 9 and 10 and related partial guidelines, and possible actions that could be taken to address those barriers. These questions were sent to all WHO FCTC Focal Points in October 2019 and then again in December 2019 after the meeting of the Expert Group on implementation of Articles 9 and 10. The draft version of this report was used as a background paper to facilitate discussions at the meeting of the Expert Group in November 2019. It should be noted that only 38 Parties provided inputs; these written inputs and the outcomes of the discussions at the Expert Group meeting have been used throughout this report.

## **III. Findings and analyses**

## Status of implementation of Articles 9 and 10

The information provided by the Parties shows that many of them, despite having comprehensive tobacco control laws, have not been fully able to implement provisions relating to Articles 9 and 10 of the WHO FCTC, including testing of the contents and emissions of tobacco products. This is mainly because of the lack of capacity, expertise and technical knowledge to set up a fully functional tobacco testing capacity that will allow testing and measurement of contents and emissions of all forms of tobacco products.

Parties' reports submitted in the 2018 reporting cycle generally demonstrated some progress in implementing Articles 9 and 10 as compared to previous years. However, implementation of these articles still lags behind the implementation of other articles of the WHO FCTC as almost half of the Parties do not have appropriate regulatory measures in place (Table 1).

#### Table 1. Status of implementation of measures under Articles 9 and 10 of the WHO FCTC <sup>1</sup>

A r t i c I e 9	<ul> <li>Have you adopted and implemented, where appropriate, legislative, executive, administrative or other measures or have you implemented, where appropriate, programmes on any of the following: <ul> <li>testing and measuring the contents of tobacco products? 46% of all Parties.</li> <li>testing and measuring the emissions of tobacco products? 45% of all Parties.</li> </ul> </li> <li>regulating the contents of tobacco products? 55% of all Parties.</li> <li>regulating the emissions of tobacco products? 47% of all Parties.</li> </ul>
A r t i c	<ul> <li>Have you adopted and implemented, where appropriate, legislative, executive, administrative or other measures or have you implemented, where appropriate, programmes on any of the following:</li> <li>requiring manufacturers or importers of tobacco products to disclose to government authorities information about:</li> </ul>

1	• the contents of tobacco products? 67% of all Parties.		
е	the emissions of tobacco products? 58% of all Parties.		
	– requiring public disclosure of information about:		
1			
0			
0	the contents of tobacco products? 56% of all Parties.		
	• the emissions of tobacco products? 46% of all Parties.		

On most of the provisions under Articles 9 and 10, the growth in the number of Parties implementing these Articles has gone up by 8 and 9 percentage points, respectively, from 2016 to 2018. However, Parties still have a long way to go on Articles 9 and 10 as the implementation status of many other articles has made much better progress.

## Barriers and challenges for implementation

The implementation of Articles 9 and 10 is resource-intensive, both financially and technically. This makes implementation difficult in jurisdictions where the resources available for tobacco control are, in general, limited. Many Parties find it challenging to adopt and implement provisions that are relevant to Articles 9 and 10 on various accounts. The discussion below highlights the types of barriers and challenges that Parties face while implementing requirements under Articles 9 and 10 of the Convention.

Availability of technical resources

- In many countries, there is a reported lack of awareness, clarity and understanding of the
  potential impact that the implementation of Articles 9 and 10 might have in a comprehensive
  tobacco control strategy. Such understanding may be limited among regulators, policy-makers
  and also nongovernmental organizations (NGOs) that have the capacity to help implement the
  Convention.
- Several Parties have indicated that, since some parts of the guidelines remain incomplete, there is a need to arrange the work that is necessary to finalize them, completing sections on toxicity, contents and emissions, and incorporating the regulation of addictiveness, attractiveness and palatability, including technical characteristics such as filters and paper. Some also suggest the inclusion of guidance on how these articles can be implemented, especially with respect to novel tobacco products, as well as on monitoring and evaluating the implementation. There is a lack of adequate technical expertise in specific areas, such as setting up testing laboratories to study the toxicity of tobacco products in order to analyse properly the data on contents and emissions reported by the tobacco industry.
- Many low-income countries have reported that they have inadequate capacity to test and measure the contents and emissions of tobacco products in their own country, and that they have no easy access to laboratories in other countries. They have also claimed that sending samples abroad is costly. Establishment of independent laboratories for the analysis of tobacco products was also reported as being resource- and technical capacity-intensive.
- Collection and analysis of data from the tobacco industry could be challenging for some Parties. For instance, in an effort to comply with the mandates of Articles 9 and 10, the European Commission established the European Union Common Entry Gate System (EU-CEG), which is a comprehensive resource for EU Member States. However, it remains to be seen how Parties can benefit from it in full. This project provides a platform to process and analyse large amounts of industry data, including on tobacco product testing.<sup>4</sup>

