

Meeting of the Expert Group on Articles 9 and 10 of the WHO FCTC

Detailed notes of the meeting

21-22 November 2019	
Bilthoven, Netherlands	17 January 2020

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Chair of WHO Study Group on Tobacco Product Regulation (WHO TobReg): Ghazi Zaatari

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Chair: Hassan Mohamed

The minutes follow the order of items as displayed in the provisional programme of the meeting (attached in the **Annex 1**).

Opening and welcome

The representative from the Government of the Netherlands opened the meeting and welcomed the participants. The head of the Secretariat of the WHO FCTC and the Protocol delivered her opening address, which was followed by introductions by all participants. The Chair for the meeting was nominated by participants and elected unanimously.



Session 1. Overview of objectives and purpose of the meeting

The Convention Secretariat made two presentations to set the background for this meeting - to introduce the objectives, the proposed agenda and the method of work, and to review the COP decisions and the mandate of the Expert Group.

Presentation

The FCTC/COP8(21) decision defines the mandate of the Expert Group and also lays down the objectives of the meeting:

- To examine and discuss factors that impede implementation of Articles 9 and 10, and related partial guidelines.
- To identify and present positive experiences from Parties in addressing barriers to their implementation of these articles and related guidelines.
- To explore the feasibility of establishing a global Knowledge Hub to support Parties in their implementation of Articles 9 and 10 of the WHO FCTC and its partial guidelines.

Discussion

- As the Convention Secretariat introduced the objectives, along with the proposed agenda, there was general support and the agenda was adopted without changes.
- The report commissioned by the Convention Secretariat (on the aforementioned aspects), will provide the platform for discussion, with a view to develop recommendations for the COP to promote and support further implementation of these articles, for a better tobacco regulation.

Session 2. Setting the scene: background information to support the discussions including on implementation of Articles 9 and 10 of the WHO FCTC, and the related partial guidelines

Recent background document on implementation of Articles 9 and 10

Presentation

- A report commissioned by the Convention Secretariat was presented. The focus of this background report is directed at analysing and documenting barriers that impede implementation of Articles 9 and 10, and identifying best practices and positive experiences from Parties in addressing barriers to their implementation of these articles and related partial guidelines.
- The preliminary stage of the report involved an extensive desk research, including an exhaustive review of the information provided through the WHO FCTC reporting instrument, including its core and voluntary questionnaires submitted by Parties in 2018. Parties' reports already analysed and reported on in the 2018 Global Progress Report on



Implementation of the WHO FCTC – were re-analyzed, specifically to understand the challenges Parties faced in implementing Articles 9 and 10.

- A set of new questions were developed as part of this study to seek Parties' opinions and perspectives on the major barriers they face while implementing Articles 9 and 10 and its partial guidelines, and possible actions that could be taken to address those barriers. These questions were sent to all WHO FCTC focal points who could be found in the records of the Convention Secretariat in October 2019. The written inputs received from 21 Parties in response to these questions have been used throughout the report.

Discussion

- Parties and experts expressed that to extract more information on the implementation of Articles 9 and 10, it is important to understand how and at what level countries are a) developing laws, and b) implementing/enforcing those laws. A detailed questionnaire was the need of the hour and not just a mere "Yes/No" answers.
- Statistical analysis is important to understand the magnitude of the problem and, therefore, the number of responses to the new set of questions should at least be 50 to capture the reality of the situation.
- The new set of questions will be sent out again to all the Parties in order to receive more responses. This will help in receiving more responses and more examples so that the background report can be finalized by early 2020.

Presentation of the WHO perspective

A representative from the WHO Prevention of Non-communicable Diseases Department will present on their perspective of the challenges and lessons learnt on the implementation of Articles 9 and 10.

Presentation

- The WHO has been working on product regulation and has identified diverse challenges that lead to low implementation of these articles. There are political, legal and economic reasons that lead to non-compliance, as the manufacturers and even the governments feel burdened to implement Articles 9 and 10.
- There is limited understanding of potential benefits and impact of proposed interventions. Parties find it difficult to implement testing methods as there is lack of understanding of complex technical information.
- Novel and emerging tobacco and nicotine products have created uncertainty as there is no international agreed approaches for testing the contents and emissions of ENDS and HTPs. These products are misleading regulators with misrepresentation of science and harm reduction arguments.
- There are certain opportunities that must be explored, especially within the governments, where a multi-sectoral approach has to be adopted and implemented. Country pairing should be supported to build capacity where a technologically



advanced country could be paired with a less advanced.

