NOTE

This report was prepared by the International Tobacco Control Policy Evaluation Project (the ITC Project) at the University of Waterloo, Canada. The report aims to provide a global evidence review on the impact of the WHO FCTC on the implementation of tobacco control legislation and the effectiveness of those implementations. Working drafts of the report served as a reference document to support the preparation of the Impact Assessment Expert Group's Report to the COP. The content in this report is current as of 29 June 2016, which corresponds with the time of completion of the Expert Group's Impact Assessment Report to COP7. Any major updates that occurred between the completion of the report (29 June 2016) and October 2016 are indicated in footnotes, where appropriate.

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The International Tobacco Control Policy Evaluation Project

Impact of the WHO Framework Convention on Tobacco Control on the Implementation and Effectiveness of Tobacco Control Measures: **A Global Evidence Review**

June 29, 2016

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Abbreviations

ACS	Acute coronary syndrome
ACT	Alliance for Tobacco Control and Health (Brazil)
AFR	African Region
AFUBRA	Brazilian Tobacco Growers' Association
AMI	Acute myocardial infarction
AMR	Region of the Americas
AMTI	Tobacco Community Alliance Indonesia
ANVISA	National Health Surveillance Agency (Brazil)
BIT	Bilateral investment treaty
BAT	British American Tobacco
BATK	British American Tobacco Kenya Limited
BBC	British Broadcasting Corporation
CACORE	Costa Rican Chamber of Restaurants
CDC	Centers for Disease Control and Prevention (United States of America)
CNTC	China National Tobacco Corporation
CO	Carbon monoxide
CONICQ	National Commission for the Implementation of the WHO FCTC (Brazil)
COP	Conference of the Parties
COTPA	Cigarette and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (India)
CSR	Corporate social responsibility
CTFK	Campaign for Tobacco-Free Kids
DH	Department of Health (United Kingdom)
EC	European Commission

ELONS	Evaluating Long-term Outcomes of NHS Stop Smoking Services (United Kingdom)
EMR	Eastern Mediterranean Region
EU	European Union
EUR	European Region
GATS	Global Adult Tobacco Survey
GATT	General Agreement on Tariffs and Trade
GCGH	Giving Cigarettes is Giving Harm (China)
GHPSS	Global Health Professions Student Survey
GP	General practitioner
GRPs	Gross rating points
GTS	Green tobacco sickness
GYTS	Global Youth Tobacco Survey
HICs	High-income countries
HWL	Health warning label
ICSID	International Centre for Settlement of Investment Disputes
IDRC	International Development Research Centre (Canada)
IGTC	Institute for Global Tobacco Control (United States of America)
ITB	Indian Tobacco Board
ITC	Indian Tobacco Company
ITC Project	International Tobacco Control Policy Evaluation Project
ITGA	International Tobacco Growers' Association
ITIC	International Tax and Investment Center
ITL	Imperial Tobacco Limited
JTI	Japan Tobacco International
KRA	Kenya Revenue Authority
KRW	Korean Won

LICs	Low-income countries
LMICs	Low- and middle-income countries
MICs	Middle-income countries
MOP	Meeting of the Parties
NHS	National Health Service (United Kingdom)
NRT	Nicotine replacement therapy
NTC	National Tobacco Campaign (Australia)
NY TCP	New York Tobacco Control Program
OECD	Organization for Economic Cooperation and Development
OLAF	European Anti-Fraud Office
OMSC	Ottawa Model for Smoking Cessation
POS	Point of sale
PMA	Philip Morris Asia
PMI	Philip Morris International
PPE	Personal protective equipment
RCMP	Royal Canadian Mounted Police
SEAR	South East Asian Region
SDGs	Sustainable Development Goals
SDPC	Singapore duty-paid cigarette
SES	Socioeconomic status
SHS	Second-hand smoke
SPR	Single presentation requirement
SRNT	Society for Research on Nicotine and Tobacco
STMA	State Tobacco Monopoly Administration (China)
TAPS	Tobacco advertising, promotion, and sponsorship
TBT	Technical Barriers to Trade
TII	Tobacco industry interference

Tips	Tips From Former Smokers (United States of America)
TPD	Tobacco Products Directive (European Union)
TPP	Trans-Pacific Partnership
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UMCI	Union Ministry of Commerce and Industry
US	United States of America
USTR	United States Trade Representative
WHO FCTC	WHO Framework Convention on Tobacco Control
WHO	World Health Organization
WLF	World Lung Foundation
WPR	Western Pacific Region
WTO	World Trade Organization

Executive Summary

Tobacco use is the greatest single cause of premature mortality that kills an estimated 6 million people worldwide each year, with the greatest burden of tobacco-related illness and death occurring in low- and middle-income countries (LMICs).

The WHO Framework Convention on Tobacco Control (WHO FCTC) provides an evidence-based framework for the implementation of a broad range of tobacco control measures. Since its entry into force in 2005, the WHO FCTC has become one of the most widely adopted United Nations treaties, with 180 Parties to date. The year 2015 was an important moment in the history of tobacco control, as it marked the milestone of 10 years since the WHO FCTC entered into force, and the launch of the new Sustainable Development Goals (SDGs), a comprehensive, far-reaching, and people-centred set of universal and transformative goals and targets for all countries, both developed and developing, over the next 15 years.

Since the WHO FCTC came into force, a growing number of Parties have reported progress in the implementation of tobacco control legislation, and tobacco use has declined in a large number of high-income countries (HICs). However, more than 80% of the world's one billion smokers live in LMICs, and much progress is still needed in order for the vast majority of countries to achieve the WHO target of a 30% relative reduction in adult tobacco use worldwide by the year 2025.

In accordance with decision FCTC/COP6(13), a group of seven independent experts was established to conduct an overall assessment of the effectiveness of the implementation of the WHO FCTC. This report aims to provide a global evidence review on the impact of the WHO FCTC on the implementation of tobacco control legislation and the effectiveness of those implementations, and working drafts of this report served as a reference document to support the preparation of the Impact Assessment Expert Group's Report to the COP (http://www.who.int/fctc/cop/cop7/FCTC_COP_7_6_EN.pdf). The content in this report is current as of 29 June 2016, which corresponds with the time of completion of the Expert Group's Impact Assessment Report to the COP.[1]

Findings in this report show that the WHO FCTC has been an important driving force for the implementation of tobacco control legislation, as reported by Parties to the Conference of the Parties (COP). While the overall rate and extent of global progress in the implementation of tobacco control legislation varies across countries and policy domains, the Convention has generally had a positive impact on tobacco control.

- The WHO FCTC has contributed to significant and rapid progress in the implementation of effective measures for: protection from exposure to tobacco smoke (Article 8); packaging and labelling of tobacco products (Article 11); education, communication,

[1] Please note that any major updates that occurred during the time period between the completion and release of this report (29 June 2016 to October 2016) are indicated in footnotes, where appropriate.

training and public awareness (Article 12); sales to and by minors (Article 16); and reporting and exchange of information (Article 21).

- The WHO FCTC has contributed to progress in the implementation of measures for: price and tax (Article 6); regulation of tobacco product disclosures (Article 10); tobacco advertising, promotion, and sponsorship (TAPS; Article 13); tobacco dependence and cessation (Article 14); illicit trade (Article 15); and research, surveillance, and information exchange (Article 20), although the overall rate of progress for these measures has been slower and advancements have often been limited to partial implementation.

- The WHO FCTC has generated momentum to support the development of measures for: industry interference (Article 5.3); regulation of the contents of tobacco products (Article 9); economically viable alternatives (Article 17); protection of the environment and health of persons (Article 18); liability (Article 19); and cooperation (Article 22). While there is evidence of recent achievements in some countries, overall progress has been relatively slow.

- The WHO FCTC Treaty text and guidelines have been cited explicitly by a growing number of countries to support new tobacco control measures, and to defend against industry challenges to measures in domestic and international courts.

In spite of these achievements, more effort is needed to advance progress in several areas, and to overcome barriers to the effective implementation of the WHO FCTC. The tobacco industry continues to rely on the use of evolving strategies to further their interests and undermine the implementation of strong tobacco control measures, including continued use of third party actors to influence policymaking and ongoing involvement in global illicit trade. In recent years, the industry is increasingly turning its attention towards the use of litigation to intimidate governments and to challenge tobacco control measures in domestic and international courts. In many countries, progress in the implementation of the Convention continues to be hampered by insufficient capacity, lack of financial support or resources, and poor enforcement.

Findings presented in this report also provide strong evidence for the effectiveness of tobacco control measures that align with the WHO FCTC and its existing guidelines. An extensive body of international research has consistently shown that the implementation of price and tax increases (Article 6), comprehensive smoke-free policies (Article 8), pictorial health warnings (Article 11), mass media campaigns (Article 12), comprehensive TAPS bans (Article 13), cessation interventions (Article 14), and measures to restrict youth access to tobacco products (Article 16) are highly effective strategies to reduce tobacco consumption and tobacco-related health risks, and promote cessation. However, there are still significant gaps in the literature. There is virtually no research to date that evaluates the effectiveness of implementation of measures for the prevention of industry interference (Article 5.3), regulation of contents of tobacco products (Article 9), promotion of economically viable alternatives (Article 17), protection of the environment and health of persons (Article 18), liability (Article 19), and

cooperation (Article 22). In addition, there is limited research that examines the impact of the WHO FCTC by gender and among disadvantaged groups.

Over its first 10 years, the WHO FCTC has served as a powerful tool to initiate, support, and advance national, regional, and global tobacco control efforts. In order to sustain the gains that have been made and to ensure continued progress, future efforts will need to address ongoing challenges to the implementation of the Convention, with a strong focus on actions to counter industry interference with policymaking. Supporting research will also be critical to facilitate the effective implementation of the WHO FCTC, particularly in those policy domains where progress has lagged behind.

Introduction

Tobacco use is the leading cause of premature mortality in the world, resulting in approximately 6 million preventable deaths per year. It is estimated that if current trends continue, tobacco will kill more than 8 million people globally each year, with 80% of premature deaths occurring in LMICs (1-3).

In response to the globalization of the tobacco epidemic, the WHO FCTC was adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 February 2005 (4, 5). The WHO FCTC is one of the most widely adopted United Nations treaties, with 180 Parties as of June 2016. The COP is comprised of all Parties to the Convention and serves as the governing body of the WHO FCTC.

The WHO FCTC is the first treaty that was developed within the World Health Organization (WHO). It obligates Parties to implement a broad range of evidence-based measures to reduce both the demand (Articles 6-14) and supply (Articles 15-17) of tobacco products. The Convention also contains other key provisions that obligate Parties to take actions to ensure the participation of civil society in achieving the objective of the Convention and its protocols (Article 4.7); protect public policies from tobacco industry interference (Article 5.3); have due regard to the protection of the environment and health of persons (Article 18); to consider taking legislative action to deal with criminal and civil liability (Article 19); and establish research and surveillance programmes, and facilitate information exchange and cooperation (Articles 20-22). In addition, Parties are obligated to implement cross-cutting measures including the development of multisectoral tobacco control strategies (Article 5.1), and adoption of tobacco control legislation to prevent and reduce tobacco consumption, nicotine addiction, and exposure to tobacco smoke (Article 5.2(b)). The Convention also recognizes and calls for the provision of financial support for national tobacco control activities (Articles 2 and 26). The Convention imposes specific timelines within which Parties are obligated to implement several provisions under Articles 11 and 13 (within 3 and 5 years after entry into force of the Convention for each Party, respectively) (4, 5).

Guidelines to the WHO FCTC were developed and adopted by consensus in order to assist Parties to meet their obligations under the Convention. The seven guidelines adopted by the COP thus far cover a wide range of provisions of the WHO FCTC: protection of tobacco control policies from industry interference (Article 5.3); price and tax measures to reduce the demand for tobacco (Article 6); protection from exposure to tobacco smoke (Article 8)[2]; packaging and labelling of tobacco products (Article 11); education, communication, training and public awareness (Article 12); tobacco advertising, promotion, and sponsorship (Article 13); and demand reduction measures concerning tobacco dependence and cessation (Article 14). Partial guidelines have been developed for the regulation of the contents of tobacco products and regulation of tobacco product disclosures (Articles 9 and 10); and draft policy options and

[2] Article 8 Guidelines recommend the implementation of comprehensive smoke-free policies within 5 years of entry into force of the Convention for each Party.

recommendations for the provision of support for economically viable alternatives (Article 17), and the protection of the environment and health of persons (Article 18) were adopted by Parties at the sixth session of the COP (COP6, 13-18 October 2014) (6).

Article 33 of the WHO FCTC allows the COP to adopt protocols to the Convention. Only Parties to the WHO FCTC may be Parties to a protocol, and any protocol shall be binding only on the Parties to the protocol in question. The Protocol to Eliminate Illicit Trade in Tobacco Products, the first protocol to the WHO FCTC, was adopted on 12 November 2012 at the fifth session of the COP (COP5, 12 to 17 November 2012) (7). This Protocol was opened for signature from 10 January 2013 to 9 January 2014. It will enter into force on the 90th day following ratification, acceptance, approval or accession by 40 Parties to the WHO FCTC. As of June 2016, there are 54 Signatories and 17 Parties[3] to the Protocol. Once the Protocol enters into force, it will be governed by the Meeting of the Parties (MOP), which will comprise all Parties to the Protocol. The first session of the MOP will be convened immediately before or after the next regular session of the COP following entry into force of the Protocol (8).

The year 2015 marked the tenth anniversary of the WHO FCTC coming into force, as well as the introduction of the SDGs, a comprehensive, far-reaching, and people-centred set of universal and transformative goals and targets for all countries, both developed and developing, over the next 15 years. Over the last decade, an increasing number of countries have passed tobacco control legislation. The prevalence of tobacco use has also declined in a large number of countries, particularly in those with strong policies that align with the WHO FCTC and its guidelines (9-13). Nevertheless, progress in the implementation of the WHO FCTC has been challenging in many LMICs. There is also some recent evidence to suggest that many countries may not be on track to achieve tobacco control targets set out in the WHO global monitoring framework, by the year 2025 (14, 15).

In line with decision FCTC/COP6(13), a group of seven independent experts was established to conduct an impact assessment of the WHO FCTC after its first decade of operation (16). This report presents the findings of a global evidence review on the impact of the WHO FCTC on the implementation of tobacco control measures and on the effectiveness of those implementations. Working drafts of this report were provided to the Expert Group to support their work in the preparation of an Impact Assessment Report, which will be presented at the seventh session of the COP to be held in New Delhi from 7-12 November 2016.

This global evidence review was conducted across all 17 substantive articles of the WHO FCTC, where impact assessment was appropriate:

- Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry (Article 5.3)

[3] There was a total of 17 Parties to the Protocol to Eliminate Illicit Trade in Tobacco Products as of June 2016: Austria, Burkina Faso, Congo, Côte d'Ivoire, Ecuador, France, Gabon, Iraq, Latvia, Mongolia, Nicaragua, Portugal, Saudi Arabia, Spain, Sri Lanka, Turkmenistan, and Uruguay. As of October 2016, six additional Parties (European Union, Gambia, Mali, Panama, Senegal, and Swaziland) have become Parties to the Protocol, bringing the total number of Parties to the Protocol up to 23.

- Price and tax measures to reduce the demand for tobacco (Article 6)
- Protection from exposure to tobacco smoke (Article 8)
- Regulation of contents of tobacco products (Article 9)
- Regulation of tobacco product disclosures (Article 10)
- Packaging and labelling of tobacco products (Article 11)
- Education, communication, training, and public awareness (Article 12)
- Tobacco advertising, promotion and sponsorship (Article 13)
- Demand reduction measures concerning tobacco dependence and cessation (Article 14)
- Illicit trade in tobacco products (Article 15)
- Sales to and by minors (Article 16)
- Provision of support for economically viable alternatives (Article 17)
- Protection of the environment and the health of persons (Article 18)
- Liability (Article 19)
- Research, surveillance, and exchange of information (Article 20)
- Reporting and exchange of information (Article 21)
- Cooperation in the scientific, technical, and legal fields and provision of related expertise (Article 22)

For each of these 17 articles, the global evidence review includes the following sections:

- **Overview**. A brief description of Parties' obligations under the WHO FCTC.
- **Progress in and challenges to the implementation of WHO FCTC measures**. A brief summary of global progress and key challenges in the implementation of WHO FCTC measures, based primarily on reports on legislation and regulations in force submitted to the COP by Parties to the WHO FCTC from 2010 to 2014 (17-19), and findings based on global estimates presented in the 2015 WHO Report on the Tobacco Epidemic (20). Results and conclusions from relevant supporting documents, including published literature and policy reports were also included, where appropriate.
- **Effectiveness of the implementation of WHO FCTC measures.** A summary of key findings of selected scientific studies, commissioned reports, government documents, and other relevant literature on the effectiveness of WHO FCTC-compliant tobacco control measures.

- **Conclusions.** Overall conclusions and brief recommendations based on the key findings of the literature reviews.

Article 5.3

Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry

A. Article 5.3 Overview

Article 5.3 of the WHO FCTC obligates Parties to protect their public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry in accordance with national law. Guidelines for Article 5.3 were adopted at the third session of the COP (COP3, 17-22 November 2008) (21).

B. Progress in the Implementation of Article 5.3

The tobacco industry has a longstanding history of using various direct and indirect tactics to obstruct, delay, or weaken the implementation of effective tobacco control measures (22-28). There is some evidence for recent progress in the implementation of Article 5.3 (19):

- The total number of reporting Parties who indicated that they have taken steps to prevent tobacco industry interference (TII) with tobacco control policies increased from 80 of 146 (55%) Parties in 2012 to 89 of 130 (68%) Parties in 2014.

- In 2014, the two most frequently mentioned areas of self-reported progress included raising awareness of the need for implementation of Article 5.3 within government (14 of 130 (11%) reporting Parties), and the development of codes of conduct, ethical guidelines or administrative policies for civil servants (14 of 130 (11%) reporting Parties).

- In 2014, several Parties also reported the implementation of new measures to counter TII that align with Article 5.3 and its guidelines:

    - Jordan, Ghana, Federated States of Micronesia, Myanmar, Nepal, Solomon Islands, Thailand, and Turkey reported that they have developed or are in the process of developing national guidelines, policies or regulations on the implementation of Article 5.3 in their jurisdictions.
    - Gabon, Gambia, and the Republic of Moldova included references to Article 5.3 in their national tobacco control, health or development plans.
    - Australia and Norway have implemented measures to divest governmental funds of tobacco industry investments.
    - Panama, the Philippines, and Thailand have implemented comprehensive measures to promote and raise awareness of TII with tobacco control policies within governments, and prevent conflicts of interest for government officials and employees.

- The United Kingdom (UK) Government published revised guidance for the country's overseas posts (such as embassies) on interactions with the tobacco industry in accordance with Article 5.3. The document notes that posts should encourage and support full implementation of the WHO FCTC, and should limit interactions with the tobacco industry.

C. Challenges in the Implementation of Article 5.3

Although an increasing number of countries have reported implementing some recommendations included in the Article 5.3 guidelines in recent years, much progress is still needed. According to WHO global estimates, no country has fully implemented Article 5.3 provisions at the best practice level as of 2014 (20). The selective and incomplete implementation of recommendations set out in Article 5.3 guidelines allows the industry to continue to exert influence on tobacco control policies by adapting their strategies to take advantage of gaps in Guideline implementation. Additional opportunities for industry policy influence are created through (29):

- the introduction of tobacco control measures that are restricted to health ministries;
- the lack of measures to limit interactions with the industry that extend to all policymaking venues as well as any third parties acting on behalf of the industry;
- inadequate monitoring of industry activities; and
- the implementation of guidelines through uncodified, working norms.

The tobacco industry has also dedicated vast resources to undermine the implementation of Article 5.3 by using "harm reduction" discourse as an opportunistic tactical adaptation to policy change as opposed to a genuine commitment to promote tobacco harm reduction (30).

Moreover, data on the implementation of Article 5.3 remains limited. Until recently, no systematic assessments of implementation had been conducted at the country level (29,31). Overall, an immense amount of work is still needed in most countries to achieve the primary goals of Article 5.3, and TII continues to be a major barrier in the global implementation of strong tobacco control policies (32-35). The following section provides some examples of how the tobacco industry continues to interfere with the development and implementation of effective tobacco control policies around the world.

Industry interference: Use of strategies that are explicitly covered by Article 5.3 guidelines

Government Partnerships

The tobacco industry continues to maintain and forge partnerships with various branches of government that allow them to influence and manipulate the tobacco control agenda and policymaking.

- The Indian Tobacco Board (ITB) was established in 1975 under the Union Ministry of Commerce and Industry (UMCI) to regulate the tobacco industry. The ITB has a mandate to promote Indian varieties of tobacco and the development of tobacco industry in India. This mandate has not changed even after the Indian Government ratified the WHO FCTC in 2004, and implemented national tobacco control legislation under the Cigarette and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA) in 2003 (36, 37).

In July 2004, the European Union (EU) signed the Philip Morris International (PMI) Anti-Contraband and Anti-Counterfeit Agreement and General Release. Although this legally binding agreement assists the European Anti-Fraud Office (OLAF) to combat illicit trade by allowing access to PMI's invoice-level records and facilities involved in producing contraband, it also gives PMI the power to monitor OLAF's investigators and investigations. Moreover, as part of this agreement, PMI contracts consultants to generate data on illicit trade in Europe which is used to frame the policy debate on illicit trade despite the validity of the data being uncertain (due to a lack of clarity over how it has been produced) and self-serving (38-40). There is also evidence that EU illicit trade agreements with PMI, and three other transnational tobacco companies (Japan Tobacco International (JTI), British American Tobacco (BAT), and Imperial Tobacco Limited (ITL)) are ineffective. Because the agreements contain loopholes, seizure-based payments do not provide incentives for tobacco companies to stop cigarette smuggling, and represent a small fraction of the financial losses due to illicit cigarette trade in the EU (41).

Conflicts of Interest Arising from State-ownership of Tobacco Industry

State-ownership of the tobacco industry may pose challenges for the implementation of Article 5.3 in countries where there is a conflict of interest between a government's economic interests in the industry and its responsibility to protect public health. Governments that hold a major stake in the industry may be less willing to implement tobacco control policies that lead to reductions in tobacco-related revenues. Progress in tobacco control may also be impeded by the inherent conflict of interest that arises when responsibilities for promoting economic performance of the state-owned industry and the implementation of effective policies to reduce tobacco consumption are assigned a single administrative body (42). In 2012, states-owned tobacco companies accounted for 40% of the world's tobacco consumption, and were the primary cigarette manufacturer in 16 countries (43). In the vast majority of these countries, the state-owned tobacco company functions as a monopoly that is wholly owned and operated by the government. In countries without traditional tobacco monopolies, many governments

continue to maintain an interest in the tobacco industry by serving as primary shareholders and investors (42). For example:

- In China, the tobacco industry is both owned and regulated by the government. The China National Tobacco Corporation (CNTC), which is regulated and supervised by the State Tobacco Monopoly Administration (STMA), controls the production and sale of tobacco leaf and manufactured cigarettes in the country. The CNTC and STMA are often referred to as the same institution with different names, as they share the same set of personnel, line of command, and office (44-46).

- British American Tobacco Kenya Ltd. (BATK) has a long history of establishing strong connections with high level politicians. For example, industry documents have shown that former presidents Daniel Arap Moi and Mwai Kibaki had close ties with and expressed support for BATK (48-54). Various BATK executives, including a former chairman and several non-executive directors, have also held prominent political positions (55,56). The Kenyan Government was a major shareholder with BATK up until 2011, after which the government divested all of their BATK holdings (47, 57). Nevertheless, industry documents indicate that the company continues to have high level political connections (56, 57). A 2015 British Broadcasting Corporation (BBC) Panorama investigation also found evidence for ongoing TII with policymaking through the bribery of politicians and civil servants in Kenya and other East African countries by employees of BAT (58).

- In India, 6 of 10 top shareholders in the Indian Tobacco Company (ITC) are government-owned insurance companies (59).

- In the Republic of Korea, the National Pension Fund, which is managed by the Ministry of Health, invested 4.2 trillion Korean Won (KRW) in tobacco, alcohol, and gambling industries from 2009 to 2012, including more than 200 billion KRW for domestic tobacco business and 1.35 trillion KRW for international tobacco business during this time period (60).

Front Groups

The tobacco industry has a long history of using front groups and other third parties to lobby on its behalf to block or weaken effective health policy (35, 61-63). The tobacco industry continues to use third parties to slow the implementation of the WHO FCTC.

- The International Tobacco Growers Association (ITGA) is an organization that is funded and directed by tobacco companies (64,65). It is used by the tobacco industry to mobilise tobacco growers, despite evidence of systematic exploitation of farmers by major tobacco companies. There is recent evidence that this tobacco industry front group aims to derail strong tobacco control measures around the world:

    - In June 2010, ITGA and the Tobacco Community Alliance Indonesia (AMTI) co-hosted a meeting in Jakarta for tobacco growers from Southeast Asia. The

meeting resulted in a call for governments to reject the WHO recommendations to ban tobacco flavourings, and encouraged growers who attended the meeting to lobby against this ban in their home countries (66).

- In October 2010, ITGA provided tobacco farmers in Mexico with stipends and transportation into Mexico City to protest against a proposed tobacco tax increase (67).
- In November 2010, the ITGA, with support from the tobacco industry, mobilized tobacco farmers to oppose and protest draft guidelines for the implementation of WHO FCTC Articles 9, 10, 17, and 18, proposed during the fourth session of the COP (COP4, 15-20 November 2010) in Uruguay (68).
- In 2010, the National Health Surveillance Agency (ANVISA) announced plans to introduce a ban on the use of additives in tobacco products in Brazil. Following this announcement, the Brazilian Tobacco Growers Association (AFUBRA), an ITGA member organization, delivered a petition from tobacco producers, workers and community members to ANVISA to oppose proposed regulations to ban the use of additives in tobacco products (69, 70).

- Tobacco industry front groups in the hospitality sector have contributed to delaying and weakening the implementation of tobacco control policies.

    - In Costa Rica, after new regulations banning tobacco advertising, promotion and sponsorship (TAPS) at point of sale (POS) were finalized in June 2012, BAT and PMI issued pamphlets to merchants throughout 2014 and 2015, endorsed by long-time industry ally and hospitality front group CACORE (the Costa Rican Chamber of Restaurants). These pamphlets falsely claimed that the new regulation permitted the display of cigarette packages at POS, and argued that listing cigarette prices was the consumer's right to information. As of December 2015, TAPS at the POS was still permitted (71).

- The International Tax and Investment Center (ITIC) is an independent, non-profit research and educational foundation that was established in 1993 to promote tax reform and public-private initiatives to improve the investment climate in transition and developing economies. The ITIC works closely with ministries of finance, customs services and tax authorities in 85 countries, as well as international financial institutions including the International Monetary Fund, World Bank, World Customs Organization, and Organization for Economic Cooperation and Development. The ITIC is funded by leading transnational tobacco companies including PMI, JTI, BAT, and ITL; its Board of Directors also includes representatives from each of these companies (72). The ITIC has actively lobbied against policies for increased tobacco taxation and policies that tackle illicit trade, in addition to compiling research that argues against plain/standardized packaging (73-76).

- Following the UK Government announcement that it would consider introducing plain/standardized packaging legislation in November 2010, the tobacco industry

funded third party organizations to lobby the government and mobilized public opposition against the policy (77).

- Third party actors have been increasingly used by the industry to undermine tobacco control in the EU. For example, an analysis of tobacco industry strategies to influence the 2014 Tobacco Products Directive (TPD) found that PMI alone employed more than 160 lobbyists to subvert the TPD, and that 12 of PMI's third party coalition partners played an active role in lobbying against the European Commission (EC) and Parliament and mobilizing opposition (78).

Corporate Social Responsibility

The tobacco industry also continues to fund "corporate social responsibility" (CSR) activities in order to promote a positive image with the public and policymakers.

- A 2013 study showed that tobacco companies continue to use charitable donations to achieve political aims that include the shaping of the tobacco control agenda, securing access to policymakers, and building constituencies. These results provide strong evidence that full implementation of Article 5.3 requires a comprehensive ban on tobacco industry philanthropy (79).

- In 2014, PMI contributed a total of $31.2 million USD to various initiatives for education, empowering women, economic development, and disaster relief around the world (80).

Industry interference: Use of strategies not directly covered by Article 5.3 guidelines

Litigation

Legal challenges have been used by the tobacco industry in order to block legislative and regulatory tobacco control efforts worldwide (35). Since the WHO FCTC came into force in 2005, domestic tobacco litigation has not been as successful as national courts have cited the treaty as a legal foundation for strong tobacco control (81). Nevertheless, the tobacco industry continues to intimidate governments with litigation that is expensive to defend and delays the implementation of effective tobacco control policies. For example, the tobacco industry has recently challenged proposed legislation to:

- Increase the size of health warnings in Thailand (82), Sri Lanka (83), Nepal (84), and India (85,86).

- Introduce graphic health warnings in Paraguay (87), the Philippines (88), and Kenya (89).