<sup>&</sup>lt;sup>4</sup> Tobacco product regulation: basic handbook. Geneva: World Health Organization; 2018. (<u>https://apps.who.int/iris/bitstream/handle/10665/274262/9789241514484- eng.pdf?sequence=5&isAllowed=y</u>, accessed

#### Financial barriers

- Some Parties have reported that funds dedicated to tobacco control in general are both insufficient and irregular. Some Parties explain that they invest in certain tobacco control activities but overlook other important elements and, among those neglected, it is common to find the testing and measuring of contents and emissions of tobacco products.
- Setting up a national laboratory and obtaining the equipment to test tobacco products is relatively expensive. Additionally, many Parties do not have a national testing laboratory and/or also lack easy access to a laboratory abroad, primarily because of the financial implications and administrative difficulties (e.g. customs clearance).

## Policy prioritization and communication

- In some cases, it has been reported that tobacco control as a whole was identified as not a health priority. In other circumstances, public health priorities may be altered for instance during an epidemic such as was the case for Ebola virus disease. This may delay the development of tobacco control regulations, including the various measures that are required under Articles 9 and 10 of the Convention.
- Many Parties have faced litigation by the tobacco industry especially the court cases brought by the tobacco industry in attempts to impede implementation of Article 10.<sup>4</sup> Responding to such legal challenges could be difficult and might be considered by Parties as a barrier to implementation. Lack of knowledge among legislators and judges of the damage caused by tobacco to public health as well as the tobacco industry's interference strategies could lead to court decisions that do not advance tobacco control and could make the policies (and the intent of the regulator) less efficient. This includes the implementation of recommendations from the partial guidelines for implementation of Articles 9 and 10, such as the ban on flavours and design features, among others.
- Inadequate training and knowledge of tobacco control staff on issues related to product regulation, and the lack of specific capacity (because of low rates of recruitment of dedicated staff with expertise in product regulation) have been identified as major barriers to the relatively resource-intensive implementation of Articles 9 and 10.
- The tobacco industry is intensifying its communications on novel and emerging tobacco products, including in the area of product regulation. This means that the industry continues to seek opportunities for interaction with regulators and legislators, raising the possibilities for interference. To prevent this, good governance rules and observation of Article 5.3 of the Convention and its guidelines are even more important, especially when new regulations and legislation concerning product regulation are being developed. This could be a particular challenge in countries where Article 5.3 of the Convention has not been appropriately addressed and there are no effective barriers to prevent the tobacco industry from interfering in decision-making processes.
- The complexity (or perceived complexity) of actions required under Articles 9 and 10, and the lack of understanding of the meaning of product regulation, including by WHO FCTC focal points, government officials and decision-makers, has led to delayed or low implementation of Articles 9 and 10.
- The impact of Articles 9 and 10 on the overall outcome of tobacco control work is often perceived to be lower compared to that of other tobacco control measures. For this reason, Articles 9 and 10 have sometimes not been identified as priorities for implementation.

<sup>29</sup> July 2020).

#### Other tobacco products

- Parties' national laws and testing infrastructure usually support testing and measuring of the emissions of cigarettes. However, there is a need to strengthen the application of existing methods to the testing of contents (and emissions) of tobacco products other than cigarettes. In other words, not all tobacco products available on the market may be covered by sufficient laboratory capacity.
- The appearance in the markets of new and emerging nicotine and tobacco products raises additional concerns for regulators. The COP has adopted decisions on how to address these products, including their contents and emissions.<sup>5</sup>