- Over the years, WHO identified certain practice and lessons that must be shared and adapted by Parties in the domestic context while implementing Articles 9 and 10.
 Parties should not accept claims from the tobacco industry concerning the confidentiality of information that would prevent governmental authorities from receiving information about the contents and emissions of tobacco products.
- To reduce the burden on governments, costs related to testing and disclosure should be charged to the tobacco industry via a cost-recovery mechanism, such as: designated tobacco taxes; tobacco manufacturing and/or importing licensing fees; tobacco product registration fees; licensing of tobacco distributors and/or retailers; non-compliance fees levied on the tobacco industry and retailers; and annual tobacco surveillance fees (tobacco industry and retailers).
- Role of the civil society (important) it is recommended to partner with the Convention Secretariat to raise awareness and build support for tobacco product regulation.

Discussion

- The focus of the discussion was to understand the role that WHO has played in implementation of Articles 9 and 10, and the resources and assistance that are available for Parties (TobLabNet, TobReg, WHO, Convention Secretariat and civil society) to strengthen the implementation of Articles 9 and 10 of the WHO FCTC and to drive country impact.
- There was an agreement that tobacco product regulation is a powerful tool that can help to reduce tobacco use and lessons learnt can advance tobacco product regulation by addressing the gaps and barriers towards the low implementation of Articles 9 and 10.
- The first few presentations from the Convention Secretariat and the WHO clarified roles and responsibilities each has on tobacco product regulation.
- The experts and Parties agreed that WHO TobReg, WHO TobLabNet, WHO collaborating centres (through WHO), the Global Tobacco Regulators Forum and the Secretariat's Knowledge Hubs should collaborate and coordinate to address common issues.

Presentation of the discussions and conclusions from the cigarette ventilation meeting (18-19 November 2019, Bilthoven, Netherlands)

Presentation

As per decision FCTC/COP8(21), the Convention Secretariat in cooperation with WHO, organized a meeting on cigarette ventilation, with a wide range of relevant experts, Party representatives and observers accredited to COP independent from tobacco industry, to gain an overview of the latest scientific evidence on the impact of cigarette ventilation on cigarette use and report back their findings to the ninth session



of the COP.

- The findings were reported with strong evidence and revealed that filter ventilation is the main contributor to cigarette ventilation. It does not reduce disease risk and also misinforms consumers about the health risks of smoking, as well as reduces consumer health risk perception of smoking.
- Filter ventilation increases consumer appeal by making the smoke milder, smoother and easier to inhale. It enables elasticity, which leads to compensatory smoking behavior and lack of reduction in exposure to smoke components including tar, nicotine and carbon monoxide.

Discussion

- Two possible policy options were discussed, which included an absolute ban or setting an upper limit to a fixed percentage of filter ventilation. It was also highlighted that synergy with other tobacco control regulations, e.g. plain packaging, comprehensive ban on descriptors, flavour ban (menthol) and stop smoking support groups, would be crucial in overall implementation.

Session 3. Experience with the implementation of Articles 9 and 10, and inter-country collaboration to promote implementation

In this session, country experiences were shared by experts from Bahrain, Greece, Iran, Mauritius, Kenya, Maldives, Brazil, India, Canada, Japan, China, Netherlands and Thailand. The experts, nominated by Parties and selected by the COP Bureau, made their presentations based on their experience, both at national and regional¹ levels, on the implementation of Articles 9 and 10. Their reflections include the following: most pressing challenges, including interference by the tobacco industry with product regulation of contents and disclosures; best practices identified; establishment and operation of laboratories and testing of products in the absence of a national laboratory; applicability and limitations of the test methods referenced in the partial guidelines and/or WHO Tobacco Laboratory Network standard operating procedures.

Presentations

Bahrain

- Bahrain prioritizes implementation of the WHO FCTC, including Articles 9 and 10, and it had established tobacco testing laboratories in 2016. It also mandates the tobacco industry to submit periodic reports on contents and emissions of their products.
- <u>Challenges</u>: Eastern-Mediterranean Region (EMR) faces several challenges while implementing these articles, including political and financial difficulties, and interference from the tobacco industry. Additionally, availability of flavoured tobacco products is a major challenge, especially because the laboratory tests have limited

¹ Experts were requested to cover, in their talks, not only the experiences of their individual countries of origin, but also the patterns and recurring issues/challenges from their regions.



applicability and do not apply to all tobacco products.

- <u>Achievements</u>: Five countries in EMR have tobacco testing labs and Bahrain has partnered with one laboratory of the WHO TobLabNet and with two laboratories in Saudi Arabia to test products.
- The Working Group on Articles 9 and 10, currently suspended by COP8, should continue to complete the partial guidelines on Articles 9 and 10.

Greece

- <u>Challenges</u>: Implementation of the Convention is a political issue and Articles like 9 and 10 require strong scientific background and knowledge, as they are technical in nature.
- New and better steps are being taken by countries and a new law banning smoking in indoor public places has been adopted in Greece.
- Parties have specially dedicated institutions for tobacco control, but the implementation status of these articles is still not complete in many countries.