- Restrict public smoking in Uganda (90), Kenya (90), Mexico (91), Argentina (92), and Nigeria (93).

- Restrict tobacco advertising in South Africa (90) and Scotland (94).

- Restrict the use of additives in tobacco products in Brazil (95).

- Introduce plain/standardized tobacco product packaging in France (96).

On 22 May 2015, PMI and BAT filed a lawsuit in the UK High Court to challenge forthcoming Standardised Packaging of Tobacco Products Regulations 2015 on the grounds that the new legislation was a breach of intellectual property and a violation UK and European laws on the free movement of goods (97). On 26 May 2015, JTI also filed a High Court action on the premise that plain packaging measures violate the UK's obligations under the WTO TRIPS Agreement (98).[4]

Trade and Investment Agreements

Beginning in the 1990s, the tobacco industry has used trade and investment agreements (that are not directly covered under existing Article 5.3 guidelines) as a basis for making legal threats to delay or prevent the implementation of proposed legislation. For example, in response to proposals to introduce strong tobacco control laws including plain packaging in Canada (99), graphic warning labels in South Africa (100), and a ban on misleading descriptions in the EU (101), the tobacco industry threatened governments that such laws would breach international trade laws and violate intellectual property rights.

In recent years, the tobacco industry has started to use trade and investment agreements, including those overseen by the World Trade Organization (WTO), to support legal challenges against existing tobacco control policies and prevent the implementation of new policies (in both domestic and international tribunals) (28, 35, 102).

- In 2010, PMI launched legal action against the Norwegian Government to challenge legislation banning tobacco product displays in retail stores. PMI argued that the law improperly restricted the free movement of goods, and thereby violated the European Economic Area Agreement (83).

- In 2010, PMI initiated legal proceedings against the Government of Uruguay to challenge legislation requiring 80% front and back pictorial warnings on tobacco product packaging (80/80 Regulations), and a single presentation requirement (SPR) that prohibits tobacco manufacturers from marketing more than one variant of cigarette per brand family. PMI argued that the 80/80 Regulations and SPR were in violation of a bilateral investment treaty (BIT) between Switzerland (PMI's corporate headquarters) and Uruguay, and infringed their intellectual property rights. As of June 2016, Uruguay was still currently defending this legal challenge[5] (103, 104).

[4] In May 2016, the UK High Court dismissed the legal challenges to the Standardised Packaging of Tobacco Product Regulations 2015 that were filed by PMI, BAT, and JTI.

[5] On 8 July 2016, the Government of Uruguay won the legal case against PMI. The World Bank's International Centre for Settlement of Investment Disputes (ICSID) ruled in favour of Uruguay, and rejected PMI's claim that

- On 1 December 2012, Australia became the first country in the world to implement plain/standardized packaging. The tobacco industry has challenged Australia's Tobacco Plain Packaging Act on the grounds that the law is in violation of trade and investment treaties between Australia and other countries.

    - One challenge is from Philip Morris Asia (PMA), on the basis of the claim that legislation violates a BIT between Australia and Hong Kong (105).[6]
    - The other challenge is from five countries - Ukraine, Honduras, the Dominican Republic, Cuba, and Indonesia (of which four have received financial assistance from the tobacco industry) – who have launched formal WTO dispute cases against Australia's plain/standardized packaging legislation based on the grounds that plain packaging laws are inconsistent with rules set out in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the Technical Barriers to Trade (TBT) Agreement, and the General Agreement on Tariffs and Trade (GATT) (106, 107). On 28 May 2015, Ukraine requested to suspend its legal proceedings with a view to finding a mutually agreed solution. The request was accepted by Australia on 29 May 2015, and panel granted Ukraine's request on 2 June 2015 (107).

In recent years, tobacco companies have also directed greater attention towards strategies to shape new trade and investment agreements in order to increase their ability to influence policymaking, and strengthen their capacity to challenge tobacco control policies. For example, PMI has made efforts to influence the Trans-Pacific Partnership (TPP), a major trade and investment agreement (originally proposed by the United States of America (US), who is not a Party to the WHO FCTC) which may eventually cover 40% of the world's population, in order to enhance their power to challenge plain/standardized packaging legislation. Specifically, PMI has made formal requests to the United States Trade Representative (USTR) that would allow them to use the TPP to strengthen corporate access to the policymaking process at the national level; extend current standards of protection for intellectual property rights provided under the TRIPS to trademark use; and provide greater power to litigate against governments directly. This highlights the importance of the implementation of strong restrictions on industry involvement in the policymaking process that extend to all policymaking venues and third parties, as well as the need to develop strategies to counter industry efforts to influence health policy through negotiations of trade and investment agreements that involve non-Parties to the WHO FCTC (29, 108).

Better Regulation Agendas

Many countries have established business-oriented "Better Regulation" practices that generally tend to privilege the interests of corporations in policymaking by requiring consultation with

legislation requiring 80% (80% front, 80% back) pictorial health warnings and single brand presentation were in violation of a bilateral investment treaty (BIT) between Uruguay and Switzerland.

[6] In December 2015, an Arbitral Tribunal at the ICSID dismissed PMA's challenge to Australia's Tobacco Plain Packaging Act, and unanimously ruled that the law was not in violation of a BIT between Australia and Hong Kong.

stakeholders likely to be affected by legislation and enabling these stakeholders to play a key role in providing or contesting evidence for the proposed policy (109). Industry documents provide evidence that the tobacco industry played a central role in implementing Better Regulation into the EU, including making the key tools of Better Regulation - stakeholder consultation and economic impact assessment - mandatory (110). It did so because it anticipated this would make it harder to pass public health policies (109, 110). Subsequent work shows that the tobacco companies have gone on to harness Better Regulation in their efforts to prevent public health policies, successfully using it to weaken and delay the EU TPD and slow the implementation of plain/standardized packaging in the UK (78, 111). A key way they did this was to produce highly misleading evidence and feed this into the consultation process (112-114).

D. Conclusions

One decade after the WHO FCTC entered into force in 2005, there has been very little global progress in the implementation of measures to counter TII. In recent years, a small number of reporting Parties have made advancements in the implementation of Article 5.3 measures to prevent TII with policymaking. However, no countries have fully implemented Article 5.3, and no systematic country-level assessments on the effectiveness of implemented measures have been conducted to date. Opportunities for the industry to continue to exert influence on tobacco control policies are created by the selective and incomplete implementation of Article 5.3 guidelines; the introduction of measures that are restricted to health ministries; and the lack of measures to limit interactions with the industry that extend to all policymaking venues as well as the use of third parties acting on behalf of tobacco companies. The tobacco industry also continues to adapt to and undermine the implementation of Article 5.3 through the use of third party actors to influence policymaking, ongoing involvement in global illicit trade, and engagement in harm reduction discourse. In recent years, trade and investment agreements that are not directly covered under Article 5.3 guidelines, have been increasingly used by the industry to launch legal challenges against tobacco control policies in both domestic and international courts. Many countries have also established “Better Regulation” practices, which tend to privilege the interests of corporations in policymaking. TII continues to be a major barrier to the global implementation of strong tobacco control policies, and the tobacco industry continues to rely on the use of tactics such as litigation, government partnerships, front groups, CSR activities, and “Better Regulation” agendas to further their interests.

Article 6

Price and tax measures to reduce the demand for tobacco

A. Article 6 Overview

Article 6 of the WHO FCTC obligates Parties to adopt pricing and taxation measures in order to reduce tobacco consumption. Guidelines for the implementation of Article 6 were adopted at the sixth session of the COP (COP6, 13 to 18 October 2014) (115).

B. Progress in the Implementation of Article 6

Tax increases that raise the price of tobacco products are recognized as the single most effective population-based strategy to reduce tobacco consumption and encourage cessation among tobacco users (116,117). It is estimated that for each 10% increase in retail prices, consumption will decrease by about 2.5% to 5% in HICs, and by 2% to 8% in LMICs (117-119). Existing studies have also consistently shown that tobacco price increases are particularly effective for reducing tobacco consumption and prevalence of tobacco use among price responsive groups such as youth and persons of low socioeconomic status (120-123).

Implementation of Price and Tax Increases

There is some evidence of progress in the implementation of tobacco pricing and taxation measures from 2010 to 2014 (19):

- The total number of reporting Parties who indicated that they levy excise taxes on tobacco products increased from 90 of 135 (67%) Parties in 2010 to 119 of 130 (92%) Parties in 2014.

- The average proportion of all taxes in the retail price of tobacco products reported by Parties increased from 57% in 2012 to 67% in 2014.

- A total of 46 of 115 (40%)[7] reporting Parties have increased tax rates from 2012 to 2014, with increases to specific tax rates reported by 28 of 115 (24%) Parties; increases to ad valorem tax rates reported by 8 of 115 (7%) Parties; and increases to both specific and ad valorem tax rates reported by 10 of 115 (9%) Parties).

[7] Based on information about tax rates in 2012 and 2014 that was available for a total of 115 reporting Parties.

- A total of 86 of 102 (84%)[8] reporting Parties indicated that they increased the nominal prices of cigarettes from 2012 to 2014.

Implementation of Effective Tax Systems

In recent years, several Parties have made efforts to implement more effective tax systems.

- In 2013, Pakistan and the Philippines replaced their complex, multi-tiered tax systems with simplified two-tier specific tax systems that are not only easier to implement, but also maximize health and revenue impacts and reduce the likelihood of tobacco industry manipulation to circumvent tax increases (20, 124-126).

- Between 2012 to 2014, Chile and Costa Rica changed from a purely ad valorem taxation structure to a mixed excise system that levies both specific and ad valorem taxes (19).

- Longitudinal data collected at a global level by the WHO from 2008 to 2014 shows that mixed and specific tax systems have become more widely used over time. Of 180 countries that had comparable data for all 4 years, roughly equal numbers reported the use of specific, mixed, and ad valorem taxes in 2008. By 2014, more countries reported the use of mixed tax systems (n=61) and specific tax systems (n=57) than purely ad valorem tax systems (n=45) (20).

Implementation of Tax Measures that Account for Inflation

A few Parties have also implemented or adopted plans to impose regular tax increases that are adjusted for inflation in order to decrease the affordability of tobacco products over time and reduce consumption and prevalence.

- The 2012 “Sin Tax” reform in the Philippines includes a provision for an automatic annual 4% increase in cigarette taxes starting in 2018 (127).

- In Canada, tobacco excise rates will be indexed to the Consumer Price Index and automatically adjusted every 5 years effective 1 December 2019 (128).

- In New Zealand, tobacco taxes are increased by the amount of inflation on an annual basis. Tax increases that raise inflation-adjusted prices are also implemented periodically (129).

[8] Based on information about cigarette prices in 2012 and 2014 that was available for a total of 102 reporting Parties.

- In 2013, Australia announced a series of four 12.5% cigarette tax increases effective 1 March 2014. Subsequent biannual increases are scheduled for 1 March and 1 September of each year through 2016, with increases based on average weekly earnings (130).

- As of 2014, the Government of Singapore has implemented increases to tobacco tax rates that account for price elasticity, income, and inflation (127).

C. Challenges to the Implementation of Article 6

There is some evidence for positive trends in the implementation of Article 6 in several countries, particularly in recent years. Nevertheless, most countries have made little or no progress in the implementation of effective price and tax measures, and there is still a strong need for improvement in many areas:

- There has been no change in the number of countries that reported earmarking tobacco tax revenues for different purposes, including healthcare, from 2012 to 2014 (19). According to WHO global estimates, among 30 countries that reported earmarking of tobacco tax revenues for health purposes in 2014, 5 were high-income, 21 were middle-income, and 4 were low-income (20).

- As of 2014, there is still wide variation in the type of taxes applied to cigarettes in different WHO regions. For example, the use of ad valorem only tax systems was most commonly reported in the African region (AFR; 11 of 23 (48%) reporting AFR Parties); use of specific only tax systems was most commonly reported in the Western Pacific region (WPR; 14 of 23 (61%) reporting WPR Parties); and use of mixed excise tax systems was most commonly reported in the European region (EUR; reported by 38 of 48 (79%) reporting EUR Parties) (19).

- According to WHO global estimates, only 10% of the world's people live in countries with sufficiently high tobacco taxes as of 2014.

    - Tax increases between 2012 and 2014 have not resulted in price increases that are large enough to offset growth in real incomes in several countries including Botswana, Cambodia, India, Honduras, Jordan, Republic of Moldova, Romania, and South Africa (20).
    - In low-income countries (LICs) where there have been no changes to or modest increases in price and taxes from 2008 to 2014, cigarettes have become more affordable over time (20).
    - In Cambodia, Indonesia, Lao People's Democratic Republic, the Philippines, Thailand, and Vietnam, where retail prices have failed to keep pace with economic and income growth, cigarettes have become increasingly affordable from 1999 to 2010 (131).

- Raising taxes on tobacco is the least implemented MPOWER measure and the one with the least improvement since 2007. As of 2014, only 33 (out of a total 194) countries levied taxes of more than 75% of the cigarette retail price (20).

- The use of simplified tax systems is still not uniform. In 2014, 37 of 158 countries that levy cigarette excise taxes continue to use complex, tiered tax systems that lead to greater variability in tobacco product prices (20).

- In 2014, less than half of Parties (57 of 130 (44%) reporting Parties) indicated that they prohibit or restrict sales of duty-free tobacco products to international travellers (19).

- The collection of tobacco price and tax data remains challenging, especially for tobacco products other than cigarettes (19).

- Recent findings from a 2016 report show that although the price of cigarettes increased in Bangladesh between 2011-2012 and 2014-2015, income growth more than offset the negative effect of the price increase on cigarette demand. This resulted in a shift from bidi to cigarette smoking. Similarly, while the price in real terms for smokeless tobacco also increased over this time period, this had no impact on affordability due to offsetting income growth. This may have induced switching from smokeless tobacco use to cigarette smoking. These findings suggest the importance of considering multiple types of tobacco products to curb product switching when price increases are implemented, and modifying the tax system to keep pace with inflation and rising income (132).

D. Effectiveness of the Implementation of Article 6

There is growing evidence for tax-driven reductions in cigarette sales and smoking prevalence and substantial increases in tobacco tax revenues in countries where large tax increases have been implemented.

- In Turkey, increased tax rates raised the price of cigarettes by 195% between 2005 and 2011. During this time period, cigarette tax revenues increased by 124%, while cigarette sales decreased by 15.5% (133).

- Following an increase in total taxes on cigarettes from 32% to 52% of the retail price between 1993 and 2008 in South Africa, there was a nine-fold increase in government tobacco tax revenues (134). Tobacco tax increases that doubled the price of cigarettes in the 1990s also led to a decline in smoking prevalence from 33% in the early 1990s to 27% in 2001 (135).

- In Mexico, increases to the specific tobacco tax between 2009 and 2011 raised the total taxes per pack of cigarettes to 69% of the retail price, which contributed to a 30%

decrease in cigarette sales and a 38% increase in government tobacco tax revenues (136).

- Following a series of increases to cigarette tax rates of factory prices in Thailand from 55% in 2009 to 87% in 2012, smoking prevalence during this time period decreased from 32% to 21% (127).

- In Iceland, a 20% tobacco tax increase in 2012 led to a 10% decrease in cigarette sales in 2013 (19).

- The average excise tax per pack increased by 117% in real terms in Brazil between 2006 and 2013, which contributed to a 33% decrease in domestic cigarette sales (19).

- Following a 33% increase in the average tax yield between 2012 and 2013, cigarette sales in Hungary decreased by about 50% in 2013 compared with 2008 to 2009 (19).

- In the Ukraine, a nine-fold increase in the weighted average of cigarette excise tax between 2008 and 2013 resulted in a 40% decline in cigarette sales and a three-fold increase in tobacco tax revenues during this period (19).

E. Conclusions

Since the WHO FCTC came into force in 2005, there has been some progress in the implementation of tobacco price and tax policies in a small number of countries. Over the last decade or so, the implementation of large cigarette tax increases in a few countries have led to substantial increases in tax revenues in addition to marked reductions in cigarette sales and smoking prevalence. Recent trends also show that from 2012 to 2014, more than one-third of reporting Parties have increased tax rates (46 of 115 (40%) Parties), and the vast majority of reporting Parties have increased the nominal price of tobacco products (86 of 102 (84%) Parties). In recent years, a small number of Parties have also adopted tax measures that account for inflation in order to ensure that tobacco products become progressively less affordable over time. However, overall global progress in the implementation of Article 6 has advanced slowly in comparison to other substantive articles of the WHO FCTC. Many Parties continue to use ineffective tobacco tax structures — in 2014, purely specific or ad valorem tax systems that fail to increase the real prices of cigarettes were still used by Parties in all WHO regions, with the exception of Parties in the EUR. Cigarettes have also become increasingly affordable in LMICs where tax increases have failed to keep pace with economic growth and inflation. Finally, the majority of countries around the world do not maximize the health impact of tobacco tax increases by dedicating tobacco tax revenues to health.

Article 8

Protection from exposure to tobacco smoke

A. Article 8 Overview

Article 8 of the WHO FCTC obligates Parties to adopt and implement legislative and other measures providing for protection from exposure to tobacco smoke in indoor public places, workplaces, public transport, and, as appropriate, other public places. Guidelines for the implementation of Article 8 were adopted at the second session of the COP (COP2, 30 June to 6 July 2007) (137).

B. Progress in the Implementation of Article 8

Comprehensive smoke-free laws are among the most effective tobacco control strategies available, and are the only way to protect non-smokers from involuntary exposure to second-hand smoke (SHS) (138, 139). Comprehensive smoke-free laws that are implemented with strong enforcement measures can dramatically reduce indoor smoking, indoor levels of air pollutants, and health harms of SHS among smokers and non-smokers; help smokers to quit; and increase public support for smoke-free laws (140-148).

Since the WHO FCTC came into force in 2005, there has been considerable global progress in the adoption of smoke-free legislation.

- Prior to the ratification of the WHO FCTC, a small number of countries had implemented partial and/or voluntary restrictions on smoking in some public places or workplaces, and no countries had implemented comprehensive smoke-free legislation (149).

- On 29 March 2004, Ireland became the first country to pass a comprehensive smoke-free law which banned smoking in all public places and workplaces, including restaurants and pubs. Thereafter, many countries followed suit after becoming Parties to the WHO FCTC, and scientific evidence became available.

- As of 2014, 49 countries (of which 47 are Parties to the WHO FCTC) have passed comprehensive smoke-free laws, defined as having laws which ban smoking in the following eight places: healthcare facilities; educational facilities; universities; government facilities; indoor offices and workplaces; restaurants or facilities that serve mostly food; cafés, pubs and bars or facilities that serve mostly beverages; and public transport (20) (see Table 1).

- From 2012 to 2014, there has been a steady increase in the number of reporting Parties who stated that they have implemented comprehensive smoking bans in several key

venues, including the following: private workplaces (53 of 146 (36%) Parties in 2012 vs. 59 of 130 (45%) Parties in 2014); restaurants (60 of 146 (41%) Parties in 2012 vs. 68 of 130 (52%) Parties in 2014); and pubs and bars (48 of 146 (33%) Parties in 2012 vs. 59 of 130 (45%) Parties in 2014) (19).

- Based on Parties' self-reported implementation of smoking bans, airplanes, ground public transport, healthcare facilities, educational facilities (universities excluded), government buildings, and universities are the settings with the highest level of coverage by smoke-free laws (19, 20).

- Findings from a 2016 study provide evidence that ratification of the WHO FCTC accelerated the enactment of smoke-free laws for indoor workplaces, restaurants, and bars, with the most rapid increase in the number of countries with WHO FCTC-compliant smoke-free laws in these venues occurring between 2007 and 2012. Results also indicated the WHO FCTC significantly increased the probability of a country adopting smoke-free laws in the years immediately following ratification (150).

Table 1. Year of Highest Level of Achievement in Measures for Protection from Tobacco Smoke * (20)

Country	Date of WHO FCTC Ratification	Year the Highest Level of Achievement was Attained	Level of Compliance with Smoke-free Policy**
Albania	26 Apr 2006	2006	NA
Argentina***	-	2011	Moderate
Australia	27 Oct 2004	2005	Complete
Barbados	3 Nov 2005	2010	NA
Bhutan	23 Aug 2004	2010	Complete
Brazil	3 Nov 2005	2011	Complete
Brunei Darussalam	3 Jun 2004	2012	Moderate
Bulgaria	7 Nov 2005	2012	Moderate
Burkina Faso	31 Jul 2006	2010	Moderate
Canada	26 Nov 2004	2007	Complete
Chad	30 Jan 2006	2010	Moderate
Chile	13 Jun 2005	2013	Complete
Colombia	10 Apr 2008	2008	Moderate
Congo	6 Feb 2007	2012	NA
Costa Rica	21 Aug 2008	2012	Complete
Ecuador	25 Jul 2006	2011	Moderate
Greece	27 Jan 2006	2010	Moderate

Country	Date of WHO FCTC Ratification	Year the Highest Level of Achievement was Attained	Level of Compliance with Smoke-free Policy**
Guatemala	16 Nov 2005	2008	Moderate
Honduras	16 Feb 2005	2010	Moderate
Iran (Islamic Republic of)	6 Nov 2005	2007	Moderate
Ireland	7 Nov 2005	2004	Complete
Jamaica	7 Jul 2005	2013	Moderate
Lebanon	7 Dec 2005	2011	NA
Libya	7 Jun 2005	2009	Moderate
Madagascar	22 Sep 2004	2013	Moderate
Malta	24 Sep 2003	2010	Moderate
Marshall Islands	8 Dec 2004	2006	Moderate
Mongolia	27 Jan 2004	2012	Complete
Namibia	7 Nov 2005	2010	Moderate
Nauru	29 Jun 2004	2009	Moderate
Nepal	7 Nov 2006	2011	Moderate
New Zealand	27 Jan 2004	2003	NA
Pakistan	3 Nov 2004	2009	Minimal
Panama	16 Aug 2004	2008	Complete
Papua New Guinea	25 May 2006	2012	Moderate
Peru	30 Nov 2004	2010	Complete
Saudi Arabia	9 May 2005	2012	Complete
Seychelles	12 Nov 2003	2009	Complete
Spain	11 Jan 2005	2010	Complete
Suriname	16 Dec 2008	2013	Moderate
Russian Federation	3 Jun 2008	2013	Complete
Thailand	8 Nov 2004	2010	Moderate
Trinidad and Tobago	19 Aug 2004	2009	Complete
Turkey	31 Dec 2004	2008	Complete
Turkmenistan	13 May 2011	2000	Complete
United Kingdom of Great Britain and Northern Ireland	16 Dec 2004	2006	Complete
Uruguay	9 Sep 2004	2005	Complete
Venezuela	27 Jun 2006	2011	NA
West Bank and Gaza Strip	-	2011	NA

Not a WHO FCTC Party

* All public places completely smoke-free (or at least 90% of the population covered by complete subnational smoke-free legislation).

**Compliance is assessed in each country by up to five national experts. Average scores were calculated by the WHO from the five expert assessments by assigning two points for highly enforced policies, one point for minimally enforced policies, with a potential minimum of 0 and maximum of 10 points in total from these five experts. Minimal compliance is an average score of 0-2; moderate compliance is 3-7; complete compliance is 8-10 points.

***Argentina signed the WHO FCTC on 25 September 2003, but has yet to ratify the Treaty as of 2016.

C. Challenges in the Implementation of Article 8

The adoption of 100% smoke-free policies is a critical strategy to fighting the tobacco epidemic. There remain, however, several key challenges to the effective implementation of smoke-free laws.

- The tobacco industry continues to use various strategies to delay or obstruct the implementation of smoke-free policies, including lobbying, discrediting scientific evidence on the dangers of SHS exposure, and using pro-industry conducted research to influence policymakers, media, and the public (151).

- In the vast majority of countries, there is still weak enforcement of and low compliance with smoke-free legislation. In 2009, only 2% of the world's population lived in countries where there was high compliance with smoke-free laws (152). In recent years, many Parties continue to experience enforcement-related difficulties that reduce the effectiveness of smoke-free laws (18, 19, 142).

- In many countries, smoke-free legislation still includes exemptions for private workplaces, pubs and bars, and private vehicles (19, 20).

- In 2009, the European (EU) Council called on all EU Member States to introduce measures to provide effective protection against exposure to SHS no later than November 2012. Findings from a 2012 EU Commission report indicated that all EU Member States have adopted at least partial measures to protect citizens against exposure to SHS, and that 17 (63%) EU Member States have enacted and implemented comprehensive smoke-free legislation. While this is a tremendous accomplishment, approximately one-third of EU Member States have yet to implement comprehensive smoke-free legislation that aligns with Article 8 guidelines in accordance with the time set out by the EU Council (141).

- Although an increasing number of LMICs have implemented national smoke-free legislation since the WHO FCTC came into force, overall progress in the implementation of comprehensive smoke-free laws in LMICs has been slow.

- In Latin America, 16 countries have passed strong smoke-free legislation (153). In 2006, Uruguay became the first country in the Americas to become 100% smoke-free by enacting a ban on smoking in all public spaces and workplaces including bars, restaurants, and casinos.
- Despite many political and economic challenges, several countries in the AFR have smoke-free laws that ban smoking in public places and hospitality venues (e.g., Kenya, Zambia, Senegal, Congo, Cameroon, Togo, Chad, Cote d'Ivoire, Madagascar, Comoros, Mauritius, Seychelles, and Uganda). However, many of these countries have yet to implement smoke-free laws for indoor offices.
- China ratified the WHO FCTC in 2005, but has yet to fulfill Article 8 Treaty obligations as of 2016. In recent years, China has taken important steps towards the adoption of a strong and comprehensive national smoke-free law. Since 2008, more than a dozen cities, including the national capital of Beijing, have moved to enact or amend subnational smoke-free public places legislation or directives. Beijing's new smoke-free law, effective 1 June 2015, fully aligns with Article 8 of the WHO FCTC. In November 2014, China's State Council issued a draft Regulation on "Smoking Control in Public Places" which calls for a comprehensive ban on smoking in public places.
- According to WHO global estimates, populations in 88% of LICs continue to be exposed to SHS on account of weak or absent smoke-free laws as of 2014 (20).

- A 2016 study provides some evidence to suggest that the effect of the WHO FCTC on the adoption of smoke-free legislation may decrease over time. Specifically, findings showed that the effect of the WHO FCTC on the enactment of smoke-free laws for indoor workplaces, restaurants, and bars was strongest in the years immediately after ratification. Over time, this effect diminished such that there was a 50% and 75% reduction in the effect of the WHO FCTC at 3 to 4 years and 6 to 8 years post-ratification, respectively (150).

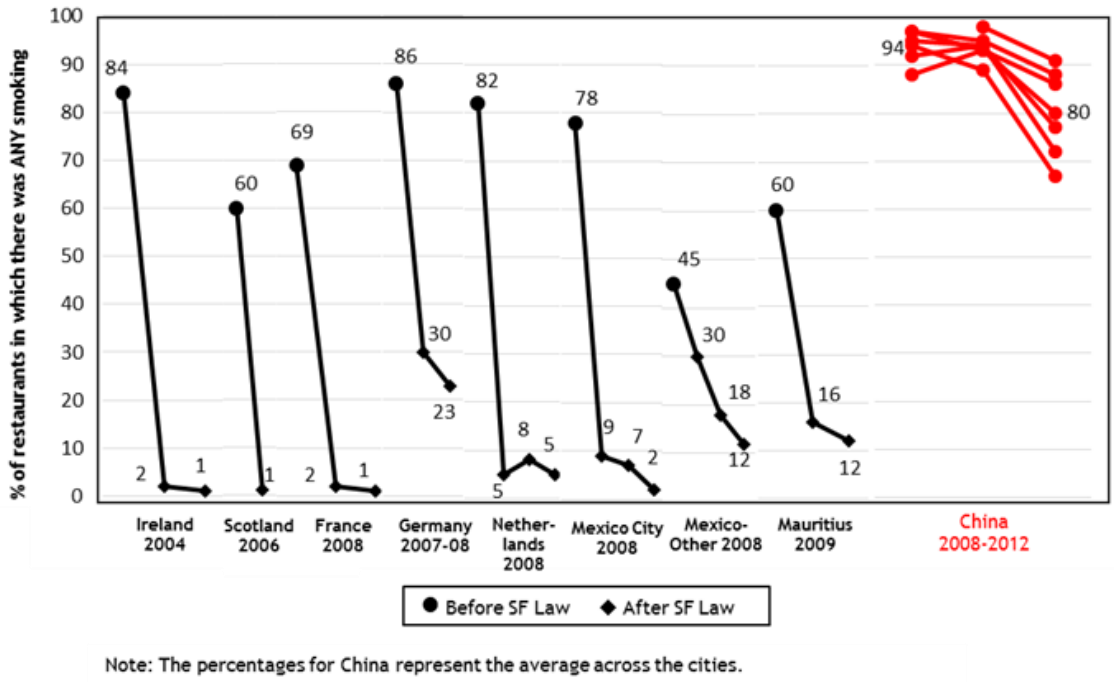
D. Effectiveness of Implementation of Article 8

Comprehensive smoke-free laws can lead to dramatic reductions in smoking in indoor public places

Scientific studies have clearly demonstrated that there are dramatic reductions in smoking indoors in countries where there was strong implementation of comprehensive smoke-free policies:

- The International Tobacco Control Policy Evaluation Project (the ITC Project) has conducted surveys of smokers before and after the implementation of indoor smoke-free policies in workplaces and hospitality venues to evaluate the effectiveness of policies in reducing the prevalence of smoking. Following the implementation of smoke-free legislation in Ireland, Scotland, France, Germany, Netherlands, Mexico City, the rest of Mexico, and Mauritius, there was a dramatic reduction in observed smoking in restaurants. In contrast, the prevalence of smoking in China remains high in the absence of a strong, national smoke-free law (140) (see Figure 1).