#### Tobacco industry interference

- The tobacco industry has always challenged Parties to the WHO FCTC to prevent them from developing effective legislation and measures to fulfill their obligations under the Convention. More often than not, many such actions are aimed at implementation of Articles 9 and especially 10. The tobacco industry actively lobbies decision-makers to prevent the banning of certain ingredients in tobacco products, or to delay the introduction of such bans.
- Some Parties have already adopted measures to require the tobacco industry to report on the constituents and emissions of their products, including additives. Some Parties have reported that the tobacco industry denied submission of some information on the pretext of it being confidential and/or a trade secret.
- The tobacco industry is also lobbying to legalize heated tobacco products (HTPs) as well as Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) as less harmful alternatives to conventional tobacco products, with more lenient restrictions compared to traditional tobacco products.
- The judicial system has also been used by the tobacco industry to impede implementation of tobacco control and public health policies through legal challenges initiated by the industry itself or its front groups.<sup>6</sup>

#### Examples of implementation of Articles 9 and 10

In spite of the many challenges and barriers described above, the implementation reports of the Parties highlight some good examples of implementation. Such examples are presented in the 2018 Global progress report on implementation of the WHO FCTC.<sup>7</sup>

As part of the ad hoc questionnaire sent to Parties by the Convention Secretariat during the preparation of this paper and in preparation for the meeting of the Expert Group on Articles 9 and 10 in late 2019, some additional information was received from the Parties with some recent examples of implementation. These are summarized in the paragraphs below.

As implementation of Articles 9 and 10 require specific knowledge and expertise, Brazil, Nigeria and Turkey each have an independent body that works in the areas covered by these articles.<sup>5</sup> The Standard Organization of Nigeria regulates the processes along the supply chain of all products manufactured,

<sup>&</sup>lt;sup>5</sup> Decision FCTC/COP8(22). Novel and emerging tobacco products. Conference of the Parties to the WHO Framework Convention on Tobacco Control, Eighth session, Geneva, Switzerland, 1–6 October 2018

<sup>(</sup>https://www.who.int/fctc/cop/sessions/cop8/FCTC\_\_COP8(22).pdf?ua=1, accessed 29 July 2020).

<sup>&</sup>lt;sup>6</sup> For example, in the Philippines, by virtue of a regional court decision in 2012, the Philippines Food and Drug Administration (FDA) lost its jurisdiction over tobacco products and, as a consequence, the country has not been able to implement fully its obligations under Articles 9 and 10 of the WHO FCTC. The Department of Health and the FDA itself have requested a review of this decision by the Supreme Court. However, the case has not progressed since 2012.

<sup>7 2018</sup> Global progress report on implementation of the WHO Framework Convention on Tobacco Control (pp 30–33). Geneva: World Health Organization; 2018 (<u>https://www.who.int/fctc/reporting/WHO-FCTC-2018\_global\_progress\_report.pdf?ua=1</u>, accessed 29 July 2020).

distributed and consumed in Nigeria, including tobacco products. The Turkish Tobacco and Alcohol Market Authority (Turkish: Tütün ve Alkol Piyasası Düzenleme Kurumu, TAPDK), created in 2007 as an administrative and financial autonomous body, regulates, supervises and controls alcoholic beverages, methanol and tobacco products. The Brazilian Health Regulatory Agency (Portuguese: Agência Nacional de Vigilância Sanitária, ANVISA), an entity linked to the Ministry of Health, is another example of such a body.

#### Tobacco industry interference

The tobacco industry and its affiliates have legally challenged governments among the Parties to the WHO FCTC on the basis of claims of supposed violations through their tobacco control measures. The European Union, Kenya, Thailand, United Kingdom and Uruguay have revised their tobacco control legislation to include provisions relating to Articles 9 and 10, for which they were confronted with litigation brought by the tobacco industry or its front groups.<sup>8</sup> These Parties have been victorious in their defence of public health, as the governments were recognized by their respective courts as having the jurisdiction to adopt tobacco product regulation measures in line with the WHO FCTC.

Further details on specific examples are provided below, showing how Parties have encountered and overcome challenges posed by the tobacco industry and have adopted regulations for comprehensive national tobacco control.

**European Union:** The European Tobacco Products Directive (TPD), which entered into force in 2014, is a best practice for countries and for all Member States of the European Union (EU). It is a shared vision that provides rules and a framework to govern the manufacturing, presentation and sale of tobacco and related products. This regulation also requires the tobacco industry to report on the ingredients used in the production of tobacco products, including information on tobacco ingredients, additives, emissions and toxicological data.<sup>2</sup> Additionally, the TPD led to a Joint Action on Tobacco Control (2017–2020), which focuses on supporting Member States in this endeavour.