Iran

- <u>Challenges</u>: Extensive costs involved in implementing these articles, tobacco flavours and tobacco industry influence are major obstacles. Due to lack of clear guidance and measures, the whole region finds it difficult to deal with water pipe, novel products and flavoured tobacco.
- <u>Achievements</u>: The Ministry of Health has launched a laboratory, and sampling and analysis are also extended to water pipe tobacco.
- In EMR, Sudan has formed a technical committee to develop regulations related to Articles 9 and 10, and is working to adopt and implement them in the near future.
- The whole region faces similar challenges as flavoured tobacco is a big menace and is not tested in most countries.
- The Working Group should assist in the completion of the partial guidelines.

Mauritius

- Articles 9 and 10 have not been adopted and implemented, as they do not form part of the national tobacco control legislation. The reason behind this is the complexity of these articles.
- <u>Challenges</u>: There are no testing laboratories in the country and one major reason is the legal uncertainty in terms of jurisdiction, as all the laboratories come under the Ministry of Agro Industry and Food Security.
- The tobacco control law is being revised, with technical assistance from WHO and certain provisions of Articles 9 and 10 have been incorporated in the new amended law.

Kenya

- <u>Challenges</u>: Lack of technical capacity to understand and implement Articles 9 and 10 at the national level and tobacco industry interference are major obstacles. The launch of new products and ambiguities between natural and synthetic nicotine lead to further



confusion while implementing tobacco control law.

- Internet marketing and sale of tobacco products is a challenge in the African region.
- Tobacco industry interference is a big challenge, especially with the launch of new products and continuous litigation threats. There is a specific case in the court on regulations related to Articles 9 and 10.
- A regional meeting on Articles 9 and 10 for policy and technical people could help in moving forward national implementation of Articles 9 and 10.
- The Working Group is important, and its mandate could be expanded. It is also relevant because there are new innovations by the tobacco industry

Maldives

- The government is committed towards tobacco control and a law was adopted in 2010. However, the level of implementation is insufficient, as the regulations/guidelines under the law impede it.
- <u>Challenges</u>: There are no laboratories and tobacco is not a priority in terms of establishing laboratories and testing tobacco products.
- Despite being a small country, Maldives still needs more workforce to understand and work on tobacco control. The delegates representing the country at COP mostly do not have the expertise in tobacco control and they look at it with a very different perspective, and lak a holistic understanding.
- The partial guidelines on Articles 9 and 10 should be completed. And a Knowledge Hub can be used to gather and maintain information on the contents of products, with full access from the Parties.

Brazil

- Brazil is one of the first few countries to adopt and implement measures related to Articles 9 and 10 to fulfil its WHO FCTC obligations under these articles.
- <u>Challenges</u>: The Region of the Americas (AMR) does not prioritize Articles 9 and 10, and the product complexity and analytical difficulties contribute to the obstacles. There is also constant tobacco industry interference by way of court cases, lobbying and introduction of new products.
- <u>Achievements</u>: Brazil and Canada have almost full implementation of Articles 9 and 10. However, the rest of AMR is lagging on this account. Uruguay has banned ammonia, and Colombia and Panama have mandated disclosure of tar, nicotine and carbon monoxide (TNCO).
- The partial guidelines should be finalized; the name "partial" is not appropriate; and an expert group could be used to prepare draft texts for the guidelines.
- For testing and measuring the contents and emissions, the expensive component is the testing of emissions. Tobacco product content could be tested with existing laboratories used for testing food, medicines, etc.
- COP should put forward the TobLabNet method for use and Parties need to know who the members of TobLabNet are.
- The Working Group could possibly finalize the partial guidelines, recommend methods



and guide discussions around legal measures and laboratory network.

India

- <u>Challenges</u>: lack of understanding of Articles 9 and 10, low priority by the government earlier, and technical obstacles like training and hiring of scientific staff were major obstacles while implementing Articles 9 and 10.
- <u>Achievements</u>: The government now prioritizes implementation of Articles 9 and 10, and in a short span of time it has set up three tobacco testing laboratories, covering three diverse locations.
- It is the first time, such laboratories have been set up to test smokeless tobacco, which is highly prevalent in India and neighbouring countries. The major laboratory established in New Delhi is also a WHO FCTC Secretariat's Knowledge Hub that aims to provide assistance to other Parties.
- There is little or no interference from tobacco industry, especially on the implementation of Articles 9 and 10. It is the bureaucracy and infrastructure that delays the success sometimes.
- The Convention Secretariat has supported the setting up of laboratories in India

Canada

- <u>Achievements</u>: Canada is making efforts in the right direction and with regulations like a ban on menthol. It is important to evaluate the impact of the adopted regulations, so that it can be documented as a lesson for other countries.
- Many Parties cannot comprehend the information generated and shared on Articles 9 and 10, which leads to inhibitions in implementing these articles. For example, many governments may not be aware of industry innovations and new products, not allowing them to tackle these challenges in time.

