### Implementation of a Tobacco Cessation Strategy in People living with HIV and Tuberculosis

Application of Article 14 of the World Health Organization Framework Convention on Tobacco Control







### **Authorities**

**Jorge Basso, MD**Minister of Public Health

Jorge Quian, MD
Director of ICCTC

### **Authors and affiliations**

### Consultants of the Knowledge Hub: International Cooperation Center on Tobacco Control, Uruguay

### Elba Esteves, MD

Fondo Nacional de Recursos, Uruguay

### Laura Llambí, MD, PhD

Facultad de Medicina, Universidad de la República, Uruguay

### Diego Rodríguez, MSc

Centro de Investigación de la Epidemia de Tabaquismo, Uruguay

### Amanda Sica, Psy D

Comisión Honoraria de Lucha Contra el Cáncer, Uruguay

### Beatriz Goja, MD

Sociedad Uruguaya de Tabacología, Uruguay

### **Disclosures**

The authors declare they have not been employed by, nor have received funding or support from any company which is directly involved with production, distribution or sales of tobacco products or with any other company which represents the tobacco industry.

They have no other conflict of interest to declare.

### **Acknowledgements**

We wish to thank Ana Lorenzo, MD former technical officer of ICCT and Enrique Soto, MD director of the Uruguayan National Tobacco Control Programme, for their constant and valuable support to this project.

We also thank Leticia Martinez at the FCTC Secretariat and Attorney Mariana Olivera and Notary Lucía Turcatti for their administrative help.

We thank Edanz Group <a href="www.edanzediting.com/ac">www.edanzediting.com/ac</a> for the English editing, and Alejandra Estévez for the professional design of this document.



### **Table of Contents**

_		
Dα	$\alpha$	Δ
гα	ч	ᆫ

15

Annexes

4	Foreward
4	Introduction
5	Recommendations
5	1. Objective
5	2. Underlying Considerations
6	3. Key Components
6	3.1 Recommendation 1: Conduct a national situation analysis
7	3.2 Recommendation 2: Develop and disseminate broad guidelines
7	3.3 Recommendation 3: Carry out comprehensive actions to implement the cessation strategy
8	3.4 Recommendation 4: Conduct follow-up and evaluation of strategy implementation
10	Implementation Plan for the Recommendations
10	1. National Situation Analysis
10	2. Comparison of the National Situation with the General Recommendations
11	3. Analysis of the Feasibility of the Implementation of each Recommendation
11	4. Roadmap for each Recommendation
12	5. Final Product: Cessation Strategy
13	Monitoring and Assessment
13	Evaluation 1
13	Evaluation 2
13	Evaluation 3
14	References



### **Foreward**

The present document was developed by the International Cooperation Center on Tobacco Control of Montevideo, Uruguay, a Knowledge Hub of the Secretariat of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC).

It is the first product of a pilot project funded by the Norwegian government to integrate tobacco cessation interventions with Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome (HIV / AIDS) treatment programs and Tuberculosis (TB) treatment programs in low and middle-income countries. This pilot project is called Application of Article 14 of the World Health Organization Framework Convention on Tobacco Control Focusing on People Living with HIV / AIDS and/or Tuberculosis.

### Introduction

Article 14 of the WHO FCTC states that "Each Party shall develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence".<sup>(1)</sup>

In the guidelines for the implementation of Article 14, one recommendation is that "Parties should consider using existing infrastructure that would provide the greatest possible access for tobacco users, including but not limited to primary health care and other services such as those providing treatment for tuberculosis and HIV / AIDS". (2)

The present document is complementary to these implementation guidelines, and joint reading is recommended. The goal of this document is to provide the theoretical framework and practical recommendations for promoting the inclusion of tobacco cessation interventions in HIV / AIDS and TB treatment programs in low and middle-income countries.

HIV infection poses a serious burden in the evolution of TB infection, and vice versa, with TB co-infection accounting for nearly 30% of all AIDS-related mortality<sup>(3)</sup>.