**India:** India enacted its tobacco control law in 2003 but was unable to implement provisions relating to testing of contents and emissions. The reasons ranged from lack of testing capacity and technical expertise to the constant pressure on the government from the tobacco industry, together with lawsuits initiated by the industry. India reported in its 2018 WHO FCTC implementation report that there is plethora of tobacco products on the market (both smoking and smokeless) and that a very large proportion of the tobacco industry – such as the bidi industry – is unorganized and unregulated. In this situation, receiving and collating information from all tobacco producers has become a real challenge. Nevertheless, India has taken positive steps and has set an example for countries with low-resource settings.<sup>4</sup> Learning from best practices, India has engaged experts, policy-makers and relevant stakeholders to build capacity. Additionally, it has dedicated special funds to set up laboratories and has partnered with laboratory networks such as the WHO Tobacco Laboratory Network (WHO TobLabNet).

**United Kingdom:** Once the EU's TPD was transposed into law, the tobacco industry challenged it on the grounds of principles of proportionality, legal certainty and free competition. None of these court challenges affected the validity of the regulations under the TPD. On the contrary, the United Kingdom successfully challenged tobacco manufacturers where their products fell outside of the requirements of the national law for emissions, resulting in those products being withdrawn from the market.

#### Examples of successful international cooperation initiatives

In order to overcome the challenges of implementing Articles 9 and 10 and related partial guidelines, it

<sup>&</sup>lt;sup>8</sup> The Secretariat of the WHO Framework Convention on Tobacco Control. Best practices in the implementation of WHO FCTC Article 10 (Regulation of tobacco product disclosures). Geneva: World Health Organization; 2015 (http://who.int/fctc/implementation/publication/Best-practices-in-implementation-article-10.pdf, accessed 29 July 2020).

is important that Parties cooperate with each other. According to the Parties, effective implementation of Articles 9 and 10 requires access to high-quality laboratories, expert scientific staff and accurate data from the tobacco industry. International cooperation could help in addressing these challenges and achieving full implementation of these articles.

In the *Global progress report 2018*, there has generally been a positive trend in providing and receiving assistance between Parties to the WHO FCTC. About one third of all Parties provided assistance to other Parties on expertise for tobacco control programmes, transfer of skills and technology, training and awareness of personnel.<sup>2</sup> However, specific information on whether such provision or receipt of technical assistance also covered Articles 9 and 10 is patchy. We provide some examples of such cooperation in the following paragraphs.

In the WHO South-East Asia Region, countries with testing laboratories have offered access to these laboratories to neighboring countries.

The development and introduction of the TPD has helped the Parties that are Member States of the EU to achieve better implementation of tobacco control provisions and to meet their obligations under the Convention. The *Global progress report 2018* already highlighted the TPD as good implementation practice. Furthermore, all respondents of Parties that are Member States of the EU to the questions sent to Parties in relation to the preparation of this report acknowledge that the adoption and implementation of the TPD necessitates strengthened international cooperation.

Through the implementation of the TPD, the EU has laid the foundation for a coordinated response in its Member States for better regulation of tobacco products, creating a common reporting database for data on contents and emissions. The Joint Action on Tobacco Control supports the implementation of the TPD.<sup>9</sup> The EU has also developed the EU-CEG, designed to reduce the reporting burdens on regulators and companies, and to make it easier to compare data. EU Member States are working together through a joint action to overcome the challenges of obtaining and managing the vast amount of data from the tobacco industry.

Canada partnered with the Pan American Health Organization (PAHO) to develop a training course on the regulation of tobacco product attractiveness for regulators of the Region of the Americas.<sup>10</sup> The training course modules were pilot-tested and are now available for use by other countries. The course has recently been successfully adapted and its use in the WHO Western Pacific Region began in 2019.

Under the FCTC 2030 project, personnel from Georgia participated in a study tour in Romania to learn from their experience and to exchange information about the implementation of Articles 9 and 10. This visit helped Georgia to design the requirements and methods for collection of information required by these articles. After the visit, with the support of WHO, an international expert on Articles 9 and 10 was sent to Georgia to conduct a training course for representatives of the executive branch.