Figure 1: Smoking Prevalence Observed in Restaurants in 7 ITC China cities from 2008 to 2012 compared to other countries before and after comprehensive smoke-free laws: Ireland (2004), Scotland (2006), France (2008), Germany (2007-2008), Netherlands (2008), Mexico City (2008), Other Mexican Cities (2008), and Mauritius (2009) (140)**.**



Note: The percentages for China represent the average across the cities.

- Eight to nine months following the implementation of comprehensive smoke-free legislation in the Republic of Ireland, there was a dramatic decline in reported smoking in workplaces (62% to 14%), restaurants (85% to 3%), and bars/pubs (98% to 5%) (144).

- In France, 8 months after the implementation of national smoke-free legislation, there was a near-total elimination of observed smoking in restaurants (71% to 2%), in bars (97% to 4%), and in workplaces (48% to 20%) (145).

- Partial bans on smoking in public places in the Netherlands and Germany were effective in reducing smoking in bars (from 88% to 34% and from 87% to 44%, respectively). However, post-ban reductions in smoking in bars were much larger in Ireland and France, where comprehensive smoke-free legislation was in force (from 97% to 3% and from 84% to 3%, respectively) (154).

Comprehensive smoke-free laws can decrease levels of air pollutants and lead to improvements in air quality

Air quality studies have shown that smoke-free laws lead to dramatic reductions in indoor air pollution, and levels of fine particulate matter less than 2.5 μm in size ($PM_{2.5}$) in bars, restaurants, and other hospitality venues (155-157):

- A 2009 study that examined indoor air quality in 128 smoke-free and smoking-permitted Irish pubs in 15 countries found that the overall level of air pollution inside smoke-free Irish pubs was 93% lower than the level found in pubs where smoking was permitted (158).

- Across 32 countries, $PM_{2.5}$ levels were on average 87% lower in countries with comprehensive smoke-free laws in comparison to countries without comprehensive smoke-free laws in effect (159).

- Evidence from China shows that $PM_{2.5}$ levels are worse in indoor venues which contain SHS, than outdoors, including on heavily polluted days (160-162).

- $PM_{2.5}$ levels were five times higher in public places across Latin America without a smoking ban than in public places with smoke-free bans (157).

Comprehensive smoke-free laws reduce the health harms of SHS among smokers and non-smokers

Comprehensive smoke-free legislation is associated with significant health benefits within relatively short periods of time. A systematic review of 77 published studies examining the impact of smoking bans in 21 countries found consistent evidence of a positive impact of national smoking bans on improving cardiovascular health outcomes, and reducing mortality

for associated smoking-related illnesses. Effects on respiratory and perinatal health were less consistent (13).

Smoke-free laws can rapidly lead to marked improvements in respiratory and cardiac health outcomes:

- Three years after the implementation of a comprehensive workplace smoking ban in Ireland, there was a 13% reduction all-cause mortality, a 26% reduction in deaths from ischemic heart disease, a 32% reduction in deaths from stroke, and a 38% reduction in deaths from chronic obstructive pulmonary disease (163).

- In Uruguay, hospital admissions for acute myocardial infarction (AMI) decreased by 22% in the 2 years following the implementation of comprehensive national smoke-free legislation in 2006 (164). A 4 year post-implementation follow-up continued to show a substantial and sustained drop in AMI admissions (17% decrease over 4 years) (165).

- Ten months after the implementation of comprehensive smoke-free legislation in Scotland, there was a 17% decrease in the number of hospital admissions for acute coronary syndrome (ACS), with non-smokers accounting for 67% of the reduction. In contrast, there was a 4% reduction in ACS hospital admissions over the same time period in England, where smoke-free legislation was not yet implemented (166).

- A 2012 meta-analysis showed that comprehensive smoking bans were associated with significantly lower rates of hospital admissions (or deaths) for coronary events, other heart disease, cerebrovascular accidents, and respiratory disease (167).

- The implementation of smoke-free laws in North America and Europe were associated with substantial reductions in preterm births (10.4% reduction) and child hospital admissions for asthma (10.1% reduction) (168).

Comprehensive smoke-free laws can help smokers to quit

In addition to reducing the amount of toxic chemicals in the air and protecting non-smokers from exposure to SHS, there is some evidence to indicate that smoke-free laws can encourage smokers to quit and discourage youth from initiating smoking (155, 169).

- A 2012 systematic review of smoke-free policies concluded that there was strong evidence that these policies reduce the prevalence of tobacco use, increase the number of tobacco users who quit, and reduce tobacco use initiation among young people (155). However, a 2016 systematic review, found that the evidence of impact of national smoke-free legislation on smoking behaviour was inconsistent. Some studies provided evidence of reductions in smoking prevalence. However, a number of studies did not detect evidence of a change in prevalence, or a change in rate of decline in prevalence,

associated with the introduction of bans, irrespective of the population studies. Four studies identified declining smoking rates in pregnant women, but reductions were not achieved in all studies (13).

- There was a 5.1% increase in quit rates among smokers in the 3-month period prior to the implementation of comprehensive smoke-free legislation in Scotland, and 44% of quitters reported that the smoke-free legislation helped them to quit (170).

- In the Republic of Ireland, 46% of smokers reported that the 2004 smoke-free law made them more likely to quit, and 88% of those who did quit said the law helped them to remain quit (144).

E. Conclusions

Prior to 2005, a limited number of countries had implemented partial and/or voluntary restrictions on smoking in some public places or workplaces, and no countries had implemented comprehensive smoke-free legislation. Since the WHO FCTC has come into force in 2005 and Article 8 guidelines were established in 2007, there has been significant and rapid progress in the global implementation of smoke-free laws. Global progress in creating smoke-free places has been strongly guided by the WHO FCTC. From 2012 to 2014, there has been a steady increase in the number of reporting Parties with comprehensive smoking bans in key venues, including private workplaces, restaurants, and pubs and bars. With a few exceptions, smoke-free laws have been passed by countries after they became Parties to the WHO FCTC. There is a strong body of evidence that comprehensive smoke-free laws can lead to significant reductions in exposure to SHS in key public venues, and improvements in the respiratory and cardiac health outcomes of smokers and non-smokers. There is more limited evidence that smoke-free laws reduce smoking prevalence. Nevertheless, the overall pace of comprehensive legislation, particularly in LMICs, has been slow – as of 2014, 49 countries have enacted comprehensive smoke-free legislation requiring all public places to be completely smoke-free (or at least 90% of the population covered by complete subnational smoke-free legislation). TII continues to be a major barrier to the development, passage, and implementation of effective smoke-free policies worldwide.

Article 9

Regulation of the contents of tobacco products

A. Article 9 Overview

Article 9 of the WHO FCTC obligates Parties to adopt and implement effective legislative, executive, and administrative or other measures for the testing, measuring, and regulation of the contents and emissions of tobacco products. Guidelines for Article 9 have not yet been fully developed. A working group to elaborate guidelines for the implementation of Articles 9 and 10 was established at the first session of the COP (COP1, 6-17 February 2006) (171). Partial guidelines were adopted at COP4 (15-20 November 2010) with amendments adopted at COP5 (12-17 November 2012) (172, 173). The working group submitted a progress report on further development of the partial guidelines for implementation of Articles 9 and 10 at COP6 (13-18 October 2014) (174).

B. Progress in the Implementation of Article 9

The danger and addictiveness of tobacco products has long been established in the scientific literature (175-177). Recent findings have also shown that over the past 50 years, the tobacco industry has used various design features and chemical additives to make cigarettes even more addictive, appealing to youth, and deadly (177, 178). In addition to nicotine, which is the primary drug that is responsible for the development of tobacco dependence, research has also confirmed that both smoked and smokeless tobacco products contain known carcinogens and toxins. Evidence for variation in the levels of carcinogens and toxins by brand both within- and between-countries provides support for the importance of regulations to limit and reduce the harmful components found in tobacco products (176, 179-182). At present, there is sufficient research to support the early stages in the development and implementation of effective Article 9 measures and its partial guidelines. Specifically, existing research has established objective criteria that can be used to define types of tobacco products that might be subject to different regulatory standards, identified a set of carcinogens/toxins to regulate and/or monitor, and provided enough information to create appropriate standardized testing regimes for the carcinogens/toxins that they are intended to regulate and/or monitor (183).

There has been some limited progress in the implementation of Article 9 measures in recent years. For example, a small number of Parties reported the implementation of new or updated legislation to regulate the contents and emissions of tobacco products in the 2014 reporting cycle (19):

- South Africa and the Republic of Korea established new standards for reduced ignition propensity (RIP) cigarettes.

- Malaysia and Singapore implemented legislation that requires the permissible standard emissions of cigarettes to be lowered.

- Brazil passed a new regulation to ban the use of additives and flavourings in all tobacco products, including menthol. This regulation is still under legal challenge and has yet to come into force.

- Under the 2014 TPD, cigarettes and roll-your-own tobacco with characterizing flavours are banned in the EU effective 20 May 2016. In the case of menthol tobacco products and other tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category, the provisions of this Article shall apply from 20 May 2020.

C. Challenges in the Implementation of Article 9

On whole, however, there has been very little or no progress in the implementation of measures for the testing, measuring, and regulation of the contents and emissions of tobacco products (19):

- As of 2014, less than half of all reporting Parties require testing and measuring of the contents and emissions of tobacco products (54 of 130 (42%) Parties and 60 of 130 (46%) Parties, respectively).

- As of 2014, just over half of all reporting Parties regulate the contents and emissions of tobacco products (70 of 130 (54%) Parties and 66 of 130 (51%) Parties, respectively).

The following were also cited as barriers to the implementation of measures for testing and measuring the contents of tobacco products by several Parties in 2014 (19):

- Lack of testing capacity in Colombia, Ecuador, Islamic Republic of Iran (Islamic Republic of), Montenegro, Myanmar, Panama, and Suriname.

- Absence of governmental laboratories for testing and measuring purposes in Georgia.

D. Conclusions

There has been virtually no progress in the implementation of Article 9 measures to regulate, measure, and test the contents and emissions of tobacco products since the FCTC came into force in 2005. As of 2014, only a small number of reporting Parties have made progress in developing and implementing measures that align with Article 9 and some of the recommendations in the partial guidelines. In the vast majority of countries around the world, there is a strong need for governments to work towards adopting legislation that provides them with the authority to regulate the harmful components found in tobacco products.

Article 10

Regulation of tobacco product disclosures

A. Article 10 Overview

Article 10 of the WHO FCTC obligates Parties to adopt and implement effective legislative, executive, administrative or other measures that require manufacturers and importers of tobacco products to disclose information about the contents and emissions of tobacco products to governmental authorities and the public. Guidelines for Article 10 have not yet been fully developed. A working group to elaborate guidelines for the implementation of Articles 9 and 10 was established at the first session of the COP (COP1, 6-17 February 2006) (171). Partial guidelines were adopted at COP4 (15-20 November 2010) with amendments adopted at COP5 (12-17 November 2012) (172, 173). The working group submitted a progress report on further development of the partial guidelines for implementation of Articles 9 and 10 at COP6 (13-18 October 2014) (174).

B. Progress in the Implementation of Article 10

The tobacco industry has a long history of using various tactics to block regulatory bodies from disclosing the ingredients used in their products (184-186). A large body of existing research has shown that both smoked and smokeless tobacco products contain known carcinogens and toxins (175-177, 187, 188) and that tobacco smoke contains more than 7,000 chemicals, including hundreds that are toxic and at least 70 that can cause cancer (189). Studies have also shown that cigarette design features, particularly filter ventilation, account for variations in cigarette tar and nicotine yields (190-192), influence smokers' beliefs about the lightness and smoothness of cigarettes, and contribute to compensatory smoking behaviour (193-195).

There is some evidence for recent progress in the implementation of Article 10 measures in the following areas (19):

- As of 2014, approximately two-thirds of all reporting Parties (86 of 130 (66%) Parties) require the disclosure of information on the contents of tobacco products to governmental authorities.

- There was a slight increase in the total number of reporting Parties who required the disclosure of information on the emissions of tobacco products to governmental authorities from 77 of 146 (53%) Parties in 2012 to 81 of 130 (62%) Parties in 2014.

In 2014, several Parties also reported progress in the development or passage of new legislation that requires the disclosure of information about the contents and emissions of tobacco products (19).

- Fiji, Jamaica, Solomon Islands, and Suriname reported the implementation of new legislation.

- Australia, Bahamas, Colombia, Georgia, Maldives, Panama, Papua New Guinea, Republic of the Republic of Moldova, Senegal, Thailand, Turkmenistan, and Yemen reported that they were in the process of implementing new or updating existing legislation.

- The Netherlands reported the launch of a comprehensive website by the National Institute for Public Health and the Environment with a databank of information on tobacco products and ingredients.

- The 2014 TPD will require strengthened reporting obligations for all ingredients and of tobacco products and emission levels in the EU effective 20 May 2016. For products already placed on the market, that information shall be submitted to competent authorities by 20 November 2016.

C. Challenges in the Implementation of Article 10

Despite the recent progress made by some Parties, there is still room for advancement in the global implementation of Article 10.

- There was virtually no change in the total number of reporting Parties who required the public disclosure of information on the contents of tobacco products from 2012 to 2014 (69 of 146 (47%) Parties in 2012 vs. 70 of 130 (54%) Parties in 2014) and emissions (63 of 146 (43%) Parties in 2012 vs. 64 of 130 (49%) Parties in 2014) (19).

- No reporting Parties to date have implemented legislation that requires industry disclosure of information on design features of tobacco products that are known to influence smokers' sensory perceptions and behaviour.

D. Conclusions

There has been limited progress in the implementation of Article 10 measures since the WHO FCTC entered into force in 2005. As of 2014, fewer than half of reporting Parties have implemented legislation requiring tobacco companies to disclose information on the ingredients and emissions of their products. Research has shown that design features of tobacco products can have an impact on smoking-related perceptions and behaviours. Nevertheless, no studies to date have evaluated progress in the implementation of measures that mandate industry disclosure of such design features. Overall, much improvement is needed for the effective implementation of measures that align with Article 10 and recommendations set out in the partial guidelines.

Article 11

Packaging and labelling of tobacco products

A. *Article 11 Overview*

Article 11 obligates Parties, within 3 years after entry into force of the WHO FCTC, to adopt and implement effective measures to prohibit misleading tobacco packaging and labelling; ensure that each unit packet and package of tobacco products and any outside packaging and labelling of such products carries health warnings and messages that cover at least 50% and shall cover no less than 30% of the principal display areas, and may include pictures; and ensure that tobacco packaging contains information on product constituents and emissions. Guidelines for the implementation of Article 11 were adopted at the third session of the COP (COP3, 17 to 22 November 2008) (196).

B. *Progress in the Implementation of Article 11*

The effectiveness of tobacco health warnings has been studied extensively, and evidence from around the world is largely consistent in its findings. Given their high frequency of exposure among smokers (with pack-a-day smokers being potentially exposed to warnings over 7,000 times per year), reach to non-smokers, and tremendous cost-effectiveness, tobacco health warnings are an extremely important measure for communicating the risks of smoking and reducing tobacco use, especially considering that many tobacco users worldwide underestimate the health effects of tobacco (2, 197-200).

Implementation of Health Warnings

There has been tremendous global progress in the implementation of tobacco health warnings since the WHO FCTC came into force and Article 11 guidelines were adopted.

- Following the ratification of the WHO FCTC in 2005, there was a shift among the public health community in viewing health warnings from a local to global context and an increase in their global diffusion. This, in turn, encouraged the implementation of Article 11 provisions despite strong industry opposition. From 2008 to 2012, there was an increase in the number of countries that required large health warnings on the front of packs (from 43 to 57) and pictorial health warnings (from 18 to 55) (197, 201).
- As of 2013, 161 countries required some form of health warnings on tobacco product packages (142).
- Overall, the number of countries that meet the Article 11 guidelines for health warnings is slowly rising, with the highest implementation rate among middle-income countries (MICs) (2, 20, 116, 142, 152).

Implementation of Pictorial Health Warnings

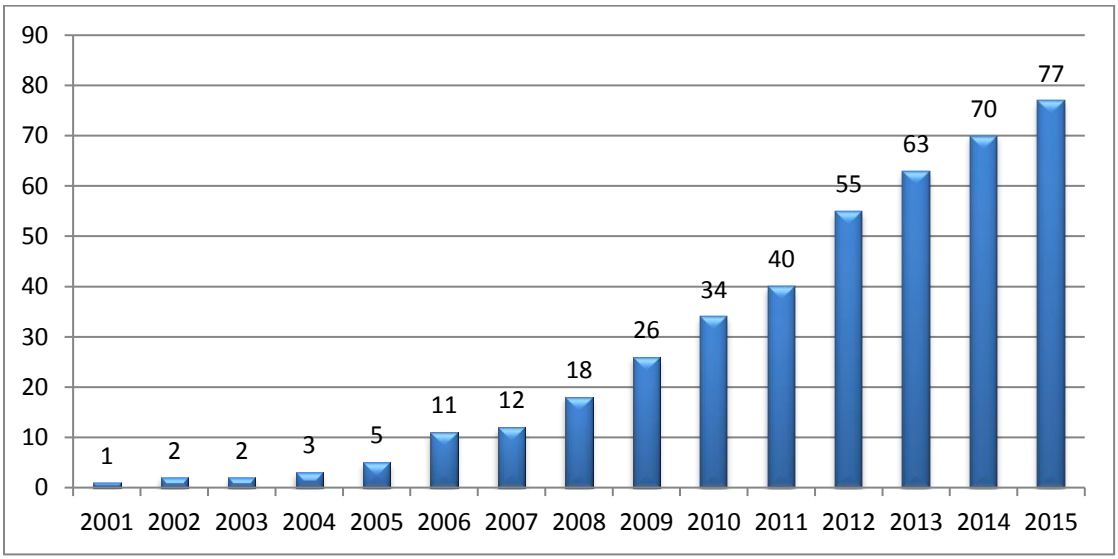
Article 11 guidelines recommend that Parties include pictures in their tobacco health warnings. There has been a dramatic increase in the number of countries that have implemented pictorial health warnings since the WHO FCTC came into force in 2005 (see Figure 2) (197):

- Canada was the first country in the world to implement pictorial health warnings in 2001, prior to the adoption of the WHO FCTC.

- By 2005, the year the WHO FCTC entered into force, five countries had implemented pictorial health warnings.

- Since 2005, there has been a steady increase in the number of countries requiring pictorial health warnings. As of September 2014, 77 countries/jurisdictions have approved legislation for pictorial warning requirements on tobacco packages (including 6 countries with first round implementation dates in 2015). This includes 4 countries/ jurisdictions from the African region (AFR), 23 from the European region (EUR), 12 from the Eastern Mediterranean region (EMR), 19 from the Region of the Americas (AMR), 5 from the South East Asian region (SEAR), and 14 from the Western Pacific region (WPR).

Figure 2. Countries/jurisdictions requiring pictorial health warnings on cigarette packages, 2001-2015.



Source: Canadian Cancer Society, Cigarette Package Health Warnings: International Status Report, Fourth Edition, September 2014 (197).

Size of Health Warnings

Article 11 specifies that health warnings should cover 50% or more of the principal display areas of the tobacco package, but shall cover no less than 30% of the principal display areas. Article 11 guidelines recommend that Parties aim to cover as much of the principal display areas as possible.

- Prior to the start of WHO FCTC negotiations in October 2000, only three countries (Canada, Poland, Thailand) required warnings covering at least 30% of the front and back of the package (202). As of 2014, 134 countries/jurisdictions had health warnings covering at least 30% of the front and back of the package, an increase from 119 in 2012, 95 in 2010, and 68 in 2008 (197).

- As of September 2014, 60 countries/jurisdictions require warnings covering at least 50% of the tobacco package (measured as the average of the front and back display areas). This represents an increase from 2012, when 47 countries/jurisdictions had implemented 50% or greater warnings; 32 in 2010; and 24 in 2008 (197).

- Several countries have implemented pictorial warnings covering much more than 50% of the package. As of June 2016, Thailand and India had the highest average front and back of the pack coverage at 85% (85% front and back), followed by Australia at 82.5% (75% front, 90% back), and Uruguay and Sri Lanka at 80% (80% front and back) (197, 203).[9]

Rotating Messages and Multiple Rounds of Health Warnings

Article 11 requires that warnings shall be rotating in order to maintain saliency and enhance impact. Article 11 guidelines further specify that Parties should consider using two types of rotation: having multiple warnings appear concurrently, and having warnings change after a set period of time.

- As of September 2014, 24 countries/jurisdictions have implemented multiple rounds of pictorial warnings (197). Uruguay is a leader in this category, having implemented eight rounds of pictorial health warnings from 2006 to 2015.

- Of the 161 countries that required health warnings as of 2013, 124 (77%) had rotating health warnings (142).

- The number of Parties with rotating warnings has increased over time, with 101 of 130 (78%) reporting Parties indicating that they had rotating warnings in 2014, up from 105

[9] In 2014, Nepal adopted legislation to increase the size of its pictorial warnings to 90% of the package front and back. As of August 2016, some packages with 90% front and back pictorial warnings have been available on the market in Nepal.

of 146 (72%) Parties in 2012, 81 of 135 (60%) Parties in 2010, and 67 of 117 (57%) Parties in 2009 (17, 19, 204).

Design Features of Health Warnings

Article 11 guidelines specify that health warnings and their messages should be large, clear, visible, and legible, and that culturally appropriate language(s) should be used.

- Of the 161 countries that required health warnings in 2013, 105 countries had laws that mandated the font style, font size, and colour of health warnings on tobacco packages, and 141 countries had health warnings written in the principal language(s) of the country (142).

- As of 2014, 105 of 130 (81%) reporting Parties said that their laws require warnings to appear in the principal language(s) of the country, compared to 93 of 146 (64%) Parties in 2012, and 90 of 135 (67%) Parties in 2010 (17, 19).

Ban on Misleading Descriptors and Quantitative Emission Yields

Article 11 requires Parties to implement measures to ensure that tobacco packaging and labelling do not create any false, misleading, or deceptive impressions about the product. This can include terms such as “low tar”, “light”, “mild”, “ultra”, or any terms/messages that might mislead consumers. Parties should also provide relevant information on constituents and emissions of tobacco products, but this should be done with descriptive text without yield numbers. Article 11 guidelines state that Parties should prohibit the display of figures for emission yields, because they are misleading.

- As of 2014, 101 of 130 (78%) reporting Parties have implemented bans on misleading or deceptive descriptors on tobacco product packaging. This represents an increase from 107 of 146 (73%) Parties in 2012, 88 of 135 (65%) Parties in 2010, and 73 of 117 (62%) Parties in 2009 (17, 19, 204).

- As of 2014, 104 of 130 (80%) reporting Parties require information concerning emissions on packaging (19).

Plain/Standardized Packaging

Guidelines for both Articles 11 and 13 recommend that Parties consider implementing plain/standardized packaging of tobacco products.

- Effective 1 December 2012, Australia became the first country in the world to implement plain/standardized packaging on all tobacco products that are licensed for sale in the country.

- There is now international momentum on plain packaging as other countries have begun to follow Australia's lead by developing or implementing plain packaging legislation of their own (197). In 2015, France, Ireland, and the UK passed legislation for plain/standardized packaging. In France and the UK, all cigarette packs manufactured after 20 May 2016 must be in plain packages. Compliance with plain/standardized packaging at the retail level will be required as of 1 January 2017 in France, and as of 20 May 2017 in the UK. Ireland is awaiting a commencement date (205-208). Other countries that are in the process of formulating plain packaging legislation include Norway, Hungary, Slovenia, Sweden, Finland, Canada, New Zealand, Singapore, Belgium, and South Africa (205). The EU's 2014 TPD (effective 20 May 2015) also states that 28 EU countries have the option of implementing plain packaging (207).[10]

C. Challenges in the Implementation of Article 11

There are ongoing challenges to the effective implementation of Article 11 in several areas:

- At least half of Parties have failed to meet their implementation deadlines for several time-bound provisions under Article 11. In 2014, 65 of 130 (50%) reporting Parties had implemented pictorial health warnings, and 53 of 130 (41%) reporting Parties had implemented health warnings covering more than 50% of the package (19).

- Very few countries have prohibited tobacco companies from placing (on their own initiative) quantitative emission yields on tobacco packaging, as recommended by Article 11 guidelines – as of 2013, only 11 countries have implemented such a ban (142).

- TII is particularly strong in the area of health warnings and can weaken, delay, and obstruct the implementation of effective packaging and labelling measures. For example:

    - The tobacco industry has used various strategies to interfere with the implementation of effective cigarette labelling policies in Latin America, including the prevention of stronger policies by lobbying authorities; signing agreements with health authorities to implement weak policies; undermining implemented policies (e.g., giving away free cigarette package covers); and litigating against policies seeking to block their implementation (209).
    - In China, the State Tobacco Monopoly Administration is responsible for the development and implementation of Article 11, as well as the regulation of the China National Tobacco Corporation, the largest manufacturer of tobacco products in the world. This inherent conflict of interest has been recognized as an impediment to progress in implementation of effective WHO FCTC-compliant tobacco control policies in China, including health warnings (210).

[10] Hungary finalized legislation for plain/standardized packaging in August 2016. This legislation will come into force at the manufacturer level as of 20 May 2018, and at the retailer level as of 20 May 2019.

- While the WHO FCTC has stimulated the diffusion of innovative health warnings worldwide, the tobacco industry continues to use various tactics to prevent and delay further advancements in the global implementation of effective packaging and labelling regulations (201). As such, it will be important for countries to take steps to improve international information exchange and cooperation to work towards the effective implementation of Article 11 provisions (197).

- The tobacco industry has attempted to use litigation to block the implementation of legislation for plain packaging, but thus far, these legal challenges have not been successful. For example, Australia's Tobacco Plain Packaging Act was upheld by both the Australian High Court (August 2012), and an Arbitral Tribunal at the ICSID (December 2015). In May 2016, the UK High Court dismissed a legal challenge to the UK's Standardised Packaging of Tobacco Products Regulations 2015.[11] The 2014 TPD, which will allow EU Member States to implement plain packaging as well as other strong tobacco control policies, was also upheld by the European Court of Justice (May 2016).

- An analysis of health warning implementation in LMICs indicated that states with weaker capacity were less likely to implement WHO FCTC-compliant health warnings, and countries with voluntary health warnings in 1992 were less likely to comply with Article 11 regulations in 2013. These findings provide evidence for path-dependency – that is, once an ineffective policy is put in place, it tends to stay in motion and it is difficult to introduce improvements to an existing policy (211). However, encouragingly, an increasing number of states with weaker capacity are making significant strides with warning requirements.

D. Effectiveness of Implementation of Article 11

Characteristics of Effective Health Warnings

The large body of research on the features of effective health warnings was critical in establishing the guidelines for implementation of Article 11. Studies provide clear evidence that:

- Larger warnings are more visible; allow for a larger font size, pictures, and more information such as links to cessation services; and reduce the space available for promotional branding (197).

- Pictorial warnings are more effective than text-only warnings, because they are noticed more, provide more information, and evoke emotional responses (142).

- Pictorial warnings are particularly effective for those with low literacy (212).

[11] Please see the section on Article 5.3 (Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry) for further details on these court cases.

- Warnings placed near the top of both the front and back of the package have greater visibility and impact compared to warnings near the bottom or only one side of the package (213).

- It is critically important to have warnings on the front of the package, which is displayed and viewed more often (214).

- Photographic picture warnings are perceived as more real and effective than illustrations or cartoons (215).

- Warnings with colour, contrasting text, and large font size are more visible and legible (216).

- Warnings that are rotated and refreshed periodically are more readily recalled (142).

- Warning content that evokes negative emotional reactions, such as fear-arousing or graphic pictures, depicts elements of human suffering, and uses personal testimonials are highly effective (212).

- The inclusion of cessation information for smokers who want to quit is important and may further motivate smokers to quit, and the inclusion of telephone quitline numbers on packaging is a particularly effective means of promoting cessation and raising awareness of cessation help services (2, 213).

- Tar, nicotine, and carbon monoxide emission numbers mislead smokers about the risks of tobacco use and promote the false belief that some tobacco products are less harmful than others, and should be replaced with descriptive information about tobacco constituents and emissions and their health effects (213).