The WHO's recommendations for reducing the burden of this co-infection include a 12-component method to establish and strengthen mechanisms of collaboration and joint management between HIV programs and TB-control programs. This approach aims at enabling the delivery of integrated TB and HIV services, preferably at the same time and location. Given that tobacco use negatively impacts both infections, the present initiative proposes a collaborative strategy to mitigate the triple burden of TB, HIV, and tobacco use<sup>(4)</sup>.

TB is a bacterial infection caused by *Mycobacterium* tuberculosis. It almost always affects the lungs and is transmitted from person to person through the inhalation

of small droplets suspended in the air that are released when an infected person coughs or sneezes.

Although TB is a curable and preventable disease, it is one of the 10 leading causes of death worldwide. In 2016, 10.4 million people were infected with TB, and 1.7 million died from this disease, including 400 thousand people with  $HIV^{(5)}$ .

More than 95% of TB deaths occur in low and middle-income countries. Ending the TB epidemic is among the health-related goals for 2030 included in the Sustainable Development Goals, which were adopted in 2015<sup>(5)</sup>.

It is estimated that a quarter of the world population has latent TB infection, meaning that they are infected by the bacillus but do not have signs of active TB. From 5% to 15% of people with latent TB infection will develop TB at some point in their lives. People living with HIV / AIDS (PLHA) are 20 to 30 times more likely than others to develop TB. Tobacco use also greatly increases the risks of developing TB disease and dying from TB. It is estimated that, worldwide, 8% of TB cases are attributable to smoking<sup>(5)</sup>.

Furthermore, tobacco use is associated with greater severity of lung and extra-pulmonary lesions, as well as with higher mortality. Smokers are believed to have lower compliance with TB treatment, a higher probability of developing drug-resistant TB, and an increased risk of relapse. It has also been shown that exposure to second-hand smoke increases the risk of TB for all age groups, but especially for children<sup>(6)</sup>.

Infection with HIV continues to be a global public health problem. In 2016, one million people died worldwide because of diseases related to this infection. At the end of 2016, there were approximately 36.7 million PLHA, and there were 1.8 million new cases of HIV / AIDS in the same year. (7).

Although a curative treatment for HIV is not yet available, highly active antiretroviral therapy controls virus replication in infected individuals, preventing transmission and resulting in long, healthy, and productive lives for PLHA $^{(8)}$ .

Tobacco use is among the greatest threats to global public health. Almost 80% of the more than one billion smokers in the world live in low or middle-income countries, creating a great burden in terms of morbidity and mortality. More than 7 million people die each year because of tobacco use, including more than 6 million users of tobacco in any of its forms and about 890,000 non-smokers exposed to second-hand smoke<sup>(9)</sup>.

Certain population groups deserve special attention from health programs because of their higher levels of risk for HIV infection and TB. These groups also show higher prevalence levels for tobacco consumption, creating a triple comorbidity that multiplies their risk of death.

Among PLHA, smoking is associated with a lack of treatment adherence, decreased effectiveness of antiretroviral therapy, and worse treatment outcomes<sup>110</sup>. Smokers with HIV lose more years of life because of



smoking than because of the viral infection itself<sup>(12)</sup>. Patients who receive smoking cessation advice and specific recommendations to quit smoking from a health care provider (HCP) in charge of treating their HIV infection have an increased likelihood of quitting smoking<sup>(13)</sup>.

The countries most affected by the HIV epidemic are generally also burdened by other epidemics such as malaria and TB, and their health care systems are usually underfunded; therefore, these countries are less prone to invest in measures aimed at preventing chronic noncommunicable diseases. In these contexts, tobacco prevention and cessation programs are often limited or

nonexistent. Care programs for HIV could pave the way for a broader system of integrated services taking a preventive approach to managing non-communicable diseases.

A 2017 study<sup>(14)</sup> conducted in 28 low and middle-income countries reported a prevalence of tobacco use among men living with HIV of 27.1% (95% confidence Interval [CI]: 22.8–31.7) and a risk ratio (RR) of 1.41 (95% CI: 1.26–1.57) compared with men without HIV (p < 0.0001). In the same study, the prevalence among women living with HIV was reported as 3.6% (95% CI: 2.3–5.2), and the RR compared with women without HIV was 1.36 (95% CI: 1.10–1.69; p = 0.005).