Japan

- <u>Challenges</u>: Japan struggles with the abundance of new tobacco and nicotine products.
- The Tobacco Business Act is to ensure the sound development of the Japanese tobacco industry, but it has provisions on packaging and labelling, as well as on advertising.
- Japan has a WHO collaborating centre on tobacco testing and research. The terms of reference for the WHO collaborating centre include to test tobacco products, provide technical trainings on tobacco content analysis and emissions measurements, support WHO in trainings and research, and provide technical assistance to countries in the Western Pacific Region (WPR) for Articles 9 and 10.
- <u>Achievements</u>: The WHO collaborating centre is a part of the WHO TobLabNet and has expertise in the measurement of contents in tobacco and cigarette filter, mainstream cigarette smoke and gaseous compounds.
- Through activities and research conducted at this WHO collaborating centre, WHO has been able to condemn its claims to promote HTPs.



China

- <u>Challenges</u>: gaps in scientific evidence and research, understanding of addictiveness and toxicity of tobacco products, and lack of precision in laboratories are major factors for low implementation. Development of accurate policies and timeliness of decision making are crucial.
- In order to implement Articles 9 and 10, it is important to a) draw on the best available scientific evidence and the experience of Parties, and 2) propose measures that may assist Parties in strengthening their tobacco control policies.
- A global assessment framework of measures to implement Articles 9 and 10 would provide more specific implementation considerations to Parties. This framework must discuss scientific evidence, legal measures, country experiences and assessment of existing policies.
- The suspended Working Group should focus on collecting existing scientific research and complete a database of available knowledge. It should involve more Parties, more key facilitators, more ways for information exchange and more work led by Parties.

Netherlands (and EU)

- <u>Challenges</u>: Lack of a comprehensive legislation requiring testing and measuring of contents and emissions, lack of product standards and inadequate exchange of information amongst Parties are major obstacles. The other impediments are the complex and technical nature of these articles, scepticism and disbelief about product regulation.
- <u>Achievements</u>: The European Union adopted the Tobacco Products Directive (TPD) in 2014 and the Netherlands complies with it. Articles 9 and 10 are well covered by it and requests Members to ban flavour capsules in filters, harmful ingredients in eliquids and notify any novel tobacco products that appear in their markets, among other important provisions.
- The reporting mechanism on ingredients and emissions through the Common Entry Gate (EU-CEG) is a useful resource that is documenting and collecting information from all the Member States that are on the system already.
- The provisions under the TPD could be improved further, e.g. on prescribed tests to assess health effects of ingredients.

Thailand

- Thailand has a Knowledge Hub that helps identify and provide with strategies and tools to counter tobacco industry interference and promote policy coherence in tobacco control at the national, regional, and global levels.

Discussion

By the end of the session on country experiences, the experts identified reasons for low implementation and possible actions that could work to address the low implementation of these articles, which are summarised as follows:

- Parties discussed that they faced similar challenges in their implementation of Articles



9 and 10 despite being different geographies. Lack of political commitment towards tobacco control and especially for the implementation of Articles 9 and 10 is a major barrier.

- Lack of human resources and insufficient opportunities for capacity building on implementation of Articles 9 and 10 are challenges, as many countries have few people to work on tobacco control programme. In such situations, they tend to prioritize other tobacco control provisions and Articles 9 and 10 remain overlooked.
- Strong scientific background and knowledge are essential to understand and implement Articles 9 and 10. Many Parties lack the strong expertise required to implement these articles at the country level.
- There are Parties that do not have access to laboratories for testing tobacco products and in some countries the reason behind this is that tobacco is not a priority in terms of testing and establishing laboratories.
- There is direct and indirect interference from tobacco industry. They tend to delay the steps that advance tobacco control. They make false claims about the harms of tobacco and reject the science and evidence that explains the harms of tobacco.
- There are new ingredients, emissions, constituents and sometimes new products that are added or launched. Parties need all-encompassing understanding to keep up with the changing environment.
- Most laboratories that are available for testing tobacco products are restricted to testing cigarettes. There are many countries, especially in South East Asia, where smokeless tobacco consumption is very high. Therefore, there is a crucial need to build laboratories and capacity to test smokeless tobacco products. India has set up such laboratories, one of which also acts as Knowledge Hub, which other Parties can reach for assistance.
- There are Parties that have extensively implemented the WHO FCTC provisions and especially implemented Articles 9 and 10, e.g. Brazil and Canada have largely implemented these articles. The positive experiences from these two countries need to be documented and shared with other Parties, especially in AMR so that they can adapt these practices for their local context.
- It is important to document positive experiences of adopting and implementing Articles 9 and 10, and their impact on the country, e.g. Canada has a ban on menthol, and it will be helpful to document the impact it has on general population.