- Brand descriptors such as “light” and “mild” mislead consumers into the false belief that some tobacco products are less harmful than others. Colours are also associated with varying levels of harm; lighter shades such as silver and white are perceived as less harmful than colours such as red (217).

Plain/standardized packaging increases the effectiveness of health warnings, reduces the appeal of packaging, and reduces the ability of the package to be used as a promotional vehicle (197, 218-221). There is also some preliminary evidence for the effectiveness of plain/standardized packaging that was introduced in Australia in 2012 (222). In addition, a Post-Implementation Review by the Australian Health Department in February 2016 concluded that tobacco plain packaging is achieving its primary aim to improve public health. First, The Post-Implementation Review found that plain packaging has decreased the appeal of tobacco products, increased the effectiveness of health warnings, and reduced the ability of tobacco

product packaging to mislead consumers about the harmful effects of tobacco use. Second, the Post-Implementation Review noted that smoking prevalence among Australians aged 14 years and older declined substantially in the 34-month period after implementation of plain packaging and estimated that plain packaging accounted for about one-quarter of this substantial decrease, equivalent to a decrease of about 0.55 percentage points. (223).

Impact of Implementation of Effective Health Warnings

Research evidence has also shown that where health warnings with effective characteristics have been implemented, they have improved knowledge of the health effects of tobacco use, noticeability and cognitive reactions towards the warnings, avoidant and cessation-related thoughts and behaviours, and have also reduced smoking prevalence. Findings from select studies on the effects of implementation of health warning policies are summarized below.

- After Canada became the first country in the world to implement pictorial health warnings in 2001, a study found that smokers who had read, thought about, and discussed the labels were more likely to intend to quit, and to have quit, made a quit attempt, or reduced their smoking at a follow-up 3 months later (224). A 2004 study found that 31% of former smokers reported that the new health warnings motivated them to quit and 27% said the warnings had helped them to remain abstinent (225). A more recent study analyzed the reduction in smoking rates in Canada after the adoption of pictorial health warnings, using the US as a control. The analysis estimated that pictorial warnings in Canada reduced smoking prevalence by 2.87 to 4.68 percentage points, controlling for cigarette prices (226).

- A study by the ITC Project surveyed representative samples of smokers in Canada, the US, the UK, and Australia about their knowledge of tobacco risks; at the time (2002), only Canada had implemented pictorial warnings. The study found that the large Canadian pictorial warnings were most effective in informing smokers about the risks of smoking compared to the smaller text-only warnings in the other countries, and that smokers living in countries with a government-mandated warning about a health risk reported greater knowledge of that risk, demonstrating the importance of health warnings, particularly pictorial warnings, in educating smokers about the harms of smoking (227).

- Another ITC study that followed nationally representative cohorts of smokers in the same four countries over five survey waves from 2002 to 2006 compared the impact of the introduction of larger text-only warnings in the UK in 2003 to the introduction of pictorial warnings in Australia in 2006. The study found that the introduction of pictorial warnings in Australia resulted in an increase in noticing and reading the health warnings, thinking about the health risks and quitting, forgoing cigarettes, and avoiding the warnings, and the increase in these cognitive and behavioural indicators of label impact was greater than the increase in the UK after enhanced text-only warnings were introduced. In addition, though there was some evidence of warning label wear-out in

Canada over time, the impact of the Canadian pictorial warnings was still greater than the newly introduced text-only warnings in the UK (214).

- After Thailand introduced pictorial health warnings in 2005, the percentage of a nationally representative cohort of adult smokers reporting that the warnings made them think about the health risks and made them more likely to quit increased (compared to when warnings were text-only), but no such increase occurred among a nationally representative cohort of adult smokers in Malaysia, where warnings remained text-only over the same time period. In addition, health warning reaction measures significantly predicted subsequent quit attempts in Thailand, but not in Malaysia (228, 229).

- Mauritius was the first African country to introduce pictorial warnings in 2009. ITC survey results from a nationally representative cohort demonstrated that smokers in Mauritius became more aware of the specific health harms of smoking, had more thoughts about quitting, and had stronger emotional reactions associated with quitting after pictorial warnings were introduced (230).

- A cross-country study to evaluate the impact of different styles and content of health warnings used ITC survey data from representative cohorts of smokers from major cities in Brazil, Mexico, and Uruguay. At the time of the surveys, Brazil's warnings covered 100% of the back of cigarette packs and included images of human suffering, disease, and death; Uruguay's warnings covered 50% of both the back and front of packs and contained abstract images of smoking-related consequences; and Mexico's warnings consisted of 50% text-only messages on the back of the pack. The study found that warnings were the most salient in Uruguay, the only country with warnings on both the front and back of the pack, and Brazil's pictorial warnings were as salient as Mexico's text-only warnings, demonstrating the reduced salience of pictures when they are placed only on the back of the package. However, the cognitive and behavioural impact of the warnings was greatest in Brazil, where images were graphic and gruesome, compared to the abstract images in Uruguay and lack of images in Mexico (231).

- A 2011 focus group study and population-based survey in India evaluated the existing warnings on tobacco products, which consisted of a drawing of a scorpion on smokeless tobacco products and a picture or x-ray of diseased lungs on smoked products. Both the focus group discussion and survey found that the majority of respondents did not understand the images and found them to be weak and ineffective. This demonstrates the importance of the content of pictorials on warnings (232).

- A 2015 evaluation of data from the Global Adult Tobacco Survey (GATS) found that adults who noticed health warnings were more knowledgeable about the harms of smoking in 17 of 22 LMICs. Adults who noticed warnings had significantly higher knowledge about the harms of smoking compared to those who did not notice the

warnings in all 9 countries with pictorial health warnings at the time of the survey, compared to only 8 of 13 countries with text-only warnings (233).

- Australia introduced pictorial health warnings in 2006 and for the first time, the warnings included a Quitline number on packages. A study that monitored calls to the Quitline 2 years before and after the new packages were introduced found a substantial and sustained increase in the number of Quitline calls, which doubled in the period after the new warnings were introduced (234). Similarly, after New Zealand introduced pictorial warnings with Quitline information in 2008, there was a sustained increase in the number of new monthly calls to the Quitline and the number of callers reporting that they obtained the Quitline number from tobacco product packaging (235, 236).

- Evidence from the ITC Project demonstrates clearly that pictorial health warnings that are placed only on the front or back of the cigarette pack are less effective than pictorial warnings on both sides of the pack. When pictorial images were introduced in the UK on 40% (plus a border) of the back of the pack (text warnings already appeared on 30% (plus a border) of the front), the percentage of smokers who noticed the new warnings only increased by 1%, and there was less than 1% change in the percentage of smokers who reported giving up a cigarette because of the warnings. In comparison, when Malaysia introduced their pictorial warnings on both sides of the package, noticing increased by 15% and the percentage of smokers who reported giving up a cigarette because of the warnings increased by 33% (237).

- Evidence from Uruguay suggests that larger pictorial health warnings (beyond the WHO FCTC minimum recommended size of 50% of the principal surfaces of the package) have a greater impact. For example, Uruguay introduced the first set of eight pictorial health warnings (PHWs) on 50% of the front and back of cigarette packages in April 2006. In February 2009, eight new PHWs were introduced with no change in size (50%), and beginning February 2010, six new PHWs occupied 80% of the front and back of the pack, becoming the largest in the world at the time. Following changes to the size (50% to 80%), content, and style of PHWs, there was a significant increase on every indicator of health warning impact (238).

- Australia became the first country in the world to implement plain packaging in December 2012, and evidence of its effectiveness subsequent to implementation has recently begun to emerge. Studies have shown that the implementation of plain packaging (along with new, larger health warnings) in Australia has reduced the appeal of tobacco packages (239), increased the salience of and attention orientation toward the health warnings (239, 240), increased avoidant behaviours towards the pack (240, 241), and increased cessation-related cognitions and behaviours, such as calls to the national Quitline (242, 243). In addition, data from the National Drugs Household Surveys showed that adult smoking prevalence fell from 15.1% in 2010 to 12.8% in the second half of 2013 (244). As discussed above, the Australian Government's Post-

Implementation Review estimated that plain packaging accounted for about one-quarter of this 2.3% decrease, or about 0.55 percentage points.

- Findings from a 2015 study provide evidence for the positive impact of the WHO FCTC on the implementation of health warnings in LMICs. Specifically, the odds that LMICs had implemented WHO FCTC-compliant warnings increased by a factor of 1.31 for each year after ratification of the Treaty, and the odds of passing pictorial health warnings increased by 1.47 per year after ratification of the Treaty. Results also indicated that state capacity and the adoption of previous laws influenced whether a country adopted effective health warning legislation (211).

E. Conclusions

Since the entry into force of the WHO FCTC in 2005, international implementation of effective tobacco health warnings has progressed significantly. Prior to the start of WHO FCTC negotiations in October 2000, only one country (Canada) had approved legislation for pictorial warning requirements (for implementation in 2001), and only three countries (Canada, Poland, Thailand) had required warnings to cover at least 30% of the package front and back. As of September 2014, 77 countries/jurisdictions have approved legislation for pictorial health warnings on tobacco packages. The number of countries that require warnings to cover at least 50% (on average) of the front and back of tobacco product packaging has also increased from 1 in 2001 (Canada) to 24 countries in 2008 and to 60 countries in 2014. In 2012, Australia became the first country in the world to implement plain/standardized packaging, and several other countries have since adopted or initiated discussions to develop similar legislation. A growing number of countries are meeting or exceeding Article 11 guideline recommendations for the size, content, and revision of health warnings. Recent evidence also suggests that ratification of the WHO FCTC has improved adoption of effective health warning policies in LMICs. Nevertheless, there are ongoing challenges to the implementation of Article 11. As of 2014, at least half of all reporting Parties have failed to meet their implementation deadlines regarding health warnings and many have not implemented legislation in accordance with Article 11 guidelines. Although the WHO FCTC has encouraged the steady diffusion of innovative health warnings, the tobacco industry continues to use different strategies to interfere with the global implementation of effective packaging and labelling regulations. Given the substantial evidence that health warnings are a cost-effective strategy to communicate the health risks of smoking and encourage cessation, it will be critical for governments to take actions to ensure stronger implementation of Article 11.

Article 12

Education, communication, training, and public awareness

A. Article 12 Overview

Article 12 of the WHO FCTC obligates Parties to promote and strengthen public awareness of tobacco control issues, using all available communication tools, as appropriate. A working group to elaborate guidelines on the implementation of Article 12 was established at the second session of the COP (COP2, 30 June-6 July 2007). The working group submitted a progress report at COP3 (17-22 November 2008), and Article 12 guidelines were adopted at COP4 (15-20 November 2010) (245, 246).

B. Progress in the Implementation of Article 12

Mass media campaigns have the potential to reach large segments of the population, and are a cost-effective public health intervention strategy to reduce smoking prevalence and tobacco-related healthcare costs (247-250). Public education campaigns are most impactful when they are comprehensive and use multiple channels (251), evidence-based and tailored for the target audience (252-254), and sustained (248, 253, 255). Extensive studies have demonstrated that media campaigns can lead to significant reductions in the uptake and prevalence of smoking among youth (123, 177, 252, 256, 257), and encourage quitting and reduce smoking rates among adults (253).

Since the WHO FCTC came into force in 2005, there has been considerable global progress in the implementation of anti-tobacco educational and public awareness programmes (17, 19).

- In 2014, 125 of 130 (96%) reporting Parties had implemented educational and public education programmes since submission of their previous implementation report, which represents an increase from 114 of 135 (84%) reporting Parties in 2010.

- Virtually all reporting Parties had implemented public awareness programmes on the health risks of tobacco consumption (all 130 (100%) Parties), the health risks of exposure to tobacco smoke (129 of 130 (99%) Parties), and the benefits of cessation (125 of 130 (96%) Parties) in 2014.

- More than half of reporting Parties indicated that the development, management, and implementation of educational and public awareness programmes were guided by research from 2012 to 2014 (89 of 146 (61%) Parties and 82 of 130 (63%) Parties, respectively).

C. Challenges in the Implementation of Article 12

Although the vast majority of reporting Parties have made significant progress in the implementation of several Article 12 provisions, there are still some areas where progress remains limited.

- As of 2014, less than half of all reporting Parties (53 of 130 (41%) Parties) have implemented educational programmes covering the economic consequences of tobacco production, and the environmental consequences of tobacco production (19).

- According to WHO global estimates, approximately two-thirds (65%) of LICs have not conducted any kind of sustained anti-tobacco mass media campaign from 2012 to 2014 (20). In 2014, a few reporting Parties noted that lack of sustainable government funding is a major barrier to implementation of Article 12 and its guidelines (19).

- WHO global estimates indicate that there has been no recent change in the proportion of countries who have aired at least one national anti-tobacco mass media campaign featuring all appropriate characteristics, which has remained at about 20% from 2012 to 2014 (20).

- Although tobacco denormalization is increasingly recognized as a key component of comprehensive tobacco control programmes, many jurisdictions are reluctant to engage in overt industry denormalization due to a lack of political will and fear of industry litigation (26, 258, 259).

D. Effectiveness of Implementation of Article 12

Impact of Mass Media Campaigns on Reducing Smoking among Youth

The tobacco industry spends billions of dollars annually to market their products. In 2012, advertising and promotional expenditure by tobacco companies exceeded $9.6 billion in the US alone (260, 261). The tobacco industry specifically targets the youth market. For example, more than 80% of youth smokers report using one of the three most heavily advertised cigarette brands (262). Indeed, the 2012 Surgeon General's report concluded that youth-oriented tobacco marketing causes young people to start and continue smoking (123).

There is a substantial body of evidence from HICs that hard-hitting public education campaigns are effective in limiting the influence of tobacco marketing, preventing the uptake of smoking among youth, and reducing the prevalence of smoking among youth.

- Two years after exposure to mass media and school interventions for cigarette smoking prevention, students from four communities in the US who were exposed to both mass media and school interventions had a significantly lower risk for weekly smoking in comparison to students who were exposed to school interventions only (263).

- A study that assessed changes in cigarette use following implementation of the Florida Pilot Program on Tobacco Control showed a significant pre-post (1998-2000) decrease in current cigarette use among middle school students (from 18.5% to 11.1%), and high school students (from 27.4% to 22.6%). There was also a significant increase in the prevalence of never use among middle school students (56.4% to 69.3%) and high school students (from 31.9% to 43.1%). In addition, there was a significant decrease in the prevalence of experimenting with cigarettes among middle school students (21.4% to 16.2%) and high school students (32.8% to 28.2%) (264).

- Following the launch of the national truth® campaign by the American Legacy Foundation in 2000, there was a significant decline in smoking prevalence among youth in the US. Specifically, smoking prevalence among youth decreased from 25.3% in 1999 to 18.0% in 2002, and approximately 22% of this decline was accounted for by the campaign (265).

- Youth exposed to the truth® campaign in Florida were significantly less likely to have smoked in the past 30 days, to have ever tried smoking, or to indicate that they could not rule out the possibility of smoking in the future (among never smokers) in comparison to their national counterparts from states without established comprehensive tobacco control programmes (266).

- Following the success of a state-wide campaign in California and the truth® campaigns targeting youth in the US, industry denormalization campaigns have been recognized as an effective tool to change perceptions of the tobacco industry and reduce smoking (267, 268). There is a growing body of evidence that industry denormalization campaigns can significantly reduce smoking, and increase anti-tobacco attitudes and beliefs among youth (256, 269-273).

- A Southern California study that examined the longitudinal impact of exposure to pro- and anti-tobacco media on adolescents' susceptibility to smoking found a significant protective effect of anti-tobacco media. That is, 6th grade students who were classified as non-susceptible and exposed to television anti-tobacco advertisements were more likely to remain non-susceptible in the 7th and 8th grades, relative to those who were not exposed to anti-tobacco advertisements (274).

- In 1997, Australia launched the National Tobacco Campaign (NTC), a mass media campaign aimed at highlighting the health effects of smoking and encouraging adult smokers to quit. Although youth were not the primary target group of the NTC, results of a study that examined adolescents' awareness of and response to this campaign showed that it was effective in promoting cessation. More than half (53%) of adolescent smokers reported that the NTC led them to make a quit attempt. In addition, among students who were established smokers, 27% reported that they

reduced the number of cigarettes smoked, and 26% said they thought about quitting because of the NTC (275).

- Exposure to anti-tobacco advertising from 1999 to 2000 contributed to significant reductions in smoking among youth in the US. Youth with mean exposure to at least one state-sponsored anti-tobacco advertisement in the past 4 months were significantly less likely to have smoked in the past 30 days (18.6%) in comparison to youth in markets with no exposure to state sponsored anti-tobacco advertisements (26.7%) (276).

- A 2010 systematic review of mass media interventions to prevent smoking in young people under the age of 25 years found seven studies that met all of the inclusion criteria, including using a controlled trial design (277). Six studies originated from the US and one from Norway. Three studies concluded that mass media reduced smoking among young people. Overall, the review concluded that there is some evidence that mass media can prevent the uptake of smoking in young people, however the evidence is not strong and contains a number of methodological flaws. Effective campaigns lasted a minimum of 3 consecutive years and were also more intense than less successful ones for both school based lessons (minimum eight lessons per grade) and media spots (minimum 4 weeks duration across multiple media channels with between 167 and 350 TV and radio spots). The timing and type of broadcast made a difference to their success, with older youth in one study preferring radio to television. Implementation of combined school based curriculum/components (i.e., school posters) and the use of repetitive media messages delivered via multiple channels (i.e., newspapers, radio, television) over a minimum period of 3 years contributed to successful campaigns. Changes in attitudes, knowledge or intention to smoke did not generally seem to affect the long-term success of the campaigns.

Impact of Mass Media Campaigns on Reducing Smoking among Adults

There is also a substantial body of research from HICs, primarily the US, showing that public education programmes can effectively encourage smokers to quit and prevent non-smokers from taking up smoking, especially when they are sustained and well-funded.

- From 2003 to 2009, the New York Tobacco Control Program (NY TCP) invested approximately $75 million in paid advertising to educate residents about the health risks of smoking and the dangers of second-hand smoke exposure. Over this time period, there was a significant increase in quit intentions (from 26% to 35%) and quit attempts (from 46% to 62%) among adult smokers. In addition, there was an 18% decrease in adult smoking in New York between 2003 and 2009, in comparison to a 5% decrease nationally over this same time period (255).

- Between 1989 and 1992, a statewide anti-smoking media campaign in California reduced cigarette consumption by 10% to 13%, with about one-fifth of the decline accounted for by the media campaign alone (278).

- Media campaigns from 1999 to 2007 have led to significant reductions in adult smoking in the US. Specifically, exposure to state sponsored anti-tobacco advertising was negatively associated with smoking and positively associated with quit intentions among current smokers, even after controlling for potential confounding state tobacco control policies (279).

- A study that examined the impact of anti-smoking ads on quitting status among adult smokers in Boston found that on average, smokers were exposed to more than 200 anti-smoking ads during a 2-year period. Results also showed that exposure to anti-smoking ads was positively associated with quitting. That is, the odds of having quit at follow-up increased by 11% with each 10 additional ad exposures (280).

- In 2012, the US Centers for Disease Control and Prevention (CDC) conducted the Tips From Former Smokers (Tips) campaign, which was the first ever federally-funded national media campaign aimed at reducing smoking. It is estimated that the 2012 Tips campaign motivated 1.6 million smokers to make a quit attempt, and helped 100,000 smokers to quit (247, 281).

- Following the launch of a nationwide mass media cessation campaign targeting the Māori in New Zealand in 2001, 54% of adult smokers stated that the campaign had made them more likely to quit (282).

- A comprehensive social marketing campaign that targeted Arabic-speakers in Australia led to a significant decline in smoking prevalence from 26% in 2005 to 20.7% in 2007 (283).

- In 2009, the Moscow City Duma (Commission on Public Health) worked with the World Lung Foundation (WLF) to adapt the “Sponge’’ campaign for use in the capital city of Russia. Among smokers who recalled the ‘‘Sponge’’ campaign, 43% of adult smokers said that they thought about quitting after seeing the advertisements (284).

- In 2012, 59% adult smokers who saw the “Sponge” campaign in Norway reported that it motivated them to make a quit attempt (142).

- Government-funded tobacco control television advertising from 2002 to 2010 was associated with significant reductions in smoking prevalence and cigarette consumption in England. A 400-point increase in tobacco control gross rating points (GRPs; a measure of per capita advertising exposure combining reach and frequency) per month was associated with a 1.80% reduction in average cigarette consumption in the following

month, and 3% lower odds of smoking 2 months later. This accounted for 11.2% of the total decline in cigarette consumption, and 13.5% of the total decline in smoking prevalence between 2002 and 2009 (285).

- In 2012, a systematic review of published literature on the impact of mass media campaigns on smoking cessation concluded that these campaigns can encourage quitting and reduce smoking rates among adults in HICs, particularly when they incorporate messages that use graphic images and/or testimonials to portray the negative health consequences of smoking (253).

- A 2013 systematic review of the effectiveness of mass media interventions in reducing smoking in adults 25 years or older assessed the evidence based on 11 studies of campaigns of variable scale and quality (286). The studies were conducted in the US (seven studies), Australia (two studies), South Africa (one study), and England (one study). Five large studies out of the nine that reported smoking prevalence found some positive changes in smoking behaviour. Three large studies out of seven that measured the quantity of tobacco smoked found reductions. Four of the seven studies that measured quit rates reported significant increases in abstinence, but this finding was difficult to interpret because studies used different definitions of smoking, smokers, and quit attempts. The review concluded that there is evidence that comprehensive tobacco control programmes that include mass media campaigns can be effective in changing smoking behaviour in adults. The intensity and duration of mass media campaigns may influence effectiveness, but length of follow-up and concurrent secular trends and events can make this difficult to quantify. No consistent relationship was observed between campaign effectiveness and age, education, ethnicity, or gender.

In contrast, only a few studies have evaluated the impact of mass media campaigns on cessation in LMICs:

- In July 2008, the China Tobacco Control Mass Media Campaign was launched by the Ministry of Health and the National Institute of Health Education. Adult smokers who reported being exposed to antismoking messages in newspapers or magazines, and on posters were more likely to have made quit attempts in comparison to those who were not exposed to antismoking messages in these media channels (287).

- A study that examined the impact of antismoking media messages and education at schools on smoking susceptibility among adolescents in Malaysia and Thailand found that only the provision of antismoking education at schools was significantly associated with reduced susceptibility to smoking among females in Malaysia (288).

- In 2009, a national television and radio mass media campaign targeting smokeless tobacco users was aired for 6 weeks in Mumbai, India. An evaluation of this campaign in 2010 showed that smokeless only users who were aware of the campaign were

significantly more likely to have seriously considered quitting, to have stronger beliefs in their ability to quit, and to have made a quit attempt in the previous 2 months than smokeless only users who were unaware of the campaign (289).

- In Bangladesh, 40% of adult smokers who recalled the 2011 "Sponge" campaign reported that they had made a quit attempt in comparison to 10% of smokers who did not recall the campaign (142).

Impact of Mass Media Campaigns on Knowledge of Health Risks of Tobacco Use

There is also some research indicating that mass media campaigns can increase smokers' knowledge of the health risks of tobacco use.

- In 2009, the Alliance for Tobacco Control and Health-WLF (ACT-WLF) mass media campaign that focused on health harms of SHS exposure aired on television in São Paulo, Brazil. Adult smokers who were exposed to the campaign were significantly more likely to believe in the risks of heart disease and mouth cancer from SHS exposure than adult smokers who were not exposed to the campaign (290).

- Adult smokers in British Columbia, Canada were more likely to agree that smoking is bad for their health after being exposed to a 2005 smoking cessation mass media campaign than they were before or during the campaign (291).

- In partnership with the WHO and World Lung Foundation, China launched the Giving Cigarettes is Giving Harm (GCGH) campaign in 2009 to raise awareness of tobacco-attributed diseases and to reduce the social acceptability of giving cigarettes as gifts. Adult smokers in the intervention cities who recalled the campaign via one or more channels had significantly greater levels of campaign-targeted knowledge of smoking harms including stroke, lung cancer in smokers, and cardiovascular disease (292).

- Knowledge of illnesses caused by exposure to SHS among adult smokers in England was highest during the time period when mass media campaigns that highlighted the toxicity of SHS ran (2003 to 2006) in comparison to earlier years (1996 to 2002) (293).

Integration of Mass Media Campaigns With Other Tobacco Control Policies

There is emerging literature to suggest that the impact of WHO FCTC tobacco control policies may be enhanced when they are implemented in conjunction with mass media campaigns.

- The combination of a cigarette tax increase and the "Sponge" campaign from 2009 to 2011 in Mauritius significantly reduced the odds of being a smoker, and significantly reduced the number of cigarettes smoked per day among adults by about 6% (294).

- A study that assessed the effects of pictorial health warning labels (HWLs) and a linked media campaign in Mexico showed that recall of pictorial HWLs in combination with the campaign was positively associated with knowledge of the dangers of SHS. Recall of pictorial HWLs only, of the campaign only, and of both interventions were all independently associated with higher levels of knowledge of the toxic constituents of tobacco smoke, thus providing evidence of an additive effect in the group that recalled both interventions (295).

- There was a significant increase in quit attempts and quit success among adult smokers in the Netherlands following the implementation of a national reimbursement policy for smoking cessation treatment and accompanying media attention in 2011 (296).

- In Australia, the introduction of pictorial health warnings on cigarette packets in 2006 was supported by a televised media campaign highlighting illnesses featured in two of the warning labels — gangrene and mouth cancer. Between 2005 and 2006, awareness that smoking causes gangrene and mouth cancer among adult smokers increased by 11.2% and 6.6%, respectively. In contrast, awareness that smoking causes throat cancer, an illness that was mentioned on cigarette pack warnings but not in television advertisements, decreased by 4.3% (297).

E. Conclusions

Since the mid-1990s, mass media campaigns have become key components of subnational and national level tobacco control programmes to reduce tobacco use. The number of Parties reporting implementation of educational campaigns to increase public awareness of tobacco-related health risks and promote smoking cessation, has continued to increase since the WHO FCTC came into force in 2005. As of 2014, all 130 (100%) reporting Parties indicated that they have implemented educational and public awareness programmes on the health risks of tobacco consumption since submission of their last implementation report. Nevertheless, implementation of Article 12 could be further strengthened by developing more broad-reaching programmes that include messages on the economic and environmental consequences of tobacco production. Overall, the number of countries that have implemented anti-tobacco mass media campaigns has increased from 2010 to 2014. However, virtually all of this progress has occurred in HICs and MICs, and the vast majority of LICs have not yet implemented any national campaigns on the harms of tobacco use or encouraging smokers to quit. There is a strong body of scientific evidence from HICs that well-funded and sustained mass media campaigns that align with Article 12 guidelines are a highly cost-effective strategy for preventing smoking initiation, decreasing the prevalence of smoking, and promoting cessation among youth and adults. Evaluation studies in LMICs are still needed for international comparisons of the impact of anti-tobacco mass media campaigns.

Article 13

Tobacco advertising, promotion and sponsorship (TAPS)

A. Article 13 Overview

Article 13 obligates Parties, within 5 years after entry into force of the WHO FCTC, to implement a comprehensive ban on all forms of TAPS. Guidelines for the implementation of Article 13 were adopted at the third session of the COP (COP3, 17-22 November 2008) (298).

B. Progress in the Implementation of Article 13

The tobacco industry spends billions of dollars each year on TAPS in order to maintain its consumer market, as well as to entice new users to begin smoking (116, 142, 252). Research demonstrates that tobacco marketing and promotional activities can lead to an increase in tobacco consumption by preventing smokers from quitting, and encouraging the uptake of smoking behaviour among youth (142, 252, 299-302).

Since the WHO FCTC came into force in 2005, there has been steady global progress in the adoption of comprehensive TAPS bans.

- Before the WHO FCTC came into force, only two countries (Madagascar and Eritrea) had adopted a comprehensive TAPS ban. Since the ratification of the WHO FCTC, there has been a steady increase in the number of countries that have passed legislation requiring a comprehensive ban on TAPS to a total of 29 countries in 2014 (see Table 2) (20).