### Recommendations

### 1. Objective

The purpose of this document is to assist selected countries in meeting their obligations under Article 14 of the WHO FCTC, maintaining consistency with the implementation guidelines, to promote tobacco cessation among people with HIV / AIDS and / or TB using practices based on the best available scientific evidence and taking into account national circumstances and priorities.

To that end, it is proposed that these countries create mechanisms to i) incorporate tobacco dependence treatment into HIV and TB treatment programs; ii) ensure wide access to support for tobacco users who wish to quit; and iii) provide sustainable resources to ensure that such support is available.

### 2. Underlying Considerations

**Tobacco creates a strong dependence.** Tobacco use and exposure to tobacco smoke have serious health, economic, environmental, and social consequences. Knowledge of the negative consequences of tobacco consumption, especially in relation to HIV / TB infection, and the benefits of quitting is necessary; however, in many cases, this knowledge is not enough to achieve cessation of tobacco use because of physical, psychological, and social tobacco dependence, which is mediated by nicotine, a highly addictive substance.

It is important to implement tobacco dependence treatment measures synergistically with other tobacco-control measures such as tobacco taxation; smoke-free environments; and advertising, promotion, and sponsorship bans. Implementing tobacco cessation and treatment measures in conjunction with population-level interventions covered by other articles of the WHO FCTC will have synergistic effects and thus maximize the impact of these measures.

**Tobacco dependence treatment should be widely available, accessible, and affordable.** To be accessible and affordable for people with HIV / TB, the most appropriate setting for this treatment is where

these infections are addressed. Affordability implies adopting measures to achieve the lowest possible cost or free treatment.

**Making the most of existing resources and infrastructure** facilitates the accessibility and affordability of treatment. The existing infrastructure for the treatment of HIV and TB could be the best setting for smokers to receive at least systematic brief counseling from the HCPs (Health Care Providers) who treat their infectious diseases. Brief counseling has been shown to double the rate of spontaneous tobacco cessation, and, when it is given by HCPs treating HIV or TB infection, quitting rates are even higher<sup>(15)</sup>.

**Stepwise approach.** After the implementation of brief counseling, progress can be made toward more intensive levels of intervention. Complementary infrastructure and coordination mechanisms between health care teams will be required to provide the most specialized tobacco dependence treatment (see the FCTC Article 14 guidelines section on "Specialized tobacco dependence treatment services").

The measures to promote quitting tobacco and the treatment of tobacco dependence must be inclusive. Factors such as gender, culture, religion, age, level of education and literacy, socioeconomic status, disability, and the specific needs of particular groups should be taken into account. In the case of people living with HIV / TB, the conditions of the pathology and the related social aspects should also be considered.

**Monitoring and evaluation are essential.** Periodic monitoring of individuals in the process of cessation and after achieving cessation is essential to achieve good outcomes. Integrating this approach in the follow-up monitoring of HIV / TB infection facilitates its implementation. Evaluation is essential for determining the effectiveness of the interventions and for detecting opportunities for improvement.

Sharing experiences at the international level will help countries to adopt new strategies or improve existing strategies, especially because tobacco cessation interventions for people living with HIV / TB are still scarce globally.



### 3. Key Components

The key components of a system to help tobacco users quit include approaches with a wide reach, such as brief advice and quitlines; more intensive approaches, such as behavioral support delivered by trained specialists; and effective medications. There is a substantial body of scientific evidence showing that behavioral support and medication are effective and cost-effective when used separately or in combination, although these approaches are especially effective when combined.

Systematic brief advice is the minimum effective intervention that should be promoted as widely as possible. Other population-level interventions that have proven to be effective are mediated by information and communication technologies: help via telephone lines, text messages, or social networks. Face-to-face behavioral support provided by trained HCPs, together with the use of specific drugs to treat withdrawal symptoms, is the intervention that has proven most effective.

All evidence-based interventions to promote tobacco cessation have been shown to be cost-effective because

lines for the implementation of Article 14 of the WHO FCTC (Figure 1).

### 3.1 Recommendation 1

Conduct a national situation analysis.