Presentations by key informants, based on their field experience in implementation of Articles 9 or 10 and in addressing challenges in tobacco product regulation and disclosures.

As experts presented on country experiences and highlighted the reasons for low implementation for Articles 9 and 10 in their countries, the key informants discussed the practical and technical factors that lead to low implementation. The session also had the Chair of WHO TobLabNet and



the Chair of WHO TobReg briefly discuss their background and mandate. The summary of presentation and key discussion points is as follows:

Presentations

- WHO TobReg was created as an outcome of the WHO FCTC and its mandate is to oversee the implementation of Articles 9 and 10 and establish a network independent of the tobacco industry, integrated by scientists in the fields of product regulation and laboratory analysis of tobacco contents, emissions, and design features.
- The WHO TobReg works on different aspects of these articles the addictiveness, the attractiveness and how tobacco products can be regulated. However, WHO TobReg is more scientific in its functioning. Therefore, it may not have the right expertise for this kind of reporting on Articles 9 and 10. The Convention Secretariat could prepare these reports and share it on its website.
- WHO TobLabNet has come a long way. It seemed like a difficult task earlier, but it worked out as a successful network. It has been into existence for 10 years.
- Before the WHO FCTC came into force, most of the testing of tobacco products was done by the tobacco industry and this was the reason behind creating a network of independent laboratories.
- TobLabNet has come up with 10 methods in just five years and its members are also ready to facilitate implementation of Articles 9 and 10. It can be instrumental in data collection and analysis from different countries.
- Articles 9 and 10 are not prioritized by the Parties and their government. The civil society understands the importance of these articles, but does not have the capacity to always support their implementation.

Discussion

- Insufficient clarity on Articles 9 and 10 in the public health ambit, for both government and non-government sectors, leads to a lack of commitment and initiative towards better implementation.
- There is lack of awareness amongst policy makers and government officials. The industry has come out with new products and innovations, and many government officials in certain countries would not be aware of these new products and innovations.
- The research that emanates from Articles 9 and 10 seem unfathomable by Parties and they have inhibitions implementing these. Countries that face challenges in implementing WHO MPOWER policies do not feel ready to understand and implement Articles 9 and 10.
- Parties to the WHO FCTC should get involved and make use of the laboratory network and the technical expertise it offers.



Presentations by observers to the Expert Group on their experiences on implementation of Articles 9 and 10 and related challenges.

Two presentations were made by experts nominated by NGOs on the low implementation of Articles 9 and 10, and their experience in assisting countries to implement the same.

Presentation

- Lesson sharing from different countries is an important feature that can help Parties to understand the challenges and successes in implementing Articles 9 and 10. As an example, the adoption of plain packaging regulations in some countries should be documented as a positive experience, which in combination with the implementation of Articles 9 and 10, it reduces attractiveness.
- Guidelines for implementation of WHO FCTC articles have diverse impact as well. All the guidelines do not necessarily need same action and same stakeholders. There are different needs when implementing these aspects, e.g. banning flavours may be different than implementing other aspects of the respective guidelines.
- Even if countries cannot implement Articles 9 and 10 comprehensively, due to any reasons, they should start implementing certain measures under these articles. For example, few measures that do not need access to laboratories and are less complex are prohibiting flavours, banning menthol, banning slim cigarettes and ingredients that create an impression of health benefits.
- There is lack of information on countries that have implemented different measures, broken down under Articles 9 and 10.
- Information sharing is crucial, as it encourages countries especially in the same region to implement similar provisions. A report/knowledge hub on this is important as a regular feature to update.
- Financing of product regulation and disclosure should rest upon tobacco manufacturers.

Discussion

- The perceived impact of implementation of Articles 9 and 10 may be low, and that could be a reason for low implementation of these articles. Parties need to understand the definite impact Articles 9 and 10 can have on the whole tobacco control program if implemented effectively.
- NGO advocacy is an essential part of tobacco control, including the implementation of Articles 9 and 10. Even if NGOs do not have the technical background, they understand and advocate for important aspects of these articles like banning flavours/menthol.
- Parties need to understand that they do not need enormous technical and financial resources to implement all the provisions of Articles 9 and 10. Expert Group could provide potential solutions and responses. For example, Parties can start with implementing provisions like ban on slims and super slims cigarettes, as these products haver more attractiveness.



- Comprehensible measures, such as banning ingredients and restricting colored cigarettes. It is important to discuss these points, as they are understandable and may be easy to advocate for and adopt.
- The costs to cover the implementation of Articles 9 and 10 should be covered by tobacco manufacturers, through registration fees and dedicated tobacco taxes, for example.