Table 2. Year of Highest Level of Achievement in Measures for Banning Tobacco Advertising, Promotion, and Sponsorship * (20)

Country	Date of WHO FCTC Ratification	Year that Highest Level of Achievement was Attained	Level of Compliance with TAPS Ban**
Albania	26 April 2006	2006	Moderate
Bahrain	20 March 2007***	2011	NA
Brazil	3 November 2005	2011	Complete
Chad	30 January 2006	2010	Moderate
Colombia	10 April 2008***	2009	Complete
Djibouti	31 July 2005	2007	NA
Eritrea	-	2004	Complete

Country	Date of WHO FCTC Ratification	Year that Highest Level of Achievement was Attained	Level of Compliance with TAPS Ban**
Ghana	29 November 2004	2012	Complete
Guinea	7 November 2007	2012	Minimal
Iran (Islamic Republic of)	6 November 2005	2007	Complete
Kenya	25 June 2004	2007	Complete
Kiribati	15 September 2005	2013	Moderate
Libya	7 June 2005	2009	Moderate
Madagascar	22 September 2004	2003	Complete
Maldives	20 May 2004	2010	Moderate
Mauritius	17 May 2004	2008	Complete
Nepal	7 November 2006	2014	Complete
Niger	25 August 2005	2006	Complete
Panama	16 August 2004	2008	Complete
Russian Federation	3 June 2008***	2013	Complete
Spain	11 January 2005	2010	Complete
Suriname	16 December 2008	2013	Moderate
Togo	15 November 2005	2012****	Complete
Turkey	31 December 2004	2012	Complete
Tuvalu	26 September 2005	2008	Complete
United Arab Emirates	7 November 2005	2014	NA
Uruguay	9 September 2004	2014	Complete
Vanuatu	16 September 2005	2008	Moderate
Yemen	22 February 2007	2013	Moderate

Not a WHO FCTC Party

*Ban on all forms of direct and indirect advertising. Direct advertising bans cover national television and radio; local magazines and newspapers; billboards and outdoor advertising; and point of sale. Indirect advertising bans cover the free distribution of tobacco products in the mail or through other means; promotional discounts; non-tobacco goods and services identified with tobacco brand names (brand stretching); brand names of non-tobacco products used for tobacco products (brand sharing); appearance of tobacco brands (product placement) or tobacco products in television and/or films; sponsorship, including corporate social responsibility programmes.

**Compliance is assessed in each country by up to five national experts. Average scores were calculated by the WHO from the five expert assessments by assigning two points for highly enforced policies, one point for minimally enforced policies, with a potential minimum of 0 and maximum of 10 points in total from these five experts. Minimal compliance is an average score of 0-2; moderate compliance is 3-7; complete compliance is 8-10 points.

***Date of accession, the international act by which countries that have not signed a treaty/ convention formally state their consent to be bound by it.

****Policy adopted but not implemented by 31 December 2014.

C. Challenges in the Implementation of Article 13

The implementation of comprehensive TAPS bans has increased steadily, however the overall rate of advancement has been slow. There are still several challenges to the global implementation of complete bans on TAPS.

- The tobacco industry continues to engage in efforts to delay, weaken, or prevent governments from implementing TAPS bans or specific measures that are designed to block TAPS. Notably, the tobacco industry has used litigation to challenge packaging and labelling regulations that prevent the industry from using tobacco product packaging as a marketing tool. For example, the industry has recently used trade and investment agreements to launch legal challenges against Australia for its plain/standardized packaging legislation, and Uruguay for its packaging and labelling requirements mandating pictorial health warnings that cover 80% of the front and back of tobacco product packages and a ban on brand variants (19, 20).

- Although many countries have a ban on some forms of TAPS, the vast majority of countries have yet to implement a comprehensive TAPS ban. The following Article 13 provisions have been identified as the most difficult to implement, particularly among HICs: promotional discounts, brand sharing and stretching, POS advertising, and event sponsorship (19, 20).

- Exposure to tobacco marketing continues to be ubiquitous, even in countries that are Parties to the WHO FCTC. For example, a study of tobacco marketing in 16 countries (of which 14 were Parties to the WHO FCTC) found that of 11842 interviewees, 1184 (10%) reported seeing at least five types of tobacco marketing, and 5349 (45%) reported exposure to at least one type of tobacco marketing in the previous 6 months. The frequency and type of tobacco marketing varied by income level and community type – the reported number of tobacco advertisements was 81 times higher in LICs than HICs, and exposure to nearly all types of tobacco marketing was significantly lower in rural communities than urban communities (303).

- Parties have identified the lack of financial and human resources, insufficient political support, and weak monitoring as barriers to the effective implementation of Article 13 (19).

- In the vast majority of countries, TAPS bans do not include provisions that prohibit tobacco displays at POS and advertising via global Internet.

    - In 2014, 70 of 130 (54%) reporting Parties indicated that they had implemented a ban on tobacco displays at POS (19).
    - In 2014, 42 of 130 (32%) reporting Parties indicated that their TAPS bans include provisions that prohibit tobacco advertising via global Internet (19).

- There is higher compliance with bans on direct versus indirect forms of TAPS (142).

D. Effectiveness of Implementation of Article 13

Impact of Comprehensive TAPS Bans on Exposure to Tobacco-related Marketing

There is a substantial body of research showing that comprehensive TAPS bans can lead to dramatic reductions in public exposure to marketing by the tobacco industry.

- Following the implementation of a comprehensive TAPS ban (exception for tobacco advertising at POS which was later banned in 2014) in Uruguay in 2008, there was a dramatic reduction in the percentage of smokers who noticed tobacco advertising on television (86% to 12%); posters, bus stops, or billboards (72% to 15%); radio (63% to 7%); newspapers or magazines (43% to 6%); discos, bars and pubs (32% to 11%); and coffee shops, tea shops or restaurants (28% to 12%). In contrast, there was a smaller decrease in the percentage of smokers who noticed tobacco advertising in venues where POS advertising was still permitted, including convenience stores, supermarkets, or kiosks (53% to 33%) (304).

- A cross-country comparison of data from the GATS collected in 14 countries from 2008 to 2010 showed that in 12 countries, more respondents were aware of advertising in stores than advertising via any other marketing channel. Notably, three of the four countries where awareness of tobacco advertising was lowest (less than 15%) had a comprehensive TAPS ban in effect (305).

- A study of the impact of the UK's comprehensive ban on tobacco promotion (implemented in 2003) relative to Canada, the US, and Australia (that did not yet have a comprehensive TAPS ban) showed a significant decline in tobacco promotion awareness among smokers in the UK immediately after the implementation of the advertising ban, with greater declines in awareness in those channels regulated by the new law. The change in awareness of tobacco promotions was greater in the UK than the other three countries that were not affected by the ban (306). The study followed the cohort for five additional annual waves (2004-2008) to study the long-term impact of the ban in the UK and the impact of other marketing bans enacted in the other three countries. Results showed that the effects of the marketing restrictions in the UK were largely immediate, followed by continuous awareness reduction, but at a slower rate over time. Significant decreases in awareness between 2002 and 2008 were also seen in Canada, however the decreases tended to be smaller than in the UK. Awareness of tobacco marketing at baseline was lowest in Australia, which is expected given that many marketing bans were already in place prior to 2002. US smokers had the highest awareness of tobacco marketing in 2002 and least reduction in awareness in 2008. This is expected as the US has been slower to adopt marketing restrictions compared to the

other countries. Across all four countries, reductions in awareness of tobacco marketing tended to be similar among different socioeconomic status (SES) groups (307).

- A study of tobacco advertising and promotion awareness among smokers in China, Thailand, Australia, and the US provides evidence for wide cross-country variation in effective tobacco promotion restrictions. Overall awareness of tobacco advertising and promotion was significantly higher among smokers in China than in Thailand and Australia (countries with strong policies), and lower than in the US (country with weak policies) (308).

- Following the implementation of a 2009 ban on POS tobacco displays in Ireland, there was a significant decrease in display recall among adults (49% to 22%) and teenagers (81% to 22%) (309).

- In Canada, there was a dramatic reduction in the percentage of smokers who noticed cigarette packs being displayed in shops or stores from 76% in 2006-2007 (when 5 out of 13 provinces/territories had POS display bans) to 6% in 2011 (when POS retail displays were banned in all provinces/territories) (310).

Impact of Comprehensive TAPS Bans on Smoking Behaviour

There is strong scientific evidence that comprehensive TAPS bans can reduce tobacco consumption and prevalence of tobacco use, while the impact of partial bans and voluntary restrictions is limited.

- A review of data from 22 countries showed that a comprehensive ban can reduce tobacco consumption by 6.3% (311).

- A systematic review of policies in 30 developing countries found that the imposition of a comprehensive advertising ban was associated with a 23.5% reduction in per capita consumption. In contrast, the imposition of a limited ban was associated with a 13.6% reduction (312).

- The Brazil SimSmoke Policy Simulation Model estimated that smoking prevalence in Brazil in 2010 was reduced by 46% after the introduction of tobacco control measures, and that 14% of this decrease was accounted for by marketing restrictions. The SimSmoke model also predicted an additional 2% to 7% reduction in smoking prevalence by 2050 if a comprehensive marketing ban was put in place after 2010, with all other 2010 policies held constant (313).

- A systematic review of evidence for the effect of tobacco advertising on consumption in 22 Organization for Economic Cooperation and Development (OECD) countries

concluded that a comprehensive set of tobacco advertising bans can reduce tobacco consumption, while a limited set of advertising bans will have little or no effect (311).

- A study that examined the average change in cigarette consumption 10 years after the introduction of advertising bans showed an average 9% decrease in cigarette consumption in countries with a comprehensive ban in comparison to a 1% decrease in countries without a comprehensive ban (314).

Impact of POS Tobacco Advertising and Promotion Bans on Reducing Smoking among Youth

Tobacco advertising and promotion at POS is one of the most effective strategies used by the tobacco industry to communicate with potential and current smokers. Research has demonstrated that bans on tobacco advertising and promotion at POS are effective for the prevention of smoking initiation among youth.

- Studies have shown an association between POS promotion and continued smoking, as well as the initiation and experimentation of smoking by youth (252, 315).

- A 2009 systematic review assessed the impact of tobacco promotion at POS based on 12 studies (of which 10 were focused on children). Seven out of eight observational studies found a significant association between exposure to tobacco promotion at POS and smoking initiation or susceptibility to smoking among children. Two experimental studies found a significant relationship between children's exposure to POS tobacco promotions and beliefs about ease of getting tobacco and smoking prevalence among their peers (315).

- A cross-sectional study conducted in England indicated that youth who were exposed to tobacco product displays in small shops were more susceptible to smoking initiation. The odds of ever-smoking doubled and susceptibility increased by around 60% for youth who visited shops almost daily relative to less than once a week. Noticing tobacco displays every time during store visits increased the odds of susceptibility more than threefold compared with never noticing tobacco. There was a 5% increase in odds of being an ever-smoker and 4% increase in susceptibility for each additional tobacco brand recognized at the POS. The association between frequency of visiting stores and susceptibility was predominantly due to exposure in small shops (316).

- A pre-post evaluation of the 2009 ban on POS tobacco displays in Ireland showed that the lack of visual smoking cues in shops led youth to be less likely to believe their peers were smokers, thus helping to denormalize tobacco use and reduce the likelihood of smoking initiation. Findings also showed that 38% of teenagers thought the POS ban would make it easier for children not to smoke (309).

- A pre-post evaluation of consumers' perceptions of and experiences with the 2010 POS display ban in Norway showed that before the implementation of the ban, young people were tempted by tobacco products when seeing them in the shop more often than older people. After implementation of the ban, young people found it more difficult to choose a brand. The POS display ban was perceived by consumers as an effective means to reduce youth purchases of tobacco, and lower brand influence on purchasing choices. Furthermore, consumers believed that the ban could contribute to preventing smoking initiation among young people and support cessation efforts (317).

E. Conclusions

Before the WHO FCTC came into force in 2005, virtually no countries had enacted legislation to ban all forms of TAPS. Over the last decade, there has been steady global progress in the implementation of Article 13 measures. As of 2014, 29 countries have passed a complete ban on all direct and indirect forms of TAPS. There is a consistent body of evidence that well-enforced comprehensive TAPS bans can decrease tobacco consumption and exposure to tobacco marketing, and prevent smoking initiation among youth. Nevertheless, the vast majority of countries have yet to ban all types of TAPS activities, and the industry continues to market tobacco products through unregulated channels including promotional discounts, brand sharing and stretching, POS advertising and promotion, event sponsorship, and Internet advertising. Moreover, the tobacco industry continues to employ tactics to interfere with the effective implementation of Article 13. It will be important for governments to take actions to implement comprehensive TAPS bans that keep pace with the ever-changing methods that the industry uses to promote their products.

Article 14

Demand reduction measures concerning tobacco dependence and cessation

A. Article 14 Overview

Article 14 of the WHO FCTC obligates Parties to take effective measures to promote cessation of tobacco use and treatment for tobacco dependence. Guidelines for the implementation of Article 14 were adopted at the fourth session of the COP (COP4, November 2010) (323).

B. Progress in the Implementation of Article 14

Evidence shows that smoking cessation is very difficult, with only 3% to 5% of smokers being able to achieve 6 to 12 month smoking abstinence after a quit attempt (320). Access to effective tobacco dependence treatment interventions, in accordance with Article 14 and its guidelines, is therefore critical to improve cessation outcomes among smokers, and reduce smoking-attributable mortality.

Since the WHO FCTC came into force in 2005, global progress in the implementation of Article 14 has been limited to a few areas.

- According to WHO global estimates, by 2014, more than 80% of countries have cessation services available in at least one setting, and 75% of these countries provide some cost coverage for cessation services (20).

- There has been a steady increase in the number of reporting Parties who provide cessation programmes in healthcare institutions from 2010 (57 of 104 (55%)[12] Parties) to 2014 (98 of 130 (75%) Parties) (17, 19).

- As of 2014, 95 of 130 (73%) reporting Parties indicated that they have integrated the diagnosis and treatment of tobacco dependence into their healthcare system (19).

- According to WHO global estimates, there has been rapid growth in the implementation of quitlines in HICs since 2000 (324). As of 2014, more than half of HICs report providing funding for a toll-free quitline (20).

[12] In the 2010 reporting cycle, implementation reports were submitted by a total of 135 Parties. For several questions concerning Article 14, comparable answers were available only from the revised phase 1 (Group 1 questions) and phase 2 (Group 2 questions) of the reporting instruments: the number of reports received based on these formats was 104.

- In 2014, a small number of the 130 reporting Parties indicated the use of new and innovative approaches to tobacco cessation and dependence treatment, such as text messaging services, Internet-based behavioural support, smartphone applications, and directories for tobacco cessation services providers (19).

C. Challenges in the Implementation of Article 14

On the whole, global progress in the implementation of Article 14 has been slow, particularly in LMICs (142, 325, 326).

- There has been virtually no change in the number of reporting Parties that have developed comprehensive and integrated cessation guidelines (a treaty obligation) from 2012 (77 of 146 (53%) Parties) to 2014 (75 of 130 (58%) Parties) (19).

- According to WHO global estimates, as of 2014, only 18% of LICs provide cost coverage for cessation services, and only 9% provide funding for a quitline (20).

- There is wide variation in the implementation of national treatment guidelines by country income level. In 2012, 27 (75%) HICs had guidelines, compared to 15 (42%) upper-MICs, 9 (30%) LMICs, and only 2 (11%) LICs (325).

- Results of a 2011-2012 survey of 121 WHO FCTC Parties showed that while just over half of Parties reported that their country encourages the provision of brief advice in existing services, only about one-third of Parties said that tobacco users could obtain help easily in a general/family practice setting, 17% said the same for pharmacists, 7% for dentists, and 18% for hospitals. Findings also showed that only 22% of countries mandated the recording of patients' tobacco use in medical notes, a low cost measure that should be implemented in all healthcare systems, as recommended by Article 14 guidelines (325).

- As of 2014, only 10 Parties reported that nicotine replacement therapy (NRT) is available either free of charge or at a minimal cost, at least for a certain segment of the population (19).

- One of the major challenges to the successful implementation of Article 14 is the affordability of cessation programmes and pharmaceutical products for tobacco dependence treatment.

    - The potentially high cost of producing national treatment guidelines may be a significant barrier to establishment of such guidelines, especially for LICs (327).
    - The high cost of NRT and pharmaceutical products for tobacco dependence treatment makes them inaccessible to many smokers (19).
    - LMICs have less infrastructure for cessation support than HICs, resulting in under-implementation of cessation measures. Access to affordable cessation medications is also limited in LICs (325).

D. Effectiveness of Implementation of Article 14

Clinical cessation interventions are one of the most cost-effective healthcare interventions to increase quit rates (328). There is strong evidence that cessation advice in primary healthcare systems, quitlines, and pharmacological therapy should be included as key components of comprehensive tobacco control programmes, and that the integration of these interventions can improve rates of smoking cessation at the population level (329, 330).

- A 2015 systematic review of evidence from randomized trials of smoking cessation advice from medical practitioners found that advice from doctors helps smokers to quit, even when it is brief simple advice. A brief advice intervention can increase cessation rates (measured as at least 6 months after follow-up) by 1% to 3% (321), and is affordable for countries in all World Bank income categories (331).

- Research has also shown that training programmes can improve the delivery of smoking cessation interventions by health professionals. However, there is evidence to suggest that in many countries, there is a lack of effective and appropriate training on cessation techniques for health professionals.

    - A 2012 systematic review of the effectiveness of skills training on health professionals' delivery of smoking cessation interventions to their patients assessed the evidence based on 17 randomized controlled trials. The studies were conducted in the US (11 studies), Switzerland (1 study), the UK (1 study), Scotland (1 study), Germany (1 study), Taiwan (1 study), and Canada (1 study). Results indicated that training health professionals to provide smoking cessation interventions had a significant effect on the point prevalence of smoking and continuous abstinence. Healthcare professionals who received training were more likely to provide cessation treatments than untrained controls, including asking patients to set a quit date, making follow-up appointments, counselling, provision of self-help material, and prescription of a quit date (332).
    - A cross-country comparison of data from the Global Health Professions Student Survey (GHPSS) collected in 81 survey sites (across 31 countries) from 2005 and 2007 showed that the majority of students believed that they should receive training on counselling patients to quit using tobacco, but less than 40% of students in 73 sites reported they received such training (333).
    - More recent cross-sectional data from the GHPSS shows that in some countries, there has been little progress in the implementation of training programmes on cessation strategies for health professionals. For example, less than one-quarter of students pursuing advanced health professional degrees receive formal training in smoking cessation approaches in China (reported by 16.4% of students in 2013) (334), and Italy (reported by 21.3% of students in the city of Catania in 2012) (335).

- A 2011-2012 survey of tobacco dependence treatment services in 121 countries showed that 68 (56%) countries encouraged brief advice in existing healthcare services. However, only 31 (26%) countries had national training standards – of these countries, 3 were low-income, 4 were low-middle income, 9 were upper-middle income, and 15 were high-income (325).
- A 2013 survey of the availability of training programmes for the delivery of tobacco cessation treatment in 84 countries found that 18 (21%) countries (mostly LMICs) had no training programmes at all. The proportion of countries with at least one training programme ranged from 94% among HICs to 50% among LMICs. More than half of programmes (54%) reported funding challenges, with government funding more commonly reported by HICs than LMICs (336).

- Documentation of tobacco use status for patients in the healthcare system by a physician or member of a healthcare team on a regular basis can increase the rate of clinician intervention (322). Nevertheless, findings from a 2011-2012 survey of 121 WHO FCTC Parties showed that only 22% of Parties mandated the recording of patients' tobacco use in medical notes (325).

- There is well-established evidence from clinical trials that NRT, buproprion, varenicline, and cytisine are efficacious aids to smoking cessation (322, 337). While there is insufficient data to show that one form of NRT is more effective than another, evidence suggests that higher dose forms of NRT may be more effective than lower dose forms. Buproprion is a useful cessation aid for moderately heavy or heavy smokers, at least in the context of behavioural support, and is at least as effective as single form NRT. Varenicline is more effective than buproprion and single form NRT, and at least as effective as combination NRT. Cytisine is also an effective cessation aid in moderately heavy to heavy smokers, and has the potential to be easily affordable to large segments of the population in countries where it is available (331).

- Telephone-based quitlines, when implemented correctly, have been shown to be effective in increasing success rates for quitting, including long-term abstinence (325, 338, 339). Research has demonstrated that the most effective quitlines are those that offer comprehensive, proactive, multisession behaviour modification counselling programmes, rather than brief reactive services (324).

- Population-based approaches such as quitlines and counselling services integrated into healthcare, as well as brief interventions in primary care and individual counselling, and the provision of pharmaceutical products are all effective approaches to smoking cessation treatment and should be complementary components of a smoking cessation strategy (337).

- A 2015 review of the efficacy, effectiveness, and affordability of various healthcare interventions to promote and assist tobacco cessation identified the following as

effective and globally affordable measures to encourage cessation: brief opportunistic advice from a healthcare worker, printed self-help materials, proactive telephone support, and automated text messaging. Multi-session face-to-face behavioural support is also an effective means of promoting cessation when appropriate procedures and evidence-based protocols are in place, and is affordable in MICs and HICs. Pharmaceutical interventions that are effective when provided by a healthcare worker and with at least some behavioural support include NRT, buproprion, nortriptyline, varenicline and cytisine; of those, cytisine and nortripyline are globally affordable. Finally, the most effective combination of interventions is face-to-face behavioural support together with NRT or varenicline (331).

- A 2016 commentary by leading experts in tobacco dependence treatment identified the following as low cost, effective measures that could be implemented by most countries: recording of tobacco use in all medical notes; integrating brief advice into existing healthcare systems; helping healthcare workers to stop smoking; establishing a text messaging support programme; providing affordable medications such as cytisine; and developing an official national cessation strategy and national treatment guidelines (326).

- A 2016 Canadian study provides evidence that greater adoption of hospital-initiated tobacco cessation interventions can lead to significant improvements in patient outcomes and reductions in subsequent healthcare usage. Patients who received the "Ottawa Model" for Smoking Cessation (OMSC) intervention experienced significantly lower rates of all-cause and smoking-related readmissions, and all-cause emergency department visits than usual care controls at 30 day, 1 year, and 2 year follow-up time points. Findings also showed that 35% of OMSC intervention patients remained quit at 6 month follow-up compared to 20% of usual care patients, as well as a 40% reduction in 2 year mortality risk among OMSC intervention patients (340).

Research that examines the effectiveness of Article 14 provisions has been conducted primarily in HICs, and the population impact of the implementation of smoking cessation strategies is difficult to measure as the majority of evidence comes from clinical trials and individual-level approaches. Nevertheless, some studies of real-world implementation of cessation measures have shown that population-based interventions can be effective for the promotion of smoking cessation at the population level.

- In June 1997, Australia integrated its quitline services to form a national quitline as part of its first nationally coordinated anti-smoking campaign. This number was included at the end of a set of televisions advertisements, which included one advertisement solely promoting the idea of calling the quitline. In the 1 year period following June 1997, nearly 1 in 25 adult smokers called the quitline; weekly call volume was strongly related to the viewing of the television ads, with a further increase in calls when the quitline-specific ad was broadcasted (341).

- Hong Kong established its first quitline in December 2000. Although the quitline was advertised through only low-cost means including press conferences, media reports, posters, and pamphlets, it achieved comparable quit rates to better funded quitlines in Western countries; of the contacted callers in the 2 years following the establishment of the quitline, 12% had quit at a 6-month follow-up (342).

- Findings from a longitudinal study suggest that the use of help for smoking cessation has become increasingly normalized among adult smokers in Australia attempting to quit from 2002 to 2006. In 2006-2007, use of NRT was five times greater than the use of prescription medication for cessation, but after varenicline was made available on the Pharmaceutical Benefits Scheme in 2008, this difference largely disappeared as reported use of varenicline rose sharply. Among smokers who tried to quit over the survey period, use of help more broadly (including pharmacotherapy and behavioural forms of support) increased from 37% in 2002 to 59% in 2009 (343).

- From 1999 to 2001, the UK aimed to expand the utilization of pharmacotherapy to treat tobacco dependence by making buproprion and NRT reimbursable and widening sales of NRT products to include non-prescription general sales settings. An evaluation of the impact of these changes found that they had a major impact on medication usage, with a large increase in sales of medications over the study period and an increase in the proportion of smokers using these medicines, which doubled from 8% to 9% in 1999 to 17% in 2002. Results also showed that making these medications reimbursable appeared to have the largest impact on usage (344).

- An evaluation of the use of stop-smoking medications among smokers in the US, the UK, Canada, and Australia found that smokers were more likely to succeed in their quit attempts if they used varenicline, buproprion, or the nicotine patch (345).

- A cross-country study that examined quitting behaviour and the extent to which health professionals advised patients to quit across 15 countries showed that there was higher overall use of medication for quitting than behavioural support. However, there were considerable differences in quitting activity, as well as level and type of quitting support used across countries. Smokers in MICs had comparable interest in quitting to smokers in HICs, but reported lower use of cessation medications and health professional services. Smokers in LICs were especially less likely to visit health professionals, making the role that health professionals could play in cessation more limited (346).

- A national smoking cessation strategy has been in place in the UK since 1998. National Health Service (NHS) stop smoking services have been scaled up over time to include a wide range of government-funded services to support smokers who are attempting to quit, such as brief advice and referrals to services from a range of health professionals, a toll-free telephone quitline, a national network of stop smoking services which provide pharmaceutical and behavioural support, as well as the availability of NRT, buproprion,

and varenicline either free or for a subsidized fee. There is a strong body of evidence for the effectiveness of NHS smoking cessation services in helping smokers in the UK to quit. For example:

- A study that examined the impact of the UK's national smoking cessation strategy on smokers' quit attempts, use of treatment and short-term abstinence, relative to the US, Canada, and Australia, provided evidence for cross-country variation in quitting behaviour and use of cessation support. Smokers in the UK (where strong support is provided) were less likely to have attempted to quit smoking, but were more likely to use help when attempting to quit (pharmacotherapy and/or support from a clinic, helpline, or health professional) than smokers in the US, Canada, and Australia (where less support is provided). Smokers in the UK were also more likely to achieve 28-day abstinence from smoking than smokers in the other three countries (347).
- A 2010 systematic review of 20 studies on the impact of NHS stop smoking services on cessation concluded that these services are effective in supporting short- and long-term quit rates among smokers in the UK. Evidence suggested that group interventions for smoking cessation may be more effective than one-on-one interventions (348). The Department of Health (DH) commissioned a national evaluation of NHS stop smoking services in England between 2001 and 2004. Findings from this evaluation showed a decrease in the percentage of clients that were CO-validated as quitters from 53% (60.7% when self-report cases were included) to 14.6% (17.7% when self-report cases were included) at 4 week and 1 year follow-up, respectively (349, 350).
- A prospective cohort study evaluating long-term outcomes of NHS stop smoking services (ELONS) provides evidence for the effectiveness of these services in England from 2010 to 2013. Specifically, findings showed a decrease in the percentage of clients that were CO-validated as quitters from 41% to 8% at 4 week and 1 year follow-up, respectively. Clients who received specialist one-to-one behavioural support were twice as likely to have remained abstinent than those who were seen by a general practitioner (GP) practice and pharmacy providers, and those who received group behavioural support were three times more likely to stop smoking than those who were seen by a GP practice or pharmacy providers. It was estimated that NHS services provided support for smoking cessation to 36,249 clients in the year 2012-2013 (351).

- Studies that have examined evidence from treatment episodes across the English network of stop smoking services have found that smokers receiving stop smoking support from specialist clinics, treatment in groups, and varenicline or combination NRT were more likely to succeed in quitting than those receiving treatment in primary care, one-to-one treatment, and single NRT (352). However, there was variability in effectiveness between individual practitioners, highlighting the need for trained professionals when delivering face-to-face behavioural support (353).

E. Conclusions

Since the WHO FCTC came into force in 2005, there has been some advancement in the global implementation of comprehensive measures to promote cessation of tobacco use and treatment for tobacco dependence. As of 2014, more than 80% of countries have cessation services available in at least one setting, and 73% (95 of 130) of reporting Parties indicated that they have integrated the diagnosis and treatment of tobacco dependence into their healthcare system. There is a consistent body of research showing that the implementation of cessation measures that align with Article 14 and its guidelines can be effective in improving cessation outcomes. Findings from clinical trials as well as population-based studies provide evidence for the effectiveness of national cessation strategies, brief interventions, telephone-based quitlines, and the provision of pharmaceutical products on quitting outcomes among smokers. However, overall progress in the global implementation of Article 14 has generally been slow, particularly in LMICs. As of 2014, only 18% of LICs provide cost coverage for cessation services, 11% have implemented national treatment guidelines, and 9% provide funding for a quitline. Emerging evidence suggests that countries in any income category should be able to afford to implement cessation interventions of established efficacy, but many LICs continue to cite the high cost of cessation programmes and pharmaceutical products for tobacco dependence treatment as a major barrier to the implementation of Article 14.

Article 15

Illicit trade in tobacco products

A. Article 15 Overview

Article 15 of the WHO FCTC encourages Parties to adopt measures to eliminate all forms of illicit trade in tobacco products, including smuggling, illicit manufacturing, and counterfeiting. Guidelines for Article 15 have not yet been developed. However, the Protocol to Eliminate Illicit Trade in Tobacco Products, the first protocol to the WHO FCTC, was adopted on 12 November 2012 (7). As of June 2016, there are 54 Signatories and 17 Parties to the Protocol.[13]

B. Progress in the Implementation of Article 15

The illicit trade of tobacco products undermines the effectiveness of tobacco taxation policies because it increases consumption and leads to significant losses in government revenue (122, 354, 355).

There is some evidence for recent progress in the implementation of Article 15 in the following areas (19):

- The total number of reporting Parties who indicated that they promoted cooperation for investigations increased from 80 of 146 (55%) Parties in 2012 to 87 of 130 (67%) Parties in 2014.