It is necessary to carry out an in-depth analysis of the context and national situation, with the objective of assessing the following when appropriate:

a) Level of implementation of the FCTC in the country, in particular the articles aimed at reducing the demand for tobacco products, with emphasis on the status of the implementation of Article 14, which has the goal of promoting tobacco cessation and providing tobacco dependence treatment. In addition, an analysis of the situation regarding the synergistic articles aimed at establishing price and tax measures (Article 6); smokefree environments (Article 8); labeling and packaging (Article 11); education and awareness of the population (Article 12); and advertising, promotion, and sponsorship bans (Article 13) should be conducted.

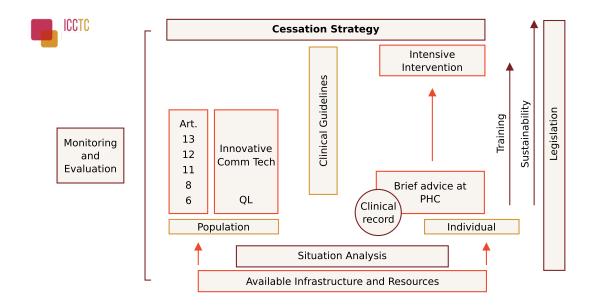


Figure 1. Diagram of the guidelines for the implementation of Article 14 of the Framework Convention on Tobacco Control. Note. Comm Tech: Communication Technology; PHC: Primary Health Care; QL: Quitline

of the high costs associated with the consequences of tobacco use for individuals, health systems, and societies as a whole.

It is essential that a person, commission, or agency is responsible for and takes charge of the articulation of all the actions recommended in this document, which will ultimately be the focal point in the country for the application of Article 14 in the target population.

The recommendations for addressing tobacco use in the population living with HIV / TB are framed in the general diagram presented above, which summarizes the guide-

- b) Level of implementation of the WHO policy on collaborative activities regarding  $\mbox{H\sc IV}/\mbox{TB}.$
- c) Status of treatment services for tobacco dependence.  $\,$
- d) Situation regarding HIV and TB treatment services.

Obtaining the necessary data to develop a realistic and accurate analysis of these factors will require the involvement of local clinical and program management experts in the various topics to be analyzed.



### 3.2 Recommendation 2

Develop and disseminate broad guidelines.

Taking into account the findings of the national situation analysis, countries should develop and disseminate management and clinical guidelines for promoting the integration of anti-tobacco interventions with TB and HIV treatments, based on the best available scientific evidence and practices. These guidelines should include two major components: a cessation strategy and clinical practice guidelines.

- a) **Cessation strategy.** A cessation strategy is needed to integrate tobacco cessation into HIV and TB treatment. This strategy should take the form of management guidelines addressed mostly toward policy makers and those responsible for funding. The cessation strategy will be developed after an analysis of Strengths, Weaknesses, Opportunities, and Threats (SWOT) in relation to each of the gaps detected in the situation analysis.
- b) Clinical practice guidelines. The clinical practice guidelines are treatment recommendations to help service managers, practitioners, HCPs, and patients to make decisions about appropriate treatment for tobacco dependence and cessation. The general clinical practice guidelines for the tobacco dependence treatment of smokers should be applicable to PLHA and individuals with TB. The guidelines should include the widest possible range of interventions, from less intensive to specialized. It is recommended that practical summary documents be prepared that are specific to the scope of the objective of the application to facilitate the applicability of these guidelines.

### 3.3 Recommendation 3

Carry out comprehensive actions to implement the cessation strategy.

The gradual, stepwise implementation of the cessation strategy is recommended to achieve short-term progress. The order of the activities proposed below will depend on the national circumstances and the priorities of each country.

 Establish a sustainable funding source for cessation support services.

Integrating tobacco cessation interventions with HIV and TB care requires that these interventions also be included in the funding plans for these conditions.

· Train the health care team in minimal and comprehensive interventions for smoking.

All health care workers involved in the treatment of PLHA and those with TB must receive training on performing minimal or **brief interventions** to promote the cessation of tobacco use (WHO Strategy 5A).