Session 4. Discussion on the factors that impede implementation of Articles 9 and 10, and related partial guidelines, and how to promote the best practices identified among Parties. During the discussion, the experts will come up with specific proposals on how to strengthen implementation of these Articles. Experts will also discuss the need and feasibility of establishing a WHO FCTC Knowledge Hub for Articles 9 and 10, to support the implementation of these articles by the Parties

In the backdrop of the presentations and the discussions from day one, the aim of the second day was to discuss factors that impede implementation of Articles 9 and 10 and present recommendations that can address these discussed challenges. While the experts discussed challenges and possible potential solutions to those challenges, they were also expected to deliberate on the feasibility of a WHO FCTC Knowledge Hub for Articles 9 and 10.

The session started by dividing the participants into two groups, which were provided a list of questions to guide the discussions in relation to the topics identified (Annex 2). After the discussions, the two groups reported back to the Expert Group plenary.

Questions -

- 1. What challenges have you faced while implementing Articles 9 and 10 and their partial guidelines? Please include the following points in your discussion
 - a. For the challenges identified
 - b. Provide examples of successfully addressing those challenges
 - c. What are the options of strengthening implementation of articles 9 and 10 on those areas?
 - d. Make recommendation on how the cop should address those findings/challenges?
- 2. Could you please provide good practices and potential solutions from your countries/regions?
- 3. What are the pros and cons of establishing a Knowledge Hub?
- 4. What actions can to be taken on cigarette ventilation?

5. What should happen with the partial guidelines (how to complete it, what should happen to the working group that is currently suspended)?



The summary of the observations discussed is the following:

- 1. Challenges
- Technical resources:
 - Lack of awareness, clarity and understanding of the potential impact of Articles 9 and 10 in the comprehensive tobacco control strategy amongst regulators, policy makers and NGOs.
 - Inadequate capacity to test tobacco products and no easy access to laboratories in other countries.
 - Lack of testing capacity for non-cigarette products and novel tobacco and nicotine products.
- Communication gap:
 - Complexity (and perceived complexity) of certain provisions under Articles 9 and 10.
 - Perceived low impact compared to other tobacco control measures.
 - WHO FCTC focal points and sometimes government officials do not understand product regulation, either fully or in its complexity. Certain provisions are very difficult to understand. For example, once AMR held a workshop on tobacco control, where most of the participants did not even know about Articles 9 and 10.
- Legal and political challenges:
 - Withstanding legal challenges for some measures is a problem.
 - Lack of political will to implement these articles.
 - No legislation or regulation on Articles 9 and 10 at the national level.
 - Articles 9 and 10 are mostly not part of the national programme on tobacco control, due to a lack of priority or comprehension of what they entail.
- Financial barriers:
 - Setting up costs for a laboratory and machinery are expensive.
 - Cost (financing) and lack of resources (capacity) for some measures (real and/or perceived) are an issue for many Parties.
- Tobacco industry:
 - Interference from the tobacco industry becomes challenging, especially because there is lack of expertise in the government to manage Articles 9 and 10.
 - Tobacco industry engages in litigation, especially against implementation of Articles 9 and 10.



- 2. Potential Solutions and good practices
- Knowledge and capacity building:
 - There is a need for more awareness about product regulation through tools needs assessment and checklist; stepwise guide for implementation of Articles 9 and 10: roadmap, quick wins, prioritization.
 - It is crucial to raise the understanding that not all Parties need to have their own laboratories; besides, any laboratory in the region should provide assistance. The cost of testing and transportation of the samples could be facilitated.
- Communication:
 - Clarity on the understanding of Articles 9 and 10 is crucial to avoid misconceptions about these articles.
 - Advocacy for Articles 9 and 10 through campaigns, workshops, webinars, and simple policy briefs should be promoted.
 - Public reports listing all countries that have implemented each of the specific measures and the guidelines could be developed.
- Financial Resources:
 - $\circ\,$ A roadmap on the estimated costs to implement Articles 9 and 10 should be developed.
 - There should be dedicated financial contribution from Parties and donors for Articles 9 and 10.
 - Public report of/by countries on costs and financing by the industry should be make available.
 - A potential solution for the financial constrain is that the tobacco industry should bear the costs. For example, in the United States o America and the United Kingdom the tobacco industry is expected to cover the costs under Article 9.
- Collaboration between the Convention Secretariat, WHO and Member States:
 - TobLabNet testing methods for smoking products should be popularized. As there are no methods to test smokeless tobacco products, WHO can develop standard operating procedures (SOP) to test these products.
 - Develop business model for sustainable financial solutions to support work on Articles 9 and 10, e.g. financing of TobLabNet.
- International collaboration:
 - A needs assessment on testing and laboratories should be conducted by either WHO, Convention Secretariat or TobLabNet.
 - It is essential to collaborate and share such examples with the other regions.
 - Regional integration groups should be involved in regional policy making.
 - Non-communicable diseases should be integrated with the Sustainable Development Goals. This can give a push to overall tobacco control strategy.