In relation to overcoming technical barriers, Panama stated that it has received technical advice from countries in the Americas Region – such as Brazil and Canada – as they are more advanced in implementing product regulation measures.

Another example of international cooperation comes from Jamaica, which brought different actors together as partners to tackle the challenges presented by the tobacco industry, especially in the implementation of Articles 9 and 10. Jamaica worked together with, and received assistance from, the Convention Secretariat, PAHO, the Campaign for Tobacco Free Kids and the Convention Secretariat's

<sup>&</sup>lt;sup>9</sup> Joint Action on Tobacco Control (JATC) (<u>http://jaotc.eu/our-mission/10</u>, accessed 29 July 2020).

<sup>&</sup>lt;sup>10</sup> Training material on regulation of tobacco products. Washington (DC): Pan American Health Organization (<u>https://www.paho.org/hq/index.php?option=com\_content&view=article&id=11986:2016-toolkit-regulation-tobacco-products&Itemid=1188&Iang=en</u>, accessed 29 July 2020).

Knowledge Hub on Legal Challenges (hosted at the McCabe Centre for Law and Cancer) to respond to tobacco industry interference. This cooperation supported Jamaica further through capacity-building workshops that were designed to improve implementation of WHO FCTC provisions, including Articles 9 and 10.

# Feasibility of establishing a global knowledge hub for Articles 9 and 10

The Convention Secretariat has established seven WHO FCTC knowledge hubs to help provide assistance to Parties in implementing the Convention. Knowledge hubs located in each of the WHO regions could provide assistance in areas such as tobacco industry interference, litigation against the tobacco industry, smoke-free environments, packaging and labelling of tobacco products, tobacco cessation, waterpipe tobacco use, smokeless tobacco use, and tobacco-related research and surveillance.<sup>11</sup> Decision FCTC/COP8(21) requested the Convention Secretariat "to explore the feasibility of establishing a global Knowledge Hub to support Parties in their implementation of Articles 9 and 10 of the Convention and its partial guidelines".

Most of the Parties, in their responses to the ad hoc questionnaire sent out by the Convention Secretariat in late 2019, highlighted that knowledge hubs could help with capacity-building, information-sharing and provision of technical assistance. A knowledge hub for Articles 9 and 10 could fulfil the same functions. According to respondents, it could also organize webinars to discuss policy approaches, hold workshops on country or region-specific challenges and prepare reports and conduct analyses of implementation practices related to Articles 9 and 10. Best practices, successful models and experience-sharing through the knowledge hub could aid in addressing the challenges associated with the implementation of Articles 9 and 10.

If a knowledge hub is created for this purpose, it is important that it has the required technical knowhow and also experience in transferring that know-how. It is also imperative that, even if such a hub is created, it works together and in synergy with existing WHO collaborating centres to ensure that there is no duplication of efforts between the two.

#### **IV.** Key observations

The following key observations, based on the analysis above, could assist the Expert Group established by COP8 to examine the reasons for lowimplementation of Articles 9 and 10 of the Convention. The observations derive from the *Global progress report 2018* and from analysis of the few questions sent to the WHO FCTC Parties.

Below is a brief summary of such observations.

#### Comprehensive set of measures to implement Articles 9 and 10

To have the most impact in controlling tobacco, the requirements of Articles 9 and 10 of the WHO FCTC should be implemented as part of a comprehensive multisectoral national tobacco control strategy, plan and programme, in accordance with Article 5 of the Convention.

The partial guidelines for the implementation of Articles 9 and 10 (Regulation of the contents of tobacco products and regulation of tobacco product disclosures) describe the interventions that should be pursued by the Parties to ensure full compliance with the requirements of these articles. Unfortunately, only 44% of Parties reported in 2018 that they have taken account of the partial guidelines in developing their policies.

<sup>&</sup>lt;sup>11</sup> The WHO FCTC Secretariat's Knowledge Hubs and the tobacco industry monitoring centres (observatories). (<u>https://www.who.int/fctc/implementation/knowledge-management</u>, accessed 29 July 2020).