- The total number of reporting Parties who indicated that they regulated the storage and distribution of tobacco products increased from 77 of 146 (53%) Parties in 2012 to 85 of 130 (65%) Parties in 2014.

- The total number of reporting Parties who indicated that they facilitated information exchange increased from 66 of 146 (45%) Parties in 2012 to 81 of 130 (62%) reporting Parties in 2014.

[13] The 17 Parties to the Protocol to Eliminate Illicit Trade in Tobacco Products as of June 2016 are Austria, Burkina Faso, Congo, Côte d'Ivoire, Ecuador, France, Gabon, Iraq, Latvia, Mongolia, Nicaragua, Portugal, Saudi Arabia, Spain, Sri Lanka, Turkmenistan, and Uruguay. As of October 2016, six additional Parties (European Union, Gambia, Mali, Panama, Senegal, and Swaziland) have become Parties to the Protocol, bringing the total number of Parties to the Protocol up to 23.

As of 2014, more than two-thirds of reporting Parties said that they have implemented the following Article 15 provisions to counter illicit trade (19):

- 92 of 130 (71%) reporting Parties indicated that they implemented new or strengthened existing legislation against illicit trade in tobacco products.

- 91 of 130 (70%) reporting Parties required a legible marking on tobacco products.

- 91 of 130 (70%) reporting Parties required destruction of confiscated manufacturing equipment.

- 88 of 130 (68%) reporting Parties required licensing actions to control tobacco production and distribution.

In 2014, several Parties also reported the implementation of new measures to counter illicit trade (19).

- Singapore implemented legislation that requires a revised “SDPC” (Singapore Duty-Paid Cigarette) mark on cigarette sticks, which also features a series of vertical bars around cigarette sticks.

- Colombia introduced a new tracking system for tobacco products.

- Canada implemented a new enhanced tobacco stamping regime for cigarettes, tobacco sticks, and fine-cut tobacco.

- Australia and Canada reported measures that mandate increased penalties for tobacco smuggling.

- Serbia, South Africa, and Venezuela (Bolivarian Republic of) reported the use of scanners for the inspection of tobacco products.

- Australia established new offences related to tobacco smuggling.

- Palau introduced a web-based customs software, which enables customs to connect with other relevant systems, such as quarantine and immigrations.

C. Challenges in the Implementation of Article 15

Although there has been steady progress in the implementation of some Article 15 provisions in recent years, there are still several areas where the rate of global progress has either slowed or remained unchanged over time (19):

- There has been very little change in the total number of reporting Parties who required destruction of confiscated manufacturing equipment from 2012 to 2014 (88 of 146 (60%) Parties and 91 of 130 (70%) Parties, respectively); and reported confiscation of proceeds derived from illicit trade from 2012 to 2014 (79 of 146 (54%) Parties and 83 of 130 (64%) Parties, respectively).

- Only half of reporting Parties required the monitoring of cross-border trade in 2012 (73 of 146 (50%) Parties) and 2014 (69 of 130 (53%) Parties).

- As of 2014, only 34 of 130 (26%) reporting Parties have developed a tracking and tracing regime, and 49 of 130 (38%) reporting Parties required a statement on destination on all tobacco product packages.

The tobacco industry uses various techniques to interfere with the implementation of effective Article 15 measures.

- The tobacco industry has a longstanding history of facilitating the global illicit tobacco trade (356-359).

- Industry documents provide evidence for the involvement of tobacco companies in cigarette smuggling in Asia, Africa, the Middle East, and the former Soviet Union (360-362).

- There is emerging evidence to suggest that transnational tobacco companies have continued to be involved in illicit trade after signing anti-smuggling agreements (41, 357, 363).

- The tobacco industry continues to use the threat of illicit tobacco trade to prevent the implementation of tobacco control policies including tax and price increases, and standardized/plain packaging (27, 35, 112, 364, 365).

D. Effectiveness of the Implementation of Article 15

Case studies from several countries provide some evidence that the implementation of comprehensive measures that interrupt the supply chain from manufacturers to illegal markets can lead to significant reductions in illicit tobacco trade.

- In 2008, the Contraband Tobacco Enforcement Strategy was implemented by the Royal Canadian Mounted Police (RCMP) in order to reduce the availability of, and demand for, contraband tobacco in Canada. There was a dramatic increase in RCMP seizures of cartons and unmarked bags of illegal cigarettes in 2008 and 2009. However, these numbers have continued to decrease steadily since 2010 — the RCMP reported a 22% decrease over 2010 seizures in 2011, and a 67% decrease over 2011 seizures in 2012 (366, 367). This reduction in contraband activity is due in large part to increased enforcement action by the Federal, Ontario, and Quebec Governments since 2008. Results from a recent study also show that the percentage of smokers reporting the purchase of low- or untaxed cigarettes has levelled off or decreased in Canada since 2008 (368).

- The UK Government has implemented various measures to combat illicit trade under the Tackling Tobacco Smuggling Strategy from 2000 to 2015, including the consolidation of multiple existing agencies into a single tax authority for the UK; the creation of the Serious Organised Crime Agency; increased capacity and cooperation among enforcement authorities; the use of fiscal markings for identification of illicit products; the use of x-ray scanners on imported products; stronger penalties for non-compliance; and the establishment of EU anti-smuggling agreements with major tobacco manufacturers (369). Since the launch of the anti-smuggling strategy, there has been a significant decline in illicit trade for cigarettes (from 20% in 2000-2001 to 10% in 2013-2014) and hand-rolled tobacco (from 61% in 2000-2001 to 39% in 2013-2014) (370).

- Spain increased investment of resources to combat cigarette smuggling from €4 million in 1993-1996 to nearly €40 million in 1996-2000 (371). The implementation of measures to reduce supply into the country at container level, increased intelligence and customs activity, and improved national and European cooperation and technology has led to a dramatic reduction of the market share of smuggled cigarettes from 16% to 2% over this time period (372, 373).

- Some countries have successfully implemented systems that use modern technology to monitor the production and distribution chain in order to reduce illicit trade. For example:

    - In Brazil, a system that uses digital tax stamps for the unique identification of each pack of domestically produced cigarettes (SCORPIOS) was fully implemented in March 2008. In 2011, unique visible codes were also required on packs of cigarettes manufactured for export. This system has been effective

in helping authorities to identify under-reporting of production by 14 cigarette companies, which in turn, led to a decrease in illegal production that accounted for much of the illicit trade market in the early 2000s (20).

- Kenya recently implemented regulations to counter tobacco product tax evasion and illicit trade. Under the 2013 Customs and Excise (Excisable Goods Management System) Regulations, which came into force on 5 November 2013, tobacco manufacturers and importers are required to register with the Commissioner-General of the Kenya Revenue Authority (KRA) and implement an Excisable Goods Management System and Electronic Cargo Tracking System, that includes the following: encrypted excise stamps that are affixed on all tobacco product packaging; track and trace system; production accounting system; software and hardware for verification of the authenticity of excise stamps; and identification and association of each package with an individual excise stamp. The regulations also state that excise stamps shall include features to deter counterfeiting; facilitate the tracking of tobacco products along the supply chain; enable accounting for the production of manufactured and imported tobacco products; allow manufacturers, importers, distributors, or retailers in the supply chain to authenticate excise stamps and tobacco products (374, 375). This system has allowed the KRA to seize more than 300,000 illegal products (20).

There is also some evidence for country-specific barriers to the implementation of measures to curb illicit trade.

- In the US, state-level variations in tax regimes provide consumers and illicit traders with incentives for tax avoidance through illegal cross-border smuggling, legal cross-border purchasing in states with lower tax rates, or Internet purchasing (376-378).

- In Canada, First Nations reserves that sell low- or untaxed cigarettes to non-First Nations individuals are the primary source of contraband cigarettes. Since 2002, there has been an increase in the prevalence of smokers purchasing cigarettes on reserves, particularly in the provinces of Ontario and Quebec (379, 380). Longitudinal data has shown that the percentage of Canadian smokers who reported last purchasing cigarettes for themselves on a First Nations reserve increased between late 2002 and 2007-2008, but has since levelled off or decreased. In Ontario, however, there was a significant increase in the percentage of smokers who reported purchasing cigarettes from a First Nations reserve increased from 30% in 2005 to 40% in 2011 (310).

- In the EU, large-scale cigarette smuggling has declined in over the last decade, but transnational tobacco companies continue to be involved in illicit cigarette trade (39, 41). Other types of illicit trade such as counterfeiting and “Cheap Whites” (new cigarette brands that are legally manufactured which are only or mainly intended for the illegal market of another country) have also emerged over this time period (381). Some recent evidence suggests that a substantial portion of “Cheap White” cigarette brands are sold legally in countries such as Russia and Ukraine. However, the vast majority of “Cheap White” brands in countries including Bangladesh (86%), Pakistan (80%), Thailand

(72%), the Philippines (80%), and Vietnam (93%) are illicit. The growing market presence of "Cheap White" cigarette brands undermines global implementation of policies for tax stamp and warning requirements, and tobacco taxation (382).

- A 2009 systematic review of 13 studies on the impact of policy measures to combat illicit cigarette trade provides evidence that anti-contraband policies are most effective when they are adapted for the specific type of illicit trade and means of distribution, which may vary by country (383).
- A 2012 systematic review on the impact of tax and price on tobacco consumption and a summary of reviews and narratives about the illicit tobacco market concluded that a multidisciplinary approach for assessment of the magnitude of illicit trade is needed to facilitate the implementation of effective measures to address country-specific illicit trade issues (384).

E. Conclusions

Since the WHO FCTC came into force in 2005, there has been some progress in the implementation of measures to combat illicit trade in a growing number of countries, particularly in recent years. As of 2014, 92 of 130 (71%) reporting Parties have implemented new or strengthened existing legislation against illicit trade in tobacco products. Recent trends also highlight notable increases in the self-reported implementation of measures that promote cooperation for investigations, regulate the storage and distribution of tobacco products, and facilitate information exchange from 2012 to 2014. There is some evidence that the implementation of measures that disrupt the supply chain for illicit tobacco can lead to significant reductions in the market presence of illicit products. However, global progress in the implementation of such measures remains limited. For example, the vast majority of Parties have yet to develop and implement tracking and tracing regimes, and require a statement on destination on all tobacco product packages. The tobacco industry continues to engage in efforts to prevent the implementation of effective Article 15 measures. As of June 2016, there are currently only 17 Parties to the Protocol to Eliminate Illicit Trade in Tobacco Products, which falls short of the 40 Parties that are required for the Protocol to enter into force.

Article 16

Sales to and by minors

A. Article 16 Overview

Article 16 of the WHO FCTC obligates Parties to adopt and implement effective legislative, executive, administrative or other measures to prohibit the sale of tobacco products to minors (persons under the age set by domestic law, national law, or 18). Guidelines for Article 16 have not yet been developed.

B. Progress in the Implementation of Article 16

The vast majority of smokers initiate use of tobacco products before 18 years of age, and many youth who experiment with cigarettes will go on to become regular, daily smokers (385, 389). Data from the Global Youth Tobacco Survey (GYTS, 1999-2001) from 75 sites in 43 countries showed that nearly one-quarter (23.9%) of youth smokers aged 13-15 years reported that they had smoked their first cigarette before the age of 10 years (386). It is estimated that if current patterns of tobacco use among youth continue, a lifetime of tobacco use would lead to the deaths of 250 million children and young people, most of them in developing countries (387). Article 16 measures aim to prohibit the sale of tobacco products to minors, with the goal of reducing smoking among youth.

Since the WHO FCTC came into force in 2005, there has been steady global progress in the implementation of Article 16 provisions, with notable improvements in several areas from 2010 onwards.

- In 2007, 2 years after the WHO FCTC came into force, there was considerable variation in the types of youth access policies that had been adopted by different WHO member states. For example, 121 member states (61%) reported the adoption of regulations to prohibit the sale of tobacco products to minors, and 119 member states (60%) had adopted regulations to prohibit the distribution of free cigarettes. However, only 7 member states (4%) had adopted regulations to prohibit the sale of tobacco products by minors, and only 19 member states (10%) had regulations that require sellers to request proof of age (152, 388).

- As of 2014, the vast majority of reporting Parties have implemented measures to prohibit the sale of tobacco products to minors (118 of 130 (91%) Parties), the distribution of free samples to minors (113 of 130 (87%) Parties), and sales of tobacco products by minors (99 of 130 (76%) Parties); and to provide for penalties against sellers (107 of 130 (82%) Parties) (19).

- In 2014, 52 of 130 (40%) reporting Parties indicated that they had made progress in the implementation of Article 16 since the last reporting period in 2012, and 17 of 130 (13%) reporting Parties indicated that they had adopted new or strengthened existing legislation (19).

C. Challenges in the Implementation of Article 16

Over the last decade, there has been significant progress in the implementation of Article 16 measures, particularly the adoption of legislation to increase the legal age of majority to further limit youth access to tobacco products. However, there are still several challenges in this area.

- There has been little or no change in the total number of reporting Parties who have implemented the following Article 16 provisions from 2012 to 2014 (19):
    - Prohibition of the manufacture and sale of sweets, snacks, or toys in the form of tobacco products (86 of 146 (59%) Parties in 2012 vs. 81 of 130 (62%) Parties in 2014);
    - Placement of a prominent indicator at POS about the prohibition of tobacco sales to minors (88 of 146 (60%) Parties in 2012 vs. 90 of 130 (69%) Parties in 2014);
    - Prohibition of tobacco vending machines (79 of 146 (54%) Parties in 2012 vs. 81 of 130 (62%) Parties in 2014);
    - Ban on the sale of tobacco from open store shelves (72 of 146 (49%) Parties in 2012 vs. 72 of 130 (55%) Parties in 2014); and
    - Requiring sellers to request proof of age (86 of 146 (59%) Parties in 2012 vs. 86 of 130 (66%) Parties in 2014).

- In 2014, only 6 of 130 (5%) reporting Parties indicated ongoing enforcement campaigns or improved enforcement of policies to prevent sales of tobacco products to and by minors (19).

D. Effectiveness of Implementation of Article 16

Impact of Article 16 Measures on Reducing Youth Access to Tobacco Products and Smoking

Research demonstrates that enforcement of laws prohibiting the sale of tobacco to minors can disrupt the commercial distribution of tobacco to minors.

- Laws and regulations to reduce access to cigarettes by minors in Texas during 1998 to 1999 led to a decrease in the percentage of middle school students who reported access to cigarettes from stores (13.2% to 5.3%) and vending machines (7.5% to 1%) (390).

- Adolescent cigarette supplies declined by about 15% following the initiation and maintenance of strong enforcement against tobacco sales to minors in Colorado (391).

- An aggressive enforcement programme to restrict the sale of tobacco to minors in New South Wales was effective in decreasing attempts to purchase tobacco by minors by 73.6% between 1993 and 2002 (392).

- Following the introduction of a ban on tobacco sales to minors in the Netherlands, the percentage of adolescents buying tobacco decreased significantly from 26.3% in 1999 to 10.8% in 2003 (393).

There is evidence that strong enforcement of laws prohibiting the sale of cigarettes to minors can lead to significant reductions in youth smoking.

- Rates of cigarette experimentation and regular use of cigarettes by adolescents were reduced by over 50% following active enforcement of legislation that prohibits the sale of cigarettes to minors in Chicago (394).

- Raising the legal age of cigarette purchase in Australia from 16 to 18 years reduced the likelihood of smoking among high school students in Grades 7 to 11 by nearly 50% (395).

- Smoking among youth in Boston decreased by 31% following active enforcement of a law that prohibits sales to minors (396).

In summary, implementation of Article 16 can be effective in limiting commercial access to tobacco products among youth, which in turn, may decrease the prevalence of youth smoking. Indeed, a comprehensive 2012 review showed that all studies that found a successful disruption in the sale of tobacco to minors also found a significant reduction in tobacco use by youth (397).

However, it should be noted that all of the research to date that evaluates the impact of Article 16 measures on smoking and access to tobacco products among youth has been conducted in HICs, and comes primarily from the US. To our knowledge, there are no empirical studies that systematically examine the impact of Article 16 measures in LMICs. As such, it is unknown whether policies that have been shown to be effective in HICs will also translate to LMICs.

Effective Enforcement of Article 16 Measures

There is a growing body of evidence showing that the implementation of Article 16 measures will have limited impact in the absence of effective enforcement.

- It is well documented that there is poor compliance with laws that prohibit the sale of tobacco products to minors, and that tobacco products remain widely available to

minors in both developed and developing countries around the world (385, 386, 398-400).

- Recent findings based on data from the ITC Project demonstrate that bans on the sale of single cigarettes in Kenya and Mexico have not been effective in reducing the availability of individual cigarettes.

    - Findings from the ITC Kenya Wave 1 (2012) Survey showed that although the sale of single cigarettes has been banned in Kenya since 2007, 83% of adult smokers stated that their last purchase of cigarettes was in the form of a single stick in 2012 (401).
    - Mexico banned the sale of single cigarettes in 1999. However, a study using data from the ITC Mexico Waves 4 to 6 (2010-2012) Surveys found a significant increase in the percentage of adult smokers who saw singles sold daily (45.2% in 2010; 51.4% in 2011; 64.9% in 2012); who bought singles at least once a week (22.3% in 2010; 29.1% in 2011; 29.1% in 2012); and whose last cigarette purchase was a single (16.6% in 2010; 20.7% in 2011; 25.8% in 2012) from 2010 to 2012 (402).

Comprehensive enforcement programmes are necessary in order to maximize the effectiveness of Article 16 measures. Research has identified a number of strategies that may enhance the impact of policies to limit youth access to tobacco products. These include the following:

- Increasing capacity and funding for enforcement (403, 404);

- Expansion of regulations to include restriction of purchases from non-commercial sources (405, 406);

- Enforcement of a graduated penalty system for violations that includes license suspension or revocation (407);

- Removal of special requirements for the conduct of routine compliance checks (e.g., pre-emption of local ordinances, lack of local authority to enforce laws) (404, 407);

- Employing routine inspections involving test purchases by minors (404);

- Increasing efforts to raise merchant education and awareness (407, 408).

Some data suggests that reported compliance rates may not always reflect ease of access to tobacco products by youth in a straightforward manner.

- Some studies have found that high vendor compliance rates had no effect on smoking behaviour among youth, and in some cases, were associated with increased smoking among youth (409, 410).

- Data from the GYTS 2000-2011 shows that although the percentage of youth aged 13-15 years who purchase cigarettes from retail stores is generally high in many countries, there are some countries where young smokers rely on other sources for cigarettes. For example, while more than 40% of youth in most countries in the EUR, SEAR, AMR, and WPR report that they purchase cigarettes in a store, less than 30% of youth in many countries in the AFR and EMR purchase cigarettes from commercial sources (411, 412).

Integration of Article 16 Measures with Other Tobacco Control Policies

Emerging evidence suggests that the impact of measures to limit youth access to tobacco products may be enhanced when they are implemented in conjunction with other tobacco control programmes and policies. For example:

- Policies to limit youth access to tobacco products may be more likely to have a greater impact when they are combined with programmes that reduce youth access to tobacco from non-commercial sources (e.g., social sources), and denormalize the social acceptability of youth smoking (405, 413).

- Article 16 measures to restrict youth access to tobacco products will be more effective in preventing and reducing tobacco use among youth when they are implemented and enforced along with other tobacco control policies, such as price and tax increases; smoke-free laws; bans on TAPS; and public education campaigns (414).

E. Conclusions

Before the WHO FCTC came into force in 2005, a small number of countries had implemented legislation to curb youth access to tobacco products. Since 2005, there has been an increase in the implementation of legislation to restrict sales of tobacco to and by minors by Parties to the WHO FCTC. As of 2014, the vast majority of reporting Parties have implemented measures to prohibit the sale of tobacco products to minors (118 of 130 (91%) Parties) and by minors (99 of 130 (76%) Parties). A substantial body of research shows that the implementation of Article 16 measures that successfully disrupt the sale of tobacco products to youth can be effective in reducing youth smoking rates in HICs, but it is unclear whether such policies will have the same impact in LMICs. In addition, there has been little or no global progress in the implementation of several Article 16 provisions, including bans on the sale of tobacco products from vending machines and open store shelves, by reporting Parties from 2012 to 2014. Strong and effective enforcement of Article 16 measures is also an ongoing challenge in many countries. In order to

reduce tobacco use among youth, efforts to limit youth access to tobacco products need to be implemented in conjunction with comprehensive enforcement programmes, and other tobacco control policies that have been shown to affect youth smoking.

Article 17

Provision of support for economically viable alternatives

A. Article 17 Overview

Article 17 of the WHO FCTC obligates Parties to promote, as appropriate, economically viable alternatives for tobacco workers, growers, and as the case may be, individual sellers. Guidelines for Article 17 have not yet been developed. However, a working group on economically sustainable alternatives to tobacco growing in relation to Articles 17 and 18 of the WHO FCTC was established at the third session of the COP (COP3, 17-22 November 2008). The working group submitted a progress report at COP4 (14-16 February 2010), which included an outline of policy options and recommendations on economically sustainable alternatives to tobacco growing (415). Draft policy options and recommendations were submitted at COP5 (12-17 November 2012), and reviewed and adopted at COP6 (13-18 October 2014) (416, 417).

B. Progress in the Implementation of Article 17

Tobacco farming takes place in at least 124 countries around the world. China is the world's largest producer of tobacco, with 3.2 million tonnes of tobacco leaf grown in 2013 (1). With increased globalization over the past 50 years, tobacco farming has shifted from HICs and become increasingly concentrated in LMICs. In 2008, more than 75% of worldwide tobacco production was accounted for by seven countries in total, of which three are Parties to the WHO FCTC (China, Brazil, and India), and four are non-Parties to the WHO FCTC (the US (signed but not ratified), Argentina (signed but not ratified), Malawi, and Indonesia) (418).

Since the WHO FCTC came into force in 2005, there has been limited progress in the implementation of Article 17 measures.

- Prior to the ratification of the WHO FCTC, there was some support for work on alternative livelihoods to tobacco farming. For example, as early as 1999-2000, the International Development Research Centre (IDRC) has funded research on tobacco farming and alternative livelihoods. During the negotiations of the WHO FCTC in 2004, IDRC launched three large projects in Bangladesh, Kenya, and Malawi. These projects initially assessed farmers' experiences with tobacco farming, their reasons for growing tobacco, and their desire to switch to alternatives; and later focused on working with tobacco farmers to assess strategies for the development of economically viable alternatives (419).

- Following the ratification of the WHO FCTC in 2005, there has been a slow but steady increase in the number of reporting Parties[14] who indicated the establishment of programmes to promote viable alternatives for tobacco growers from 10 of 104 (10%)[15] Parties in 2010 to 19 of 130 (15%) Parties in 2014[16] (17, 19).

- Malaysia and Brazil have established programmes to assist tobacco farmers in transitioning to alternative livelihoods following their ratification of the WHO FCTC.

    - Malaysia became a Party to the WHO FCTC in 2005. In 2010, the Malaysian Government implemented a specific policy and programme to assist tobacco farmers to shift completely towards alternative crops by the year 2020, providing those transitioning to kenaf (*Hibiscus cannabinus*) with financial incentives, bonuses, and other assistance (420). However, it is important to point out that the substitution of tobacco to another monocrop is not an ideal strategy because it is technically difficult and costly to substitute another monocrop in place of tobacco during the same growing season without making improvements to the soil, and the direct substitution of another monocrop limits the potential range and diversity of cropping systems and livelihood options for tobacco farmers (421). Furthermore, while the substitution of tobacco to another monocrop may be feasible in countries that produce a small tobacco crop such as Malaysia, this strategy is currently not a viable option in major tobacco growing regions, where substantial amounts of land are allocated to the cultivation of tobacco.
    - The Brazilian Government launched a comprehensive diversification programme for small tobacco farmers following ratification of the WHO FCTC in 2005. The programme invested more than $12 million USD between 2005 and 2012 to implement projects for rural extension, training, and research to assist small farmers in the development of strategies for production and income diversification. Government assistance was also provided to those making the switch to various alternative crops in the form of production and investment credits, marketing and price guarantees, and insurance and technical support (422).

[14] Please note that not all reporting Parties grow tobacco or manufacture tobacco products.

[15] Based on combined responses to questions concerning Article 17 from 104 Parties (of the 135 total reporting Parties) that completed the revised phase 1 (Group 1 questions) and phase 2 (Group 2 questions) of the reporting instrument.

[16] In the 2014 reporting cycle, Parties were required to provide information as to whether they promote economically viable alternatives for tobacco growers, tobacco workers, and sellers of tobacco products. A total 58 reporting Parties responded that this question was not applicable to them.

C. Challenges in the Implementation of Article 17

The rate of advancement in the global implementation of Article 17 has been slow, and there are still major barriers to the implementation of economically viable alternatives, particularly in LMICs.

- As of 2014, a small number of reporting Parties have established programmes to promote viable alternatives for tobacco workers and sellers (7 of 130 (5%) and 4 of 130 (3%) Parties, respectively) (19).

- In most countries, there is a lack of financial support and access to resources for tobacco farmers to shift towards sustainable alternative crops.

    - Although alternative crops can be more profitable than tobacco, they can also be expensive to grow. For example, crops identified as good alternatives to tobacco because they may offer a higher profit margin for large- and small-scale growers in Zimbabwe were just as or more expensive to grow than tobacco because they required large initial capital investment for specialized equipment and processing facilities, as well as high-input management. In addition, the most profitable crops and management systems also required specialized infrastructure (423). There is also an interactive effect with the lack of access to credit such that tobacco farmers are willing to switch to alternative crops if they have sufficient resources to support their transition. For example, a recent 2016 report on farm-level economics in Malawi (who is not a Party to the WHO FCTC) found that tobacco farmers are willing to invest in crops other than tobacco if the alternatives are well-established with reliable marketing systems, and they have access to adequate capital and inputs (424). Similarly, surveys of tobacco farmers in Kenya (2013-2014) and Zambia (2015) indicate that farmers with lower average input costs are more likely to consider switching to growing alternative crops (425, 426).
    - Very little research has examined tobacco farmers' perceptions, attitudes, and experiences with diversification. However, there is some survey data from the US and a few African countries showing that many tobacco farmers are interested in diversification, but perceive the lack of financial support as a barrier to pursuing alternative livelihoods (426-430). Results of a 2016 report also show that more than half of tobacco farmers (55.8%) in Malawi would be willing to switch over to alternative crops that had stable and reliable markets (424).

- There are challenges to the development of new supply chains for alternatives to tobacco growing.

    - Markets for most high-value products that may substitute for a loss of revenue from tobacco are much smaller and difficult to penetrate (423), or may not yet exist. The decline in traditional markets and limited government investment in

market infrastructure in tobacco-growing regions may also limit access to new markets that support alternatives to tobacco (421). As such, tobacco farmers, especially small-scale farmers in LMICs, may be reluctant to switch over to growing alternative crops.

- The tobacco industry employs different strategies to interfere with efforts to promote alternative livelihoods.

    - The tobacco industry contends that the implementation of strong tobacco control policies that discourage tobacco consumption would result in job losses that compromise the livelihoods of individual farmers, and be detrimental to local economies (431, 432). However, there is evidence that tobacco industry-sponsored studies often overestimate the impact of tobacco on local economies because they fail to consider the net impact of tobacco-related job loss that includes redistribution of former tobacco expenditures to expenditures for other products (424, 426, 433, 434). There is also evidence that the tobacco industry overstates both the dependence of economies on tobacco, and the economic gains from tobacco production at both the individual- and country-level (424-426, 435). Of the more than 100 countries that grow tobacco, there are only two (Malawi and Zimbabwe) that rely heavily on raw tobacco for their export earnings. In all other tobacco-growing countries, tobacco exports account for a very small portion of total exports (436). Moreover, the tobacco industry's political influence is largely determined by geography - political clout is magnified in countries such as Kenya and Zambia, where tobacco growing is concentrated in a limited number of districts (425, 426).
    - In some LMICs, efforts to diversify economies away from tobacco are hindered by tobacco industry influence on government. For example, following the establishment of the National Commission for the Implementation of the WHO FCTC (CONICQ) in Brazil in 2003, the Sectorial Chamber on Tobacco was established within the Ministry of Agriculture in 2003-2004. Some key informants have suggested that the Sectorial Chamber, which includes representatives from the tobacco industry, was created to protect and promote commercial interests of the tobacco sector (422, 437). Industry documents also provide evidence that representatives from AFUBRA, who are members of the Sectorial Chamber, used advertising campaigns and press releases to present their unsubstantiated arguments that WHO FCTC ratification would lead to dramatic job losses and economic decline as a result of a decrease in tobacco exports; tobacco growers were unfairly excluded in negotiations of the Treaty; alternative livelihood programmes cannot be successfully implemented at the macro-level; and that tobacco growing is profitable (438).

D. Effectiveness of Implementation of Article 17

The Profitability of Tobacco Growing

A growing body of literature has shown that tobacco farming does not provide a good income, and often traps growers in a never-ending cycle of debt.

- For many tobacco farmers, the earnings from tobacco are insufficient to cover all their operating costs, and the majority of any profits go to leaf buying companies and cigarette manufacturers (439).