- Parties should partner to visit different laboratory sites to learn and share models.
- 3. Feasibility of a Knowledge Hub
- Knowledge Hubs provide tools for Parties; technical support on the implementation of the treaty and on litigation cases; and assistance to monitor industry activities.
- Knowledge Hubs can raise the visibility of Articles 9 and 10, offer specialized knowledge and facilitate/platform for international and regional cooperation.
- Knowledge Hub could be a response to increase the understanding around Articles 9 and 10. However, as there is limited knowledge on these articles, it is important to discuss the leadership and functioning of Knowledge Hubs.
- Tobacco industry consistently makes efforts to influence in the technical area and a Knowledge Hub could help counter their interference.
- Even if a Knowledge Hub is created on Articles 9 and 10, it is imperative to make sure that there is no overlap or duplication of efforts and activities between the Knowledge Hubs and WHO collaborating centres.
- Sometimes, there is lack of information on WHO collaborating centres amongst Parties and they are unable to use the expertise. There are 800 WHO collaborating centres, out of which, 16 are on tobacco control, representing all the WHO regions.
- 4. Action on cigarette ventilation
- There was a separated meeting on cigarette ventilation prior to the Expert Group meeting. The Expert Group awaits the minutes of the meeting to develop their thoughts and viewpoints.
- There is lack of knowledge in the area of cigarette ventilation. The meeting held on the issue, provided a good foundation to the experts.
- Only one group discussed this issue during the breakout session; the other group could not reach this topic.
- 5. <u>Status of Partial Guidelines and Working Group on Articles 9 and 10</u>
- Experts had different perspectives on the partial guidelines and the Working Group.
- It was discussed that the title of the guidelines should remain as 'partial', since the guidelines are not complete, and still have some blanks. However, another view was that the title could discourage implementation sometimes.
- For the Working Group, the perception is that of it being too political in nature; therefore, it may be better to have an Expert Group on the issue of Articles 9 and 10.
- It is understood and agreed that the Working Group should remain suspended, as it could sometimes be too political and have different ways/processes of functioning.

Session 5. Upcoming work and next steps

The Chair led the Expert Group to discuss and agree upon the next steps and timelines to develop the report to COP9.



- The background report will be finalized by January 2020, which will be comprehensive, with more information from Parties and the information provided by the experts.
- The report to the COP9 will be drafted by 1 March 2020, and reviewed by the Chair and the experts by 15 March 2020 and 15 April 2020, respectively.
- The report will be finalized by 15 May 2020 and ready for circulation to the COP 60 days before the opening of COP9.

At the end of the meeting, words of thanks were given by the Chair, by the members of the Expert Group, and by the Convention Secretariat. The Government of the Netherlands and RIVM were thanked and appreciated for the organization of this meeting and their kind hospitality.

The Chair then closed the meeting.



ANNEX 1

Meeting of the Expert Group on Articles 9 and 10 of the WHO FCTC

21 November – 22 November 2019 Bilthoven, Netherlands

8 November 2019

Provisional programme (annotated)

DAY 1: THURSDAY, 21 NOVEMBER 2019

08:30 - 09:00 Registration

09:00 - 10:45 Session 1: Opening and introduction

- 09:00 09:20: Welcome and opening
 - A representative of the Government of the Netherlands will open the meeting and welcome the participants.
 - The Head of the Secretariat of the WHO FCTC and the Protocol will deliver her opening address.
- 09:20 09:45: Introductions
 - Round of introductions by all participants.
- 09:45 10:00: Objectives of the meeting: adoption of the agenda and method of work
 The Convention Secretariat will introduce the objectives of the meeting, the proposed agenda and the method of work.
- 10:00 10:15 Review of the Terms of Reference and mandate of the Expert Group
 The Convention Secretariat will provide a short overview of the relevant COP decisions on the implementation of Articles 9 and 10 of the WHO FCTC, and the mandate for this particular Expert Group based on decision FCTC/COP8(21).



10:15 – 11:15 Session 2: Setting the scene: background information to support the discussions including on implementation of Articles 9 and 10 of the WHO FCTC, and the related partial guidelines

- 10:15 11:00: Recent background document on implementation of Articles 9 and 10

 Presentation of the background report commissioned by the Convention Secretariat on the factors that impede implementation of Articles 9 and 10, and related partial guidelines, and positive experiences from Parties in addressing implementation barriers, including examples of successful international cooperation.
- 11:00 11:15: Presentation of the WHO perspective
 - A representative from the WHO Prevention of Noncommunicable Diseases Department will present on their perspective of the challenges and lessons learnt on the implementation of Articles 9 and 10.
- 11:15 11:30: Presentation of the discussions and conclusions from the cigarette ventilation meeting (18-19 November 2019, Bilthoven, Netherlands)
 - A representative from the Ministry of Health of the Netherlands will summarize the discussions and main conclusions from the meeting that took place as per decision FCTC/COP8(21).