Regulations to ensure fulfilment of Parties' obligations under Articles 9 and 10 should be comprehensive and clear so that they can be enforced effectively. A good understanding of these articles by decisionmakers is critical to learn of the needs related to their implementation. Such awareness-raising could also assist the judiciary in making accurate judgements while dealing with any legal challenges put forward by the tobacco industry.

Parties should clearly express their needs regarding implementation of these Articles to the Convention Secretariat so that targeted assistance can be provided to them. WHO FCTC implementation reports should be used to put forward such requests, as the core questionnaire provides a space for the Parties to describe their needs.

In line with the partial guidelines for the implementation of Articles 9 and 10, all costs related to measures under those articles, including that related to testing laboratories, should be requested to be borne by the tobacco industry by law.

#### Access and capacity-building

To fully implement measures under Articles 9 and 10, many Parties need to take further steps, such as identifying additional resources, and should conduct capacity-building and training. Capacity-building on developing and implementing measures related to Articles 9 and 10 has been identified as critical for technical staff, enforcement officials and other stakeholders.

It is important to understand that laboratory testing of tobacco products is only one component of implementation of Article 9. Not having a laboratory should not prevent Parties from implementing the other requirements. Even in the part related to testing, Parties do not need to have their own laboratory; any laboratory in the respective region, or elsewhere if it is accessible, could be invited to provide assistance as part of international cooperation efforts. A well-established network of laboratories (WHO TobLabNet) already exists, and these laboratories' role in helping the Parties should be promoted. This could also be helpful in providing training of laboratory analysts and other technical personnel, providing assistance in planning and designing testing laboratories, and identifying the sources of funding for this work.

National and regional meetings and sensitization workshops on different aspects of Articles 9 and 10 could be of assistance and should therefore be promoted. The Convention Secretariat, WHO and Parties should collaborate further to support and strengthen the technical exchange of information and training, as needed.

#### International cooperation

The respondents to the questions sent to Parties for the preparation of this report consider international cooperation as a necessity for scaling up implementation of Articles 9 and 10. Collaboration should be encouraged and strengthened among all relevant stakeholders, including through the existing country assistance mechanisms established by the COP – such as needs assessments and South-South and Triangular Cooperation initiatives. Expert advice on setting up measures under Articles 9 and 10, in addition to the assistance that the Convention Secretariat and WHO could provide, could also be sought from the WHO Study Group on Tobacco Product Regulation (WHO TobReg) and WHO TobLabNet. Both networks could provide advice, share experiences and give overall guidance on measures related to product regulation. WHO TobLabNet has developed 10 testing methods for smoking products, and these methods should be popularized and adapted to other products. All in all, international cooperation can be instrumental in facilitating data collection and analysis from different countries so that tobacco control regulations can be adapted.

It would be very useful to share the EU's experience of requiring measures related to Articles 9 and 10 of the Convention to be introduced in a number of WHO FCTC Parties that are EU Member States. These measures would provide valuable lessons to other WHO FCTC Parties.

Experience with establishing and operating testing laboratories is worth collecting and sharing with countries that are ready to follow suit.

#### Scientific evidence and information

Scientific evidence and research, in line with Article 20 of the Convention, form the basis for strong legislation and policies. Such research should therefore be encouraged. Research can form the basis of policy decisions and ensures that such decisions are based on scientific evidence. If there is enough evidence, attempts by the tobacco industry to challenge such policies will have much less chance of success and can be more effectively countered.

Along with scientific evidence, it is important to collate information on how regulations and policies work, and to what extent they show impact in tobacco control. This could help to develop more efficient policies in future.

Parties have recognized that available information is still limited on how to adopt effective legislation on Articles 9 and 10, on how to analyse and handle information submitted by the tobacco industry and on ongoing court cases as well as other issues. Consequently, a knowledge hub focusing on product regulation and disclosures could be a useful tool for strengthening implementation of Articles 9 and 10, including dissemination of knowledge and information, and could serve as a potential additional source of assistance to Parties.

#### <u>Advocacy</u>

According to information received by the Convention Secretariat on the work carried out by COP observer civil society organizations, Articles 9 and 10 tend to receive less attention<sup>12</sup> than other WHO FCTC articles. Sometimes, even if the NGOs do not have the technical background on Articles 9 and 10, they understand the significance of these articles and advocate for important issues – such as the banning of flavours or menthol. This is also important because mobilizing and fostering support from a broader range of stakeholders could provide impetus to strengthening the development and implementation of policies related to Articles 9 and 10.