- Tobacco manufacturers and leaf buying companies employ unfair buying practices and issue contracts that trap farmers into cycles of poverty and push them into debt.

    - In many countries, tobacco companies provide tobacco farmers with high-interest loans for the purchase of agricultural supplies and equipment. The farmers are then obligated to sell all of their product to leaf buyers at a set price, which is often less than the value of the initial loans (439-444).
    - Findings from a 2015 individual-level economic survey of tobacco farmers in Zambia showed that for the vast majority of farmers, tobacco farming is not a lucrative economic livelihood. On average, independent farmers made a small profit of approximately $200 USD per acre. Notably, tobacco farmers who have contractual agreements with leaf-buying companies often operate at a net loss because the principal (non-labour) inputs which they borrow through their contracts often exceed the revenue earned from the sales of their tobacco leaf. As a result, many indebted contract farmers enter into a cycle of continuing to grow tobacco despite poor returns on investment. Findings also showed that when actual profit per acre is calculated to include labour costs, both contract farmers and independent farmers fail to earn any profits (426).
    - Findings from a 2013-2014 survey of the economic livelihoods of tobacco farmers in Kenya showed that tobacco companies loan inputs to contract farmers at inflated costs, with non-labour per acre input costs being 25% higher for contract farmers than independent farmers. Results also indicated that after factoring in labour costs, most smallholder tobacco farmers fail to earn a profit and often become indebted to leaf-buying companies (425).
    - Because tobacco leaf buyers operate as a monopsony or oligopsony, tobacco farmers have no recourse but to accept what is offered for the selling of their product. As a result, there is very little competition in the pricing of the tobacco, which results in low payout to tobacco farmers in relation to their initial investment (442).

- There is some evidence from developing countries to indicate that the health costs associated with tobacco growing and consumption may outweigh the economic benefits (if any) derived from tobacco farming (445). Nevertheless, it is important to note that

there are some instances where tobacco farming makes a significant contribution to total household income. For example, a 2016 report on the farm-level economics of tobacco production in Malawi (a top tobacco producing country that is not a Party to the WHO FCTC) indicated that the share of tobacco income to total household income in the 2013-2014 growing season was 0.68, and it was higher for contract farmers (0.78) than independent farmers (0.61). Despite their higher costs of production, contract farmers had higher profit levels than independent farmers. Results also showed that contract tobacco farmers on average, earned higher profits than both independent tobacco farmers and farmers who grew alternative crops such as birds' eye chillies, paprika, and soybean. However, the profitability of these alternative crops may increase over time as improved supply chains for these products are developed (424).

Tobacco Growing and Food Insecurity

Data also suggest that replacing food crops with tobacco may contribute to and exacerbate food insecurity in some countries. However, the dynamic is complex and the various factors that influence relations between tobacco farming and food insecurity may vary by country.

- Many of the largest tobacco-growing countries are also among the most food-insecure. For example, half of the 25 top leaf producing countries in 2012, also had undernourishment rates that exceeded 10% from 2011 to 2013 (446, 447).

- A 2007 survey of economic gains and losses of tobacco farmers in Bangladesh showed that tobacco farmers experienced higher levels of food insecurity than farmers testing alternative mixed cropping systems. That is, tobacco farmers reported an annual net loss in food independence (adequate food supply for 3 months or more) while mixed crop farmers reported an annual net gain. These results suggest that modest investments in programmes to assist tobacco farmers to transition to alternative crops can contribute directly to national food security objectives (448).

- A 2015 survey of the economic livelihoods of tobacco farmers in Zambia showed that while nearly all farmers (485 (97%)) reported that they grow their own maize (which is a staple food in Zambia), more than one-quarter (135 (27%)) reported they did not grow enough maize to feed their family for the year and thus had to purchase maize to make up for the difference. In addition, farmers with larger incomes and/or land plots were not always growing more maize, but were allocating more land to the cultivation of the tobacco cash crop. That is, farmers may choose to grow other cash crops (such as tobacco) and use any earnings to purchase maize. Taken together, these findings suggest that the nature of the relation between tobacco growing and food security may be affected by two dynamics. First, there is a macro-level dynamic whereby increasing amounts of land in a country are allocated for the cultivation of tobacco, which in turn, may potentially decrease the broader food supply. Second, there is a micro-level dynamic in which farmers make a rational decision to grow tobacco for cash that can be used to purchase staple food crops, which may reflect farmers' choice to participate in

the agricultural marketplace as opposed to indicating food insecurity. The relation between tobacco growing and food security is also dependent on factors such as farmers' age and experience. For example, farmers who were older, worked on labour-intensive farms with low tobacco yields and low overall incomes were more likely to report higher food security precisely because they were growing more maize for household consumption (426).

- Similar to the findings of the 2015 survey of tobacco farmers in Zambia reported above, a 2013-2014 survey of tobacco farmers in Kenya also found that farmers with larger incomes and more land were not always growing more maize (a staple food crop in Kenya). Instead, some of these tobacco farmers were allocating more of their land and resources to the cultivation of tobacco as a cash crop, and then using part of their earnings from selling tobacco to purchase maize and other food (425).

Case Studies: Effectiveness of Alternative Livelihood Programmes

A small number of case studies conducted in LMICs have shown that a number of commercial crops can produce a better net profit and rate of return than tobacco.

- In 2008, a tobacco crop substitution pilot project was initiated among more than 450 families in the Yuxi municipality of the Yunnan Province in China. In 2010, farmers increased their annual profit per acre by up to 110% by growing other crops (449).

- In 2006, the Tobacco-to-Bamboo Project was launched in Kenya to compare tobacco and non-tobacco farmers in their livelihood strategies, and to investigate the viability and sustainability of replacing tobacco with bamboo. Preliminary findings indicated that 93.6% of tobacco farmers expressed willingness to adopt bamboo as an alternative to tobacco production. Results from the market analysis also estimated that the annual income from bamboo farming would be 4 to 5 times higher than that from tobacco farming at farm gate prices, and 10 times higher when processed at the community level to make products such as baskets and furniture. In addition, there were promising results regarding sustainability – growing bamboo not only provides more income than tobacco, but also allows for additional income from other crops because it can be intercropped (450-452). Nevertheless, it should be noted that the success of this programme was determined by a number of different factors including the specific locations that were available for the initial introduction of bamboo as an alternative crop, the rate at which the amount of land was shifted out of tobacco, and the types of seasonal crops that were selected for intercropping. Moreover, the limited market demand for bamboo products in Kenya suggests that alternative crop programmes that replace tobacco with bamboo need to be implemented in combination with other strategies to ensure positive long-term outcomes and sustainability (453).

- A Zimbabwe case study examined the financial costs and returns for tobacco and 12 other important crops grown by farmers in 2001 (423). Findings showed that crops that may offer similar or higher net profit for large-scale commercial farmers included roses, paprika, coffee, and supermarket vegetables; and for smallholder growers, paprika, coffee, and cotton. However, it should be noted that cotton farming is very hard on the environment and both cotton and coffee buyers have been known to take advantage of farmers through unfair contracts.

- Studies that have examined the costs and returns from tobacco in comparison to crop alternatives in Malawi have shown that tomato, paprika, rice, confectionary groundnuts, and coffee can all provide higher incomes for smallholder farmers than tobacco (454, 455). Recent evidence suggests that while growing birds' eye chillies, paprika, and soybean are all less profitable than growing tobacco as a contract farmer in Malawi, growing these alternative crops is more profitable and sustainable than growing tobacco as an independent farmer. Given that the total averaged profits for independent and contract tobacco farmers is equivalent or even slightly less than the profits of soy and chilli farmers, it is possible that improved supply chains may increase the profitability of these alternative crops in Malawi over time (424).

- In 2011, a cost-benefit analysis of the financial performance of new crop combinations compared to tobacco production in Bangladesh showed that both the net profit and rate of return on investment was much lower for tobacco than other mixed cropping systems (456).

- In 2004, a study that examined crop substitution and diversification strategies adopted in Brazil indicated that the average net income of smallholder farmers in the Rio Pardo Valley region who grew alternative crops such as vegetables, rice, and Brazilian tea, was considerably higher than the net income of those who grew tobacco crops (443).

In summary, there is some evidence for viable alternatives to tobacco farming in LMICs. Case studies in China, Kenya, Zimbabwe, Malawi, Bangladesh, and Brazil have identified a number of commercial crops that may be profitable alternatives to growing tobacco. Nevertheless, it may be difficult to extend these small-scale programmes, particularly those that produce alternative crops with limited markets, to support large numbers of tobacco growers, workers, and/or sellers. This suggests that any viable approach for alternatives to tobacco farming must utilize multi-crop and/or multi-livelihood strategies. In addition, there is very limited research to date that evaluates the long-term impact of crop substitution programmes on socioeconomic outcomes of tobacco farmers.

E. Conclusions

Prior to the WHO FCTC coming into force in 2005, there were a small number of alternative livelihood programmes in existence around the world. Since 2005, several other initiatives to promote alternative livelihoods have been launched in some LMICs and have generated promising results. Although overall progress in the implementation of Article 17 has been slow in comparison to other WHO FCTC articles, it is likely that the Treaty has had a small impact in terms of providing more opportunities for tobacco farmers to transition to economically viable alternatives to tobacco, and encouraging countries to consider options for legislation in this policy domain. Nevertheless, it is important to note that a tremendous amount of work is still needed in order to achieve the primary goals of Article 17. There is some evidence from a small number of LMICs that substituting tobacco with a number of alternative crops can be profitable to smallholder tobacco farmers, but research is still needed to evaluate the long-term effectiveness of such crop substitution programmes. The successful implementation of alternative livelihood programmes requires governments to make a strong commitment to the provision of financial and other support services to tobacco farmers interested in diversification, implementation, and promotion of research programmes to assess the economic livelihoods of tobacco farmers, as well as the removal of TII from the policy making process.

Article 18

Protection of the environment and the health of persons

A. Article 18 Overview

Article 18 of WHO FCTC obligates Parties to have due regard to the protection of the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture within their respective territories. Guidelines for Article 18 have not yet been developed. However, a working group on economically sustainable alternatives to tobacco growing in relation to Articles 17 and 18 of the WHO FCTC was established at the third session of the COP (COP3, 17-22 November 2008). The working group submitted a progress report at COP4 (14-16 February 2010), which included an outline of policy options and recommendations on economically sustainable alternatives to tobacco growing (415). Draft policy options and recommendations were submitted at COP5 (12-17 November 2012), and reviewed and adopted at COP6 (13-18 October 2014) (416, 417).

B. Progress in the Implementation of Article 18

In recent years, there is some evidence for global progress in the implementation of Article 18 measures in a few areas.

- There was an increase in the number of reporting Parties[17] who indicated the implementation of measures in respect of tobacco cultivation considering protection of the environment (20 of 146 (14%) Parties in 2012 vs. 25 of 130 (19%) Parties in 2014), and the health of persons (22 of 146 (15%) Parties in 2012 vs. 28 of 130 (22%) Parties in 2014) (19).

- There was an increase in the number of reporting Parties who indicated the implementation of measures in respect of tobacco manufacturing for the protection of the environment (28 of 146 (19%) Parties in 2012 vs. 32 of 130 (25%) Parties in 2014), and the health of persons (29 of 146 (20%) Parties in 2012 vs. 34 of 130 (26%) Parties in 2014) (19).

C. Challenges in the Implementation of Article 18

Despite the improvements made by a small number of Parties in recent years, overall progress in the implementation of Article 18 remains slow in comparison to other WHO FCTC articles.

[17] Please note that not all reporting Parties grow tobacco or manufacture tobacco products.

- In 2014, only 23 of 130 (18%) reporting Parties cited specific examples of recent progress made in the implementation of Article 18 measures that aim to protect the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture (see Table 3).

Table 3. Progress in the Implementation of Article 18 by Reporting Parties in 2014 (19, 457)

Progress Made in Implementing Article 18	Party or Parties	Total Number of Parties (of 130 reporting Parties in total)
Implementation of environmental and occupational health and safety legislation, regulations, and policies.	Australia, Canada, Ghana, Hungary, Nigeria, Pakistan, Senegal, Turkey	8
Adoption of good agricultural practices for cultivation and production of tobacco with respect to use of fertilizers, plant protection products, and water consumption.	Canada, European Union, Italy, Pakistan, Thailand	5
Allocation of land used for cultivation of tobacco for planting of trees.	Kenya	1
Provision of aid for reforestation and soil water management.	Colombia, European Union	2
Implementation of measures to improve energy savings and reduce emissions in the cigarette manufacturing process.	China	1
Enforcement of standards for reduced ignition propensity cigarettes.	Bulgaria, Republic of Korea, South Africa	3
Currently working on legislation to classify cigarette butts as special waste.	Costa Rica	1
Provision of periodical medical check-ups for tobacco growers.	Islamic Republic of Iran, The former Yugoslav Republic of Macedonia	2
Require protective gear for tobacco farmers and tobacco industry workers.	Italy, Kenya	2

The tobacco industry continues to interfere with the development and implementation of effective Article 18 measures by promoting policies that avoid all environmental responsibility for producers, and using corporate social responsibility programmes to divert public attention from their environmental responsibilities (458).

D. Effectiveness of Implementation of Article 18

Each stage of the lifecycle of tobacco production and use (tobacco growing and curing; product manufacturing and distribution; product consumption; and post-consumption waste) has a significant impact on the environment and health of persons (459).

The following section provides an overview of research to date on the three impact indicators to evaluate the implementation of Article 18, as suggested by the working group in the draft policy options and recommendations that were reviewed and adopted at COP6 (13-18 October 2014).

Prevalence of Green Tobacco Sickness and Harms Linked to Tobacco Growing

Green tobacco sickness (GTS) is a potential occupational health risk that can affect individuals working with the green tobacco plant. GTS is a form of nicotine poisoning caused by the absorption of nicotine through the skin as a result of contact with wet tobacco leaves. The characteristic symptoms of GTS include nausea, weakness, dizziness, abdominal cramps, and fluctuations in blood pressure and heart rates (460-464). In order to evaluate the impact of Article 18 on reducing health risks related to tobacco farming, it is important to have a baseline analysis of the prevalence of GTS. Overall, there is a lack of global surveillance to document the prevalence of GTS. Moreover, there are very little and in some cases no data on the prevalence of GTS in top tobacco-producing countries such as China, Brazil, India, the US, Argentina, Malawi, and Indonesia.

- Incidence of GTS in the US was first described in the medical literature in the 1970s, and has since been documented among tobacco farmers in a few LMICs including India, Brazil, and Vietnam (460, 465-468).

- Literature on the prevalence of GTS remains limited, and there are wide variations in the prevalence rates reported in existing studies.

    - A 2007 review of 31 studies of health risks associated with tobacco farming found that seasonal prevalence of GTS ranged from 8% to 89%. Incidence was reported to be 1.9 cases per 100 person days (445).
    - A 2012 meta-analysis identified only three epidemiological studies on the prevalence of GTS (469). Two of these studies were based on data from the US. The first study used US and Kentucky Department of Agriculture data, and estimated the incidence of GTS to be 1% (10 out of 1000 workers) (472). A second study conducted in North Carolina estimated prevalence of GTS to be 9%

(5400 out of 60 000 workers) (474). A third study that assessed the prevalence of GTS among tobacco harvesters in four villages of Gujarat, India showed that the prevalence of GTS was higher among beedi tobacco cultivators (86.2%) and chewing tobacco and snuff tobacco cultivators (47.0%) in comparison to cigarette tobacco cultivators (60.6%) (465).

- A 2014 study reported prevalence of GTS to be 6.6% among male tobacco farmers, and 11.9% among female tobacco farmers in Southern Brazil (471).

There is some evidence, primarily from studies conducted in the US, that use of personal protective equipment (PPE) such as water-resistant clothing and chemical-resistant gloves can reduce the amount of nicotine absorbed by workers in contact with green tobacco, and the incidence of GTS symptoms.

- A case-control study that assessed the risk factors for GTS among tobacco workers in Kentucky indicated that GTS may be prevented by avoiding work in wet tobacco or by use of protective clothing (472).

- A study conducted in the US showed that covering exposed skin seems to be the most effective way of preventing GTS among tobacco harvesters (460).

- Wearing rubberized nylon rainsuits effectively prevented nicotine absorption among volunteers in North Carolina who picked wet tobacco, nicotine absorption was demonstrated among tobacco workers who wore clothing that was not waterproof (462).

- There was a significant reduction in nicotine absorption (as measured by nicotine and cotinine excretion rates), as well as a reduction in GTS symptoms, among tobacco harvesters in India who wore boots, socks, and gloves (461, 473).

- A study conducted in North Carolina demonstrated that wearing a rain suit while working in wet tobacco can significantly reduce the risk of GTS among tobacco workers (474).

- Tobacco farmers in Malaysia who did not wear PPE reported GTS symptoms more frequently than those who used PPE (470).

- Although research has demonstrated that PPE can be effective in protecting tobacco farmers against the development of GTS symptoms, virtually no countries require tobacco farmers to use PPE. As of 2014, only two WHO FCTC Parties, Italy and Kenya, require protective gear for tobacco farmers and tobacco industry workers (19, 457).

In addition to the risk of GTS, tobacco farmers are also at risk for pesticide poisoning. Because tobacco plants are sensitive and prone to many diseases, large amounts of pesticides are

routinely used in tobacco cultivation. A few studies suggest that exposure to pesticides used to grow tobacco may have a negative impact on the health of individuals who work on tobacco farms.

- Long-term exposure to organophosphate pesticides was associated with increased rates of depression and suicides among tobacco farmers in Brazil (475).

- Children who worked on tobacco farms in Mexico were exposed to toxic levels of pesticides, and had high rates of depression and anaemia (476).

- Tobacco farmers in Malaysia who were exposed to pesticides exhibited neurophysiological symptoms. Specifically, tobacco farmers had significantly lower maximal motor and sensory nerve conduction velocities, and significantly higher postural sway in comparison to controls (477).

Tobacco farmers' awareness of the risks of harvesting tobacco and the potential hazards of handling pesticides are important for prevention of negative health effects such as GTS and pesticide poisoning. Nevertheless, there is some evidence that high levels of awareness may not always lead to changes in behaviour.

- Following a 1992 public awareness campaign to educate tobacco workers and healthcare providers in the US state of Kentucky about the risks of tobacco harvesting, there was an increase in the 1993 incidence of hospital-treated GTS, which may have been due in part to the heightened awareness about GTS among tobacco workers and healthcare providers (472).

- A 2004 study found that 99% of tobacco farmers in Greece thought that pesticides can have serious adverse effects, and 58% recognized that skin contact was the most common route of exposure during pesticide use. Nevertheless, 46% of farmers reported that they did not use any protective equipment when spraying pesticides, and 68% reported that they did not use protective equipment because it is uncomfortable (478). These findings are consistent with the suggestion by other researchers that although PPE may afford tobacco farmers protection against GTS, proper use of PPE may be difficult for tobacco farmers, given that it must be impermeable yet comfortable for use when working under high temperatures (461, 473, 474).
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Child Labour in Tobacco Growing

Information on child labour practices in the tobacco growing sector is limited, and estimates of the total number or percentage of children who work on tobacco farms around the world remain unavailable. However, there is some evidence that contractual obligations may create conditions that continue to promote the use of child labour among family farm tobacco operations, particularly in LMICs (440, 479, 480).

- A 2014 report released by the US Department of Labor showed that as of 2012 to 2013, the following 15 LMICs continue to use child labour in the production of tobacco: Argentina, Brazil, Cambodia, Indonesia, Kenya, Kyrgyz Republic, Lebanon, Malawi, Mexico, Mozambique, Nicaragua, Philippines, Tanzania, Uganda, and Zambia (481).

- A few studies have shown that child labour in tobacco production still exists in HICs such as the US, where children who are members of tobacco farming families, migrant youth laborers (primarily Latinos), and other local hired children, continue to work on tobacco farms (482-484).

- There are also some data indicating that child labour continues to be a serious problem in the tobacco growing sector in Kenya and Malawi. It is estimated that 60% of the workforce in plantations in the Central province of Kenya are children, and that 57% of all children in the Kasungu and Dowa districts of Malawi are involved in child labour on tobacco farms (485, 486).

- In a 2015 survey that examined the economic livelihoods of tobacco farmers in Zambia, 22.5% of respondents reported that children were engaged in tobacco production activities on their farms (426).

Impact of Tobacco Growing on Forest Degradation and Deforestation

Deforestation for the purpose of cultivating and curing tobacco results in loss of biodiversity, soil degradation, loss of land and food resources, land pollution through the use of pesticides, and water pollution, which in turn, have a negative impact on human health (487-489).

In many LMICs, trees are often cut down to allow for the planting of tobacco crops, and additional trees are cut down for use during the flue curing process. There is some evidence that tobacco cultivation accounts for high rates of deforestation on a local and global scale, especially in LMICs:

- A study that assessed the global amount of tobacco-related deforestation between 1990 and 1995 found that an estimated 200,000 ha of forests and woodlands were removed for tobacco farming each year. Deforestation occurred primarily in developing countries, and accounted for 1.7% of the net amount of forest cover removed annually on a global scale, and 4.6% of total national deforestation. Results also identified 35 countries with an estimated serious, high, and medium degree of tobacco-related deforestation, mainly in Southern Africa, the Middle East, South and East Asia, South America, and the Caribbean (490).

- A 2008 report by the WHO study group on economically sustainable alternatives to tobacco growing estimated that the global share of agricultural land used to grow

tobacco is less than 1%, but the impact of growing tobacco on global deforestation is 2% to 4%, which will have implications for climate change (487).

- Between 1990 and 1995, tobacco farming accounted for 26% of deforestation in Malawi (491).

- In the Urambo tobacco-growing region of Tanzania, tobacco farming is responsible for 3.5% of annual deforestation. Farmers also use an average of 23m^3 of stacked wood per season for curing, which leads to an additional 3% of annual deforestation. In addition, 69% of tobacco farmers clear new areas of woodlands for tobacco cultivation every growing season (492). It is estimated that shifting cultivation is associated with nearly all (96%) of deforestation cases in Tanzania (493).

- In the West Nile region of Uganda, more than 60,000 m^3 of wood was used to flue cure tobacco in 1990 alone (494).

The tobacco industry has attempted to respond to growing public awareness and criticism of the impact of tobacco farming on deforestation by conducting CSR activities and campaigns that focus on reforestation efforts. However, there is some evidence to suggest these reforestation initiatives have had little or no impact on rehabilitating forest areas that were cleared for tobacco cultivation.

- Trees planted under BAT-sponsored reforestation efforts in Kenya and Uganda were comprised of non-native, fast-growing species such as cypress and eucalyptus, which are not ecologically-suited the growing conditions of these regions, require time-consuming care, and utilize vast quantities of water (494, 495).

- There is no monitoring to determine whether the proportion of trees that are actually planted or survived matches the number of trees that the tobacco industry claims to have distributed in their reforestation initiatives (496).

In summary, there is a small body of evidence showing that a substantial proportion of deforestation is attributable to tobacco farming. However, there is still a lack of scientific data to estimate the extent of tobacco-related deforestation, the rate at which it is changing, and the impact of reforestation initiatives (497). It is also difficult to make international comparisons of tobacco-related deforestation due to the lack of standardized research methodologies to monitor and assess the impact of tobacco growing on ecosystems (444). Furthermore, there has been little progress in government support for reforestation efforts over time. As of 2014, only two WHO FCTC Parties, Colombia and the EU, reported the provision of aid for reforestation and soil water management (19, 457). Finally, there does not appear to be any research conducted to date that compares the percentage of forest degradation and deforestation in tobacco growing areas versus alternative crop growing areas, and assesses the environmental impact of growing alternative crops instead of tobacco.

E. Conclusions

Since the WHO FCTC came into force in 2005, there has been an increase in the number of Parties reporting strategies, plans, and programmes that address the health and environmental impacts related to the cultivation and manufacture of tobacco. It is conceivable that the WHO FCTC has been effective to the extent that it has stimulated the discussion and development of national policies in this domain in some countries, but much progress is still needed. Although the total number of Parties reporting implementation of measures in respect to tobacco cultivation and manufacturing considering the protection of the environment and health of persons has increased from 2012 to 2014, overall progress in implementation of Article 18 has been slow. There is also a major gap in research that evaluates the effectiveness of implementation of Article 18. Scientific studies are still needed to determine the baseline prevalence of known health risks related to tobacco farming such as GTS, the percentage of child labour in tobacco growing regions, and the extent of deforestation or forest degradation caused by tobacco cultivation. In addition to working towards a baseline analysis of problems to be changed by tobacco control policies, governments in tobacco growing regions also need to strengthen health surveillance, implement legislation that sufficiently protects tobacco farmers against occupational health risks and eliminates child labour on tobacco farms, and provide financial aid for evidence-based and sustainable reforestation initiatives.

Article 19

Liability

A. Article 19 Overview

Article 19 of the WHO FCTC obligates Parties to consider taking legislative action to deal with criminal and civil liability, including compensation where appropriate; afford one another related assistance in legal proceedings; and cooperate with each other in exchanging information through the COP in accordance with Article 21. Guidelines for Article 19 have not yet been developed. However, an expert group on Article 19 was established by the fifth session of the COP (COP5, 12-17, November 2012). In accordance with decision FCTC/COP5(9), the expert group submitted a working report at COP6 (13-18 October 2014) (498, 499).

B. Progress in the Implementation of Article 19

In recent years, there has been some global progress in the implementation of Article 19 measures in a few specific areas.

- In 2012, only one-quarter of reporting Parties indicated having implemented any measures to tackle liability. In 2014, nearly half of all reporting Parties had criminal liability measures in tobacco control legislation (59 (45%) of 130 Parties); and more than one-third of all reporting Parties had general civil liability measures that could apply to tobacco control (46 (35%) of 130 Parties) (19).

- As of 1 September 2012, 51 jurisdictions around the world have referenced and incorporated the WHO FCTC into legislative objectives, definitions, and/or substantive provisions (500).

C. Challenges in the Implementation of Article 19

Overall global progress in the implementation of Article 19 remains slow in comparison to virtually all other substantive articles of the WHO FCTC (19).

- In 2014, just over one-quarter of all reporting Parties indicated having in place separate liability provisions on tobacco control outside of tobacco control legislation (36 (28%) of 130 Parties); and civil liability measures that are specific to tobacco control (34 (26%) of 130 Parties).

- In 2014, only a small number of reporting Parties indicated that they have taken any liability action within the scope of legislation for criminal and civil liability.

    - 23 of 130 (18%) Parties reported that any person in their jurisdiction had launched a criminal and/or civil liability action against any tobacco company in relation to the adverse effects of tobacco use.
    - 13 of 130 (10%) Parties reported having taken any legislative, executive, administrative and/or other action against the tobacco industry for full or partial reimbursement of medical, social, and other relevant costs related to tobacco use in their jurisdictions.

- In 2014, 23 of 130 (18%) reporting Parties indicated that they had civil or criminal liability provisions that stipulate compensation for adverse health effects of tobacco and/or for reimbursement of medical, social or other relevant costs.

D. Effectiveness of the Implementation of Article 19

A background paper prepared for the WHO FCTC Impact Assessment Expert Group by the McCabe Centre for Law and Cancer and the International Legal Consortium of the Campaign for Tobacco-Free Kids (CTFK) provides evidence that the WHO FCTC has been effective in assisting governments to defend against legal challenges to tobacco control measures in four broad ways (501).

1. The WHO FCTC has been invoked in litigation by Parties as a legal instrument that imposes an obligation to implement tobacco control measures. For example:

    - In the 2012 South African case of British American Tobacco South Africa v. Minister of Health, a Supreme Court Appeal ruling to uphold a TAPS ban included reference to South Africa's obligations to implement domestic tobacco control legislation as a Party to the WHO FCTC (502).
    - In the 2013 Sri Lankan case of Ceylon Tobacco Co v. Minister of Health, the Court of Appeal recognized Sri Lanka's international commitments under the WHO FCTC and Article 11 guidelines and upheld regulations requiring pictorial health warnings on tobacco packaging (503).
    - In the 2011 Peruvian case of 5000 Citizens v. Article 3 of Law 28705, the Constitutional Court concluded that the Government of Peru was obliged to implement a smoking ban in enclosed public spaces as a Party to the WHO FCTC (504).