<u> 11:30 – 11:45 Coffee break</u>

11:30 – 16:45 Session 3: Roundtable discussion: experience with the implementation of Articles 9 and 10, and inter-country collaboration to promote implementation

• 11:45 – 13:15: Presentations by experts nominated by Parties on their experience, both at national and regional level, on the implementation of Articles 9 and 10, including: most pressing challenges, including interference by the tobacco industry with product regulation of contents and disclosures; best practices identified; establishment and operation of laboratories and testing of products in the absence of a national laboratory; applicability and limitations of the test methods referenced in the partial guidelines and/or WHO Tobacco Laboratory Network standard operating procedures.

<u>13:15 – 14:15 Lunch Break</u>

- 14:15 14:45: Continuation of presentations from experts.
- 14:45 15:45: Presentations by key informants, based on their field experience in implementation of Articles 9 or 10 and in addressing challenges in tobacco product



regulation and disclosures. Key informants could also comment on the experiences shared by experts in the previous session.

<u> 15:45 – 16:00 Coffee Break</u>

- 16:00 16:45: Presentations by observers to the Expert Group on their experiences on implementation of Articles 9 and 10 and related challenges.
- 16:00 17:15: Questions and answers and initial discussion with a view to identifying successful practices and implementation challenges, including reasons for low implementation of Articles 9 and 10 and adoption of test methods. The discussions on addressing specific challenges will continue on Day 2.

<u> 17:15 – 17:30 Wrap-up Day 1</u>

DAY 2: FRIDAY, 22 NOVEMBER 2019

<u>09:00 – 09:10 Opening Day 2</u>

- Short summary of proceedings of Day 1.
- Presentation of the programme of work for Day 2.

09:10 - 14:30 Session 4: General discussion

• 09:10 – 11:00: Discussion on the *factors that impede implementation of Articles 9* and 10, and related partial guidelines, and how to promote the best practices identified among Parties. During the discussion, the experts will come up with specific proposals on how to strengthen implementation of these Articles.

11:00 -11:15 Coffee Break

• 11:15 – 12:30: Discussion on the *factors that impede the adoption of test methods* referenced in operative paragraph 7 of decision FCTC/COP8(21) and their application.



During the discussion, the experts will come up with specific proposals on how to strengthen adoption of such methods.

<u>12:30 – 13:30 Lunch Break</u>

- 13:30 14:30: Summary of discussion of possible options for strengthening implementation of Articles 9 and 10, and related partial guidelines, by the Parties.
- 14:30 15:00: Discussion on the need and feasibility of establishing a WHO FCTC Knowledge Hub for Articles 9 and 10, to support the implementation of these articles by the Parties.

<u> 15:00 – 15:15 Coffee Break</u>

15:15 – 16:00 Session 5: Upcoming work and next steps

- *15:15 15:45*: Preparation of the report of the Expert Group to COP9: next steps, milestones and timeline.
- 15:45 16:45: Any other business.

<u>16:45 – 17:00 Closure of session</u>

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ANNEX 2

List of issues for consideration by the breakout groups

Instructions

- 1. Challenges in implementation (Please review the list of challenges below and add to the list any new items that you might identify) Each group to identify 3 most critical challenges
 - For the challenges identified, provide examples of successfully addressing those challenges.
 - What are the options of strengthening implementation of articles 9 and 10 on those areas?
 - Make recommendation on how the cop should address those findings/challenges?
- 2. Provide good practices from your countries/regions.

Also address:

- Pros and cons of establishing a Knowledge Hub.
- Any actions to be taken on cigarette ventilation.
- What should happen with the partial guidelines (how to complete them, what should happen to the Working Group that is currently suspended)?

Challenges:

Technical

- No (independent) laboratories in the country and no easy access to laboratories in other countries.
- Machinery is expensive.
- Lack of testing capacity for non-cigarette products and for novel tobacco products.
- No utilisation of testing methods proposed in the guidelines and those proposed by TobLabNet and TobReg.

Capacity (building) and resources

- Insufficient qualified staff and expertise.
- Insufficient training opportunities.
- Lack of financial resources.
- Raise awareness of existing resources.

Political (including policy)

- No political will.
- No legislation/regulation on Articles 9 and 10.



- Integration of Articles 9 and 10 in national tobacco control strategies, plans and programmes.
- Banning cigarette/filter ventilation.

TI interference

- Challenge development of effective policies and measures.
- Litigation especially against implementation of Article 10 (and 9 as well).

International collaboration (examples and opportunities)

- South-south and triangular cooperation.
- o Needs assessment.
- Involving regional integration groups in regional policy making.
- Integration with NCDs and SDGs.
- Implementation of the Global Strategy.
- Site visits to each other's 'laboratories, for example.

Communication

- Need for more awareness raising: campaigns and simple policy briefs.
- Disclosures to the government and the public.