Parties and relevant stakeholders must also unite with competent medical and scientific authorities to counter fraudulent and misleading claims made by the tobacco industry in relation to traditional and new tobacco and nicotine products, taking into account Article 5.3 of the Convention and its implementation guidelines.

<sup>&</sup>lt;sup>12</sup> Document FCTC/COP/8/19. Review of accreditation of observers to the Conference of the Parties. Conference of the Parties to the WHO Framework Convention on Tobacco Control, Eighth session, Geneva, Switzerland, 1–6 October 2018 (https://www.who.int/fctc/cop/sessions/cop8/FCTC\_COP\_8\_19-en.pdf, accessed 29 July 2020).

#### Sources of information

- 1. Party responses to the ad hoc questionnaire sent out in October 2019 for the preparation of this report.
- 2. Parties' reports on the implementation of the WHO FCTC submitted in the 2018 reporting cycle.
- 3. Global progress report on implementation of the WHO Framework Convention on Tobacco Control. Geneva: World Health Organization; 2018 (<u>https://www.who.int/fctc/reporting/WHO-FCTC-2018 global progress report.pdf</u>, accessed 29 July 2020).
- Tobacco product regulation: basic handbook. Geneva: World Health Organization; 2018 (<u>https://apps.who.int/iris/bitstream/handle/10665/274262/9789241514484-</u> eng.pdf?sequence=5&isAllowed=y, accessed 29 July 2020).
- The Secretariat of the WHO Framework Convention on Tobacco Control. Best practices in the implementation of WHO FCTC Article 10 (Regulation of tobacco product disclosures). Geneva: World Health Organization; 2015 (<u>http://who.int/fctc/implementation/publication/Bestpractices-in-implementation-article-10.pdf</u>, accessed 29 July 2020).
- Partial guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (Regulation of the contents of tobacco products and Regulation of tobacco product disclosures). (<u>https://www.who.int/fctc/treaty\_instruments/guidelines\_articles\_9\_10\_2017\_english.pdf?ua=</u><u>1</u>, accessed 29 July 2020).
- Document FCTC/COP/8/19. Review of accreditation of observers to the Conference of the Parties. Conference of the Parties to the WHO Framework Convention on Tobacco Control, Eighth session, Geneva, Switzerland, 1–6 October 2018 (<u>https://www.who.int/fctc/cop/sessions/cop8/FCTC\_COP\_8\_19-en.pdf?ua=1</u>, accessed 29 July 2020).

#### Annex 1: Questions of the ad hoc questionnaire

- 1. Have you encountered any barriers (political, technical, financial or other) while implementing Articles 9 and 10 of the WHO FCTC and its related partial guidelines? How have you addressed these challenges, if at all?
- 2. Have you identified any attempts by the tobacco industry in your country and/or region to undermine the implementation of Articles 9 and 10?
- 3. Have you adopted and implemented methods for testing and measuring the contents and emissions of cigarettes and other tobacco products? If so, are these based on the methods of the WHO Tobacco Laboratory Network? Do the test methods cover all available tobacco products in your country and region?
- 4. Do you have access to a laboratory for tobacco product regulation? If so, is it a national laboratory or a regional laboratory? Do you have access to any other technical resources to implement Articles9 and 10? If not, what gaps have you identified in this regard?
- 5. How do Articles 9 and 10 complement the implementation of other articles under the WHO FCTC?
- 6. Have you implemented the partial guidelines for implementation of Articles 9 and 10? As the guidelines are currently partial, what steps could be taken to develop the guidelines further?
- 7. Do you think that establishing a Knowledge Hub is the answer to address the challenges associated with implementation of Articles 9 and 10? If so, how do you envision the support to be provided? If not, please suggest other avenues for addressing the challenges.
- 8. Please share any positive experience/example that you may have encountered in your country or region while implementing Articles 9 and 10. Can you identify examples of successful international cooperation in which your country has engaged regarding the implementation of these articles?
- 9. What further assistance have you identified as a requirement for fully implementing Articles 9 and 10 and its partial guidelines? How would that assistance be ideally provided?
- 10. What actions/next steps do you recommend for promoting implementation of Articles 9 and 10 of the WHO FCTC in your country and region?