2. The WHO FCTC has been used in legal proceedings to support the constitutionality of domestic laws that protect the right to health. For example:

    - In the 2012 case of Philip Morris Norway v. Health and Care Services of Norway, the District Court upheld a ban on tobacco displays, citing provisions under Article 13 guidelines and concluding that the display ban did not constitute a restriction under Article 11 of the European Economic Area (EEA) Agreement (505).
    - In the 2010 Colombian case of Caceres Corrales v. Colombia, the Constitutional Court made significant reference to the WHO FCTC in the decision that a comprehensive TAPS ban permissibly restricted commercial speech because it aims to reduce tobacco consumption (506).
    - In the 2010 case of Guatemala Chamber of Commerce v. Guatemala, the Court ruled that the smoke-free law, in accordance with the WHO FCTC, recognizes the right to health (507).
    - In 2014, the Supreme Court of Justice in Panama ruled that a ban POS tobacco product displays complied with the Constitution of Panama, citing the WHO FCTC and Article 13 guidelines (508).
    - In the 2008 case of Sindicato da indústria do fumo no Estado do Rio Grande do Sul v. ANVISA in Brazil, the Regional Federal Court supported the constitutionality of health warnings, with specific reference to Articles 2, 3, 4, 7, 11, and 13 of the WHO FCTC (509).
    - In the 2011 Turkish case of Izmir Association of Coffeehouses v. Prime Minister, the Constitutional Court ruled that the national smoke-free law did not violate the constitutional rights of coffee shop owners, with reference to the WHO FCTC and Article 8 (510).

3. The WHO FCTC has established international norms and practices that courts have cited to uphold tobacco control measures in individual jurisdictions. For example:

    - In the 2007 case of Canada (Attorney General) v. JTI-Macdonald Corporation, the Court made reference to anti-tobacco measures implemented in other countries and Canada's obligations as a Party to the WHO FCTC in the decision to uphold a law mandating tobacco control measures, including pictorial health warning labels on 50% of the front and back of cigarette packs (511).
    - In the 2012 case of British American Tobacco South Africa (Pty) Limited v. Minister of Health, the Court referred to South Africa's obligation to implement TAPS bans that have already been adopted in other countries (512).
    - In the 2013 case of Ceylon Tobacco Co v. Minister of Health in Sri Lanka, the Court decision to uphold regulations requiring pictorial health warnings on tobacco product packaging included reference to the implementation of such warnings in other countries around the world (503).

4. The WHO FCTC has been cited in case law as an authoritative source of scientific evidence for the harms of tobacco use and the effectiveness of strong tobacco control measures. For example:

    - In the 2008 case of Saenz Sibaja v. Municipality of Oreamuno in Costa Rica, the Court decision to order an employer to relocate a smoking area from near a dining area to protect rights to health and a safe work environment included reference to the WHO FCTC as evidence for health harms due to SHS exposure (513).
    - In the 2006 case of Irit Shemesh v. Focaccetta Ltd., the Israel Supreme Court made specific reference to Article 8 as a source of scientific evidence for the health harms caused by SHS exposure, in the decision to award monetary compensation to a pregnant diner and her family who were exposed to SHS in a restaurant (514).

In addition to being used as an important instrument to assist Parties in defending against legal challenges to tobacco control measures in domestic courts, the WHO FCTC has also been used by civil society organizations to initiate litigation to compel Governments to implement stronger tobacco control measures (501). For example, notable references to the WHO FCTC were made to support court decisions to remove exemptions to smoking bans in Belgium (515), the Netherlands (516), and New Zealand (517); and to allow a civil society organization to petition for the implementation of plain/standardized packaging in India (518). Finally, the WHO FCTC may also have the potential to serve as legal instrument to assist Parties in defending against legal challenges to tobacco control measures that the tobacco industry claims are in breach of international trade and investment agreements. For example, the WHO FCTC was recently invoked by Australia and Uruguay in defense of challenges to their tobacco product packaging and labelling measures in international trade and investment cases (via BITs in both countries, and in the case of Australia, an additional challenge brought before the WTO) at the time of writing this report (519, 520).[18]

E. Conclusions

Since the WHO FCTC came into force in 2005, the Treaty has served as an important legal instrument to defend Parties against legal challenges to tobacco control measures, and to facilitate legal proceedings to require governments to strengthen existing legislation. Moreover, specific references to the WHO FCTC have been incorporated into domestic legislation by a growing number of countries around the world. Although these trends provide evidence for the positive impact of the WHO FCTC on legislation and litigation over the last decade, there is still much room for improvement. As of 2014, less than one-quarter of Parties have actually taken any liability action against the tobacco industry. International cooperation

[18] Please see the section on Article 5.3 (Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry) for further details on these court cases.

and exchange of information, in addition to other forms of technical assistance, will be important to support Parties in their efforts to litigate against the tobacco industry.

Article 20

Research, surveillance, and exchange of information

A. Article 20 Overview

Article 20 of the WHO FCTC obligates Parties to establish national, regional and global health surveillance programmes; implement and promote tobacco control-related research; facilitate the cooperative exchange of tobacco control-related information; and provide support to developing country Parties and Parties with economies in transition to meet their Article 20 Treaty obligations. Guidelines for Article 20 have not yet been developed.

B. Progress in the Implementation of Article 20

The WHO FCTC obligates Parties to implement evidence-based strategies in order to reduce the adverse outcomes associated with tobacco use. In order to achieve this, strong research programmes and surveillance systems are critical to the success of monitoring and addressing the tobacco epidemic (119, 522).

Since the WHO FCTC came into force in 2005, there has been some progress in the implementation of Article 20 provisions. However, these developments have been largely limited to the implementation of programmes for tobacco-related research, surveillance, and information exchange in a few specific areas.

- There was an increase in the number of reporting Parties who indicated that they have carried out research on the consequences of tobacco consumption from 80 of 146 (55%) Parties in 2012 to 88 of 130 (68%) Parties in 2014 (19).

- The number of reporting Parties who indicated that their national epidemiological surveillance systems cover social, economic, and health indicators related to tobacco consumption increased from 58 of 146 (40%) Parties in 2012 to 65 of 130 (50%) Parties in 2014 (19).

- In 2014, just over half of all reporting Parties (72 of 130 (55%) Parties) indicated that they have training programmes for those engaged in tobacco control activities (19).

- As of 2014, more than half of all reporting Parties have established research programmes that address the determinants of tobacco consumption (88 of 130 (68%) Parties), and the consequences of exposure to tobacco smoke (75 of 130 (58%) Parties); and implemented surveillance systems for exposure to tobacco smoke (74 of 130 (57%) Parties) (19).

- As of 2014, more than two-thirds of reporting Parties (88 of 130 (68%) Parties) have established a database of national laws and regulations on tobacco control, and more than half of reporting Parties (70 of 130 (54%) Parties) have established a database of information about the enforcement of tobacco control laws (19).

- More than half of reporting Parties (81 of 130 (62%) Parties) reported the exchange of scientific, technical, socioeconomic, commercial, or legal information in 2014 (19).

- An analysis of tobacco control papers published in peer-reviewed journals across 31 European countries between 2000 and 2012 found that the overall volume of publications had almost doubled within 10 years. The increase in scientific output accelerated around 2003, coinciding with the signature of the WHO FCTC by the EU (523).

C. Challenges in the Implementation of Article 20

On the whole, global progress in the implementation of Article 20 provisions has been slow.

- There has been very little change in the number of reporting Parties who have conducted research on the social and economic indicators related to tobacco consumption from 2012 (77 of 146 (53%) Parties) to 2014 (81 of 130 (62%) Parties) (19).

- As of 2014, only 5 of 130 (4%) reporting Parties (Australia, Finland, Mexico, Sweden, and the United Kingdom) have established training programmes and strategies that aim to strengthen tobacco control capacity (19).

- As of 2014, less than half of reporting Parties have conducted research on tobacco use among women (62 of 130 (48%) Parties), and the identification of effective tobacco dependence treatment programmes (59 of 130 (45%) Parties). The area in which the fewest reporting Parties have conducted research was the identification of alternative crops, reported by only 20 of 130 (15%) Parties in 2014 (19).

- From 2012 to 2014, there was little change in the number of reporting Parties with surveillance systems that cover the following (19):

    - Patterns of tobacco consumption: 86 of 146 (59%) Parties in 2012 vs. 88 of 130 (68%) Parties in 2014.
    - Determinants of tobacco consumption: 66 of 146 (45%) Parties in 2012 vs. 62 of 130 (48%) Parties in 2014.
    - Consequences of tobacco consumption: 58 of 146 (40%) Parties in 2012 vs. to 59 of 130 (45%) Parties) in 2014.

- According to WHO global estimates, more than two-thirds of HICs adequately monitor tobacco use among both adults and youth through the use of representative and periodic surveys as of 2014. However, this level of achievement has been accomplished by only one-quarter of MICs and one LIC (20).

- From 2012 to 2014, there was very little progress in the exchange of information by reporting Parties in the following areas (19):

    - Tobacco industry practices: 58 of 146 (40%) Parties in 2012 vs. 56 of 130 (43%) Parties in 2014.
    - Cultivation of tobacco: 37 of 146 (25%) Parties in 2012 vs. 36 of 130 (28%) Parties in 2014.

- In Europe, there was a near two-fold increase in the volume of published research in the area of tobacco control from 2000 to 2012. However, research output was unevenly distributed across Europe, with relatively few publications from Eastern European countries that lack funding to support research programmes (523).

D. Conclusions

Since the WHO FCTC came into force in 2005, there has been some global progress in the implementation of measures to promote research, surveillance, and information exchange. As of 2014, more than half of all reporting Parties have established research programmes that address the determinants of tobacco consumption and the consequences of exposure to tobacco smoke; promoted the exchange of publicly available scientific, technical, socioeconomic, commercial, or legal information; and implemented national epidemiological surveillance systems that cover exposure to tobacco smoke. In addition, there was a notable increase in the number of reporting Parties who have implemented national surveillance systems that assess the social, economic, and health indicators related to tobacco consumption from 2012 to 2014. Nevertheless, overall global progress in the implementation of Article 20 has been slow. Specific areas where much progress is still needed include the development of training programmes for individuals who work in tobacco control; the establishment of research programmes in areas such as the identification of alternative crops; the implementation of national surveillance systems for monitoring tobacco use, particularly in LMICs; and the promotion of international exchange of information on tobacco industry practices and the cultivation of tobacco. Progress in the implementation of Article 20 will be particularly important for building the evidence base to strengthen and accelerate WHO FCTC implementation.

Article 21

Reporting and exchange of information

A. Article 21 Overview

Article 21 of the WHO FCTC obligates Parties to submit to the COP, through the Secretariat, periodic reports on its implementation of the Convention. Although the frequency and format of such reports is determined by the COP, each Party is obligated to make its initial report within 2 years of the entry into force of the Convention for that Party. The COP, pursuant to Articles 22 and 26, shall also consider arrangements to assist developing country Parties and Parties with economies in transition, at their request, in meeting their obligations under Article 21. Guidelines for Article 21 have not yet been developed.

B. Progress in the Implementation of Article 21

Prior to 2012, each Party was requested to submit reports on implementation of the Convention after 2 and 5 years of entry into force of the Convention for that Party. Beginning in 2012, a standardized biennial reporting schedule was established, and Parties are now expected to submit implementation reports 6 months before each regular session of the COP.

Since the first reporting cycle in 2007, there has been steady progress in the submission of reports on the implementation of the Convention by Parties (19).

- The Secretariat has received at least one implementation report from 168 out of 178 Parties (94%) over the period from February 2007 to June 2014.

- The total number of Parties who had not submitted any implementation report at least once decreased from 15 Parties at the end of the 2012 reporting cycle to 9 Parties at the end of the 2014 reporting cycle.

- In 2012, a total of 146 of the 174 (84%) Parties that were due to report submitted an implementation report.

- In 2014, a total of 130 of the 177 (73%) Parties that were due to report submitted an implementation report.

- There was a notable improvement in the completeness of submitted reports from 2012 to 2014. Specifically, Parties provided more information on tobacco-related social costs, tobacco-related mortality, and exposure to tobacco smoke; more details in open-ended questions; and more supporting documentation in 2014.

The Secretariat has also made efforts to assist Parties in meeting their obligations under Article 21 by:

- Holding reporting sessions within regional meetings on implementation of the Convention;

- Establishing an Internet-based forum for the discussion of reporting and exchange of information;

- Implementing web-based training sessions; and

- Developing the WHO FCTC Indicator Compendium, which aims to promote the use of standardized indicators in data collection and epidemiological surveillance of tobacco use and related social, economic and health indicators within countries; and facilitate regional and global information exchange on these indicators.

C. Challenges in the Implementation of Article 21

Global progress in data collection and the reporting of information remains limited in several areas, and there is still a lack of data on Parties' use of implementation guidelines (19).

- As of 2014, implementation reports submitted by Parties still lack data in several areas including tobacco manufacturing; seizures of illicit tobacco products; tobacco growing; taxation and prices of tobacco products; and tobacco-related morbidity, mortality, and economic costs.

- Beginning in the 2014 reporting cycle, Parties had the opportunity to submit voluntary reports on their use of the implementation guidelines adopted by the COP. In this first reporting period, voluntary reports were submitted by only 18 of the 177 (10%) Parties that were due to report in the 2014 cycle.

- In the 2014 reporting cycle, more than one-quarter of Parties who were due to report (47 of 177 (27%) Parties) failed to submit their implementation reports by the deadline. In April 2013, the Convention Secretariat surveyed those Parties that had either not reported or reported with a substantial delay, in accordance with decision FCTC/COP5(11) (524). Of the 31 Parties contacted by the Secretariat, two responded by submitting their outstanding 2012 reports, and six responded to the survey questions. The three main reasons for the failure or delay in reporting that were identified by the six Parties who provided responses to the survey questions included the following:

    - Lack of data or capacity for national data collection and completion of the report;
    - Lack of key information to be reported or not enough progress to be reported; and

- Lack of information on the modalities of reporting and on the reporting instrument.

D. Conclusions

There has been steady progress in the submission of periodic reports on the implementation of the WHO FCTC by Parties since the Treaty came into force in 2005. The vast majority of Parties (168 out of 178 (94%) in total) have submitted at least one implementation report to the COP from February 2007 to June 2014. The recent transition to the standardized biennial reporting schedule has also been successful, with reports that were submitted by 130 of 177 (73%) Parties in the 2014 reporting cycle being of higher quality and more complete than those from the previous reporting cycle. However, the timely completion and submission of reports remains challenging for some Parties. In the 2014 reporting cycle, 47 of the 177 (27%) Parties that were due to report did not submit their implementation reports. Finally, only 18 of 177 (10%) Parties opted to submit voluntary reports on their use of the implementation guidelines in 2014.

Article 22

Cooperation in the scientific, technical, and legal fields and provision of related expertise

A. Article 22 Overview

Article 22 obligates Parties to cooperate directly or through competent international bodies to strengthen their capacity for implementing obligations arising from the Convention. Such cooperation shall promote the transfer of technical, scientific and legal expertise and technology to establish and strengthen national tobacco control strategies, plans and programmes. Guidelines for Article 22 have not yet been developed.

B. Progress in the Implementation of Article 22

Since the WHO FCTC came into force in 2005, there has been some global progress in the implementation of Article 22 in a few areas.

- From 2012 to 2014, more than half of reporting Parties indicated that they have received assistance for strengthening expertise for tobacco control programmes (74 of 146 (51%) Parties in 2012 vs. 77 of 130 (59%) Parties in 2014); and the transfer of skills and technology (74 of 146 (51%) Parties in 2012 vs. 75 of 130 (58%) Parties in 2014) (19).

- In recent years, regional organizations have provided support to strengthen the implementation of the WHO FCTC at the national and international level (19).
    - A community-based tobacco control project has been conducted by the Finnish Lung Health Association and ASH Finland in collaboration with the Ministries of Health and Education in Kyrgyzstan since 2011. The current project, which will run from 2014 to 2016, aims to support primary healthcare, village health committees, teachers, media and local authorities in their efforts to reduce tobacco use and exposure to second-hand smoke, and to change social norms and attitudes around tobacco use.
    - The Australian Government has provided financial and technical assistance to support the implementation of tobacco control measures by other Parties, particularly in the area of tobacco product packaging and labelling. For example, Australia has shared their graphic health warnings with other Parties, and provided funding for the development of technical resources and materials on plain/standardized packaging for use by other countries.

- The European Commission provided a €5.2 million grant to the Convention Secretariat to support efforts for the effective implementation of the WHO FCTC in LMICs.
- On 12 December 2012, the Caribbean Community (CARICOM) Council for Trade and Economic Development (COTED) adopted the Regional Standard for the Labelling of Retail Packages of Tobacco Products, which will require Caribbean countries to adopt rotating graphic warning labels on tobacco products.
- On 9 August 2011, the Gulf Cooperation Council (GCC) adopted a standard on labelling of tobacco product packages that mandates pictorial warnings that cover 50% of the front and back of all tobacco product packaging, and text warnings that appear in both Arabic (front of package) and English (back of package).

There is evidence that the WHO FCTC has encouraged regional cooperation and information exchange to improve the implementation of effective measures for smoke-free environments, health warnings, and promotion of cessation.

- In 2006, Uruguay became the first Latin American country, the first in the Americas region, and the first MIC worldwide to adopt comprehensive smoke-free legislation at the national level. Since then, several other countries in the region (e.g., Panama, Colombia, Peru, Venezuela, Brazil, and Costa Rica) have enacted 100% smoke-free legislation, with the assistance of policy experts from countries with successful smoke-free policies (525-527).

- Several Parties have reported regional collaboration efforts to facilitate and improve the implementation of Article 11, including exchanging information; granting licenses (without royalties) for other Parties to use established health warnings; adopting regional regulations for labelling that apply to multiple Parties; and engaging in international workshops to share experiences (18, 19).

- In 2009, the Tobacco Labelling and Packaging Toolkit and accompanying website was released. This Toolkit was created to serve as a resource to support implementation of effective tobacco packaging and labelling policies, and includes a review of evidence as well as recommendations for designing effective health warnings, including creating effective legislation (213).

- In 2009, countries in Mercosur, a regional economic bloc comprised of several South American member countries, created an electronic bank of pictorial warnings for any country within the region to use for the implementation of their own policies (209).

- In accordance with a decision reached at the third session of the COP (COP3, 17 to 22 November 2008), an international database of pictorial health warnings was established by the WHO Tobacco Free Initiative (528). The total number of Parties that have made their pictorial warnings available through this website increased from 14 Parties in 2010

to 20 Parties in 2014. Since 2010, the Secretariat has facilitated the granting of licenses to use these pictorial warnings to 22 Parties (17, 19).

- The Institute for Global Tobacco Control (IGTC) at the John Hopkins Bloomberg School of Public Health developed the Tobacco Pack Surveillance System (TPackSS) project to systematically document the variety of cigarette packages available in 14 LMICs with the greatest number of smokers. A website was created to support advocacy for the implementation of health warnings that align with WHO FCTC Article 11 guidelines. The website includes a database of tobacco packs, information on country requirements for and compliance with health warnings, and links to additional information resources (529).

- At the sixth session of the COP (COP6, 13 to 18 October 2014), the Convention Secretariat and the World Lung Foundation (WLF) launched a new online database to support pictorial warnings in Africa. This resource contains 43 images that have been rigorously field tested among smokers and non-smokers in Africa, along with corresponding text messages available in English and French. The images are available for Parties to use upon request in order to reduce the time and cost for Governments in the African region to implement effective health warnings (530, 531).

- Interference from the tobacco industry is particularly strong in the area of health warnings and can weaken and delay effective health warning legislation, but Parties have won legal battles with the tobacco industry in this regard, and strengthened international cooperation will be especially important to meet these challenges moving forward (19).

- Several resources are available to assist Parties with the implementation of Article 14.

    - Cochrane reviews on tobacco cessation, which are prepared by an international network of researchers, provide systematic reviews of the evidence base for tobacco dependence treatment and smoking cessation interventions (532).
    - The Society for Research on Nicotine and Tobacco (SRNT) has established "treatobacco.net", a website that summarizes the scientific evidence on tobacco dependence treatment, and now has a new section of resources to help countries to implement Article 14. The website includes a resource library that includes national cessation strategies, national treatment guidelines, and other tools designed specifically to help Parties to develop their own guidelines and provide cessation support (533).
    - An affordability calculator was recently published to allow countries to calculate the affordability of tobacco cessation interventions in their country in order to consider which interventions to prioritize (331).

- Other resources that have been made available by the WHO in efforts to assist countries with implementation of Article 14 include a 2011 manual on Developing and Improving National Toll-Free Tobacco Quit Line Services that aims to help LMICs in the early stages of quitline development (521); a 2014 training package aimed at training tobacco quitline counsellors (318); and a 2014 Toolkit for Delivering the 5A's and 5R's Brief Tobacco Interventions in Primary Care (319).

C. Challenges in the Implementation of Article 22

While there has been some global progress in the implementation of a few specific Article 22 provisions in recent years, the overall rate of progress in cooperative efforts by Parties to strengthen their capacity to meet obligations under the WHO FCTC has been slow (19).

- In 2014, only 2 of 130 (2%) reporting Parties indicated the use of bilateral and multilateral cooperation to promote the transfer of technology and information exchange among Parties to the WHO FCTC.
    - The EU provided a grant to the Convention Secretariat to support and enhance implementation of the WHO FCTC at the international level, with a focus on developing countries.
    - Uruguay inaugurated a new center for international cooperation in tobacco control.

- There has been very little change in the percentage of reporting Parties who indicated that they received assistance in the following areas from 2012 to 2014:
    - Training and sensitization of personnel was reported by 45% (66 of 146) of Parties in 2012 and 42% (55 of 130) of Parties in 2014.
    - Equipment, supplies, and logistics was reported by 36% (53 of 146) of in 2012 and 39% (51 of 130) of Parties in 2014.
    - Identification of methods for tobacco control, including treatment of nicotine addiction was reported by 23% (34 of 146) of Parties in 2012 and 25% (33 of 130) of Parties in 2014.
    - Research to increase the affordability of comprehensive treatment of nicotine addiction was reported by 11% (16 of 146) of Parties in 2012 and 13% (17 of 130) of Parties in 2014.

- There has been very little change in the percentage of reporting Parties who indicated that they provided assistance in specific areas linked to Article 22 provisions from 2012 to 2014.
    - The percentage of reporting Parties who provided assistance was highest in the areas of expertise for tobacco control programmes (33% (48 of 146) of Parties in 2012 and 25% (33 of 130) of Parties in 2014); and assistance on transfer of skills

and technology (28% (41 of 146) of Parties in 2012 and 26% (34 of 130) of Parties in 2014).

- The percentage of reporting Parties who provided assistance was lowest for the identification of methods for tobacco control, including treatment of nicotine addiction (14% (21 of 146) of Parties in 2012 and 12% (16 of 130) of Parties in 2014; and research to increase the affordability of comprehensive treatment of nicotine addiction (8% (12 of 146) of Parties in 2012 and 6% (8 of 130) of Parties in 2014).

D. Conclusions

Since the WHO FCTC came into force in 2005, there has been limited overall progress in cooperation at the regional and international levels to assist Parties to fulfill their obligations under the Treaty. In 2014, more than half of reporting Parties received assistance for the development and acquisition of expertise for tobacco control programmes, and the transfer of skills and technology, which represents an increase from 2012. However, there has been very little progress in other areas such as assistance for the training of personnel; provision of equipment and supplies; and the identification of affordable treatments for nicotine addiction. There is some evidence that the WHO FCTC has encouraged regional cooperation and information exchange to improve the implementation of effective measures for smoke-free environments, health warnings, and promotion of cessation. Nevertheless, greater cooperation and collaboration within the network of Parties to the WHO FCTC is still needed in order to ensure global progress in the implementation of all Treaty provisions.

Conclusions

This report presents the findings from a global review of evidence on the impact of the WHO FCTC after its first 10 years of operation. A desk review of selected scientific studies, commissioned reports, government documents, and other relevant literature was conducted to support the independent expert group in their assessment of the role of the WHO FCTC on the global implementation of tobacco control legislation and the effectiveness of those implementations.

Impact of WHO FCTC on Tobacco Control Legislation

In the decade since the WHO FCTC came into force, there have been significant gains in tobacco control implementation. Nevertheless, there is considerable variability in the overall rate and extent of global progress in the implementation of tobacco control legislation across countries and policy domains.

1. In general, time trends in implementation of tobacco control measures suggest that progress, as reported by Parties to the COP, has been more rapid and comprehensive for those Articles for which existing guidelines have been developed and specified timelines for the implementation of certain provisions have been provided.

2. The WHO FCTC has contributed to significant and rapid progress in the implementation of effective measures for: protection from exposure to tobacco smoke (Article 8); packaging and labelling of tobacco products (Article 11); education, communication, training and public awareness (Article 12); sales to and by minors (Article 16); and reporting and exchange of information (Article 21).

3. The WHO FCTC has contributed to progress in the implementation of measures for: price and tax (Article 6); regulation of tobacco product disclosures (Article 10); TAPS (Article 13); tobacco dependence and cessation (Article 14), illicit trade (Article 15); and research, surveillance, and information exchange (Article 20), although the overall rate of progress for these measures has been slower and advancements have often been limited to partial implementation.

4. The WHO FCTC has generated momentum to support the development of measures for: industry interference (Article 5.3); regulation of the contents of tobacco products (Article 9); economically viable alternatives (Article 17); protection of the environment and health of persons (Article 18); liability (Article 19); and cooperation (Article 22). While there is evidence of recent achievements in some countries, overall progress has been relatively slow.

5. The WHO FCTC Treaty text and guidelines have been cited explicitly by a growing number of countries to support new tobacco control measures, and to defend against industry challenges to measures in domestic and international courts.

Challenges to the Implementation of the WHO FCTC

Although the WHO FCTC has played an important role in driving global progress in the implementation of a wide range of tobacco control policies over the last decade, much progress is still needed in several areas. Ongoing challenges to the global implementation of the WHO FCTC include the following:

1. ***Tobacco industry interference***: The tobacco industry continues to rely on the use of strategies that are explicitly covered by Article 5.3 guidelines, including government partnerships, front groups, and CSR activities, to further their interests and undermine the implementation of strong tobacco control measures. The industry also uses strategies that are not directly covered by Article 5.3 guidelines to interfere with policymaking. Notably, the industry continues to intimidate governments with litigation, and in recent years, has directed greater attention towards the use of trade and investment agreements to challenge tobacco control measures in domestic and international courts. The industry has also increasingly focused on establishing "Better Regulation Agendas" that can be used to promote their interests and to undermine evidence-based policymaking.

2. ***Lack of guidelines***: Formal guidelines have not yet been adopted to assist Parties to meet their Treaty obligations for several key Articles of the WHO FCTC (Articles 9, 10, 15, 17 to 22).

3. ***Ineffective implementation of existing guidelines:*** Selective and incomplete implementation of existing guidelines allows the tobacco industry to take advantage of loopholes in tobacco control legislation.

4. ***Insufficient capacity****:* In many countries, there is limited capacity (e.g., administrative, technical, testing) for tobacco control at the national level.

5. ***Lack of financial support***: There is a lack of funding to support the implementation of effective measures for several WHO FCTC Articles. For example, in most countries, governments provide limited (if any) financial support for cessation services and tobacco dependence treatment, alternative livelihood programmes, measures for the protection of the environment and health of persons, and tobacco-related research programmes.

6. ***Poor enforcement***. The enforcement of tobacco control policies remains challenging. For example, many Parties continue to report difficulties in enforcing smoke-free laws, TAPS bans, and measures to limit youth access to tobacco products.

Effectiveness of WHO FCTC-Compliant Tobacco Control Measures

The WHO FCTC and its guidelines set out evidence-based strategies to reduce the social, economic, and health burdens of the global tobacco epidemic. In the decade since the WHO FCTC came into force, many countries have implemented scientifically proven tobacco control measures, and a growing body of research studies have provided further support for the effectiveness of those implementations.

1. In general, there is a substantial body of evidence supporting the effectiveness of WHO FCTC measures. Research also consistently shows that tobacco control measures are most effective when they align with the Convention and its existing guidelines.

    a. There is strong international evidence that price and tax increases (Article 6), comprehensive smoke-free policies (Article 8), pictorial health warnings (Article 11), comprehensive TAPS bans (Article 13), and cessation interventions (Article 14) are among the most effective strategies to reduce tobacco consumption and tobacco-related health risks, and encourage quitting.

    b. Research studies have also demonstrated that mass media campaigns (Article 12) and well-enforced measures to restrict youth access to tobacco products (Article 16) are highly effective strategies to prevent smoking initiation, decrease smoking prevalence, and promote cessation in HICs. Studies that examine the impact of mass media campaigns and youth access interventions in LMICs are needed to address this important research gap.

    c. A couple of studies have demonstrated that implementation of key WHO FCTC demand-reduction measures is associated with reductions in tobacco prevalence (9, 534).

2. There is a clear need for more research to evaluate the impact of tobacco control policies. Research that assesses the effectiveness of implementation of measures for several key Articles, most of which do not yet have guidelines, remains limited.

    a. In the vast majority of countries, the development and implementation of measures in the following policy domains is still in the early stages: prevention of industry interference (Article 5.3); regulation of contents of tobacco products (Article 9); promotion of economically viable alternatives (Article 17); protection of the environment and health of persons (Article 18); liability (Article 19); and cooperation (Article 22). To support Parties in meeting their obligations under these Articles, it will be important for the COP to develop guidelines for these policy domains (with the exception of Article 5.3, for which guidelines have already been adopted). Future research that evaluates the effectiveness of measures for these Articles is needed to address this current gap in the literature.

3. There is a paucity of research that has examined the impact of the WHO FCTC by gender and among disadvantaged groups.

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