Other individuals also have a role to play in tobacco cessation and tobacco dependence treatment: they can

be trained to give brief advice, encourage a quit attempt, and refer tobacco users to specialized tobacco dependence treatment services when appropriate.

Professionals from various health disciplines (particularly medicine, psychology, nursing, nutrition, pharmacists, health counselors and social work) who are interested in **specialized treatment** should be trained, integrating multidisciplinary teams to provide multicomponent interventions in specialized smoking cessation services.

HCPs treating tobacco use should be trained and sensitized on the early detection of HIV / TB infection and on the correct process for referring patients to appropriate teams for the management of HIV / TB.

### • Use existing systems and resources to guarantee the accessibility of the intervention.

Existing infrastructure, both in health care centers and in other environments, should be used to ensure that all tobacco users in HIV and / or TB treatment settings are identified and provided with at least brief advice in this context.

It should be ensured that people who want to quit have access to comprehensive treatment for tobacco dependence (behavioral and pharmacological support), ideally in the same settings that provide HIV / TB treatment, in coordination with existing tobacco treatment services.

The adequate management and referral of people with HIV / TB identified in tobacco treatment settings should be guaranteed.

### · Carry out interventions at the population level.

**Communication and awareness.** Mass communication of educational and communication interventions about the benefits of tobacco cessation aimed at PLHA and people with TB are essential for encouraging people to quit, making available resources known, and facilitating the use of these services by tobacco users.

Use of information and communication technology. Using information and communication technology, such as telephone lines for tobacco cessation (quitlines), text messages aimed at specific populations, self-help applications for mobile phones, and the dissemination of information and behavioral support through social networks, is effective for improving the population's actions. This can complement individual approaches. HCPs who manage HIV / TB care must know about these tools so that they can inform and guide consumers in using the tools.

### Implement individual interventions.

**Minimal intervention.** Brief advice should be integrated at all levels of health care, particularly at the primary care level. All HCPs should receive training to 1) **ask** about tobacco use and record it in medical notes or records; 2) **advise** cessation (**brief advice**); 3) **assess** willingness to stop smoking; 4) **assist** in achieving cessation or refer the patient to a specialized service for



the necessary support; and 5) **arrange** a follow-up (Strategy 5A).

Brief advice is more effective when it is adapted to the clinical situation of each patient. For PLHA and those with TB, emphasis should be placed on the benefits of cessation: better response to treatment, improvement in their condition (both HIV and TB), lower mortality from these diseases, and the prevention of cancer, as well as heart and vascular disease.

For people who are willing to quit, the brief advice should be complemented by an orientation to the cessation process, with concrete strategies for achieving cessation, sometimes used together with specific pharmacological interventions, or these individuals should be referred elsewhere for specialized treatment services.

**Specialized treatment of tobacco dependence.** In cases where the intervention provided by the treating HCP is not enough for patients to achieve tobacco cessation, referral to a specialized cessation service should be made accessible, or the intervention of the specialized team should otherwise be coordinated in the HIV / TB treatment setting. Along with the treatment and monitoring of HIV infection and TB, the support provided by specially trained HCPs should include behavioral and pharmacological support, making drugs available, accessible, and affordable.

### Provide specific medications for smoking cessation treatment.

Medications that have been shown to be effective (alone or in combination) for treating tobacco dependence are nicotine replacement therapies, bupropion, varenicline, cytisine, and nortriptyline.

Making at least one effective treatment affordable is necessary for increasing the success rates of intensive interventions. Greater variety in the pharmacological options available will correspond to greater chances of cessation treatment success.

In general, the most affordable drugs, even in low-income countries, are forms of nicotine replacement therapy and cytisine<sup>(16)</sup>. These medications cost much less than do HIV / TB treatments. Integrating these drugs in the budget for HIV / TB treatment can be an option to facilitate their accessibility.

Cessation medications can be managed by HCPs in charge of HIV / TB care who have received training on this.

### · Track tobacco use.

Because tobacco use is a chronic condition with the potential for relapse, it is necessary to follow up its evolution to prevent relapse or treat it early. Given that those living with HIV / TB constitute a captive population, monitoring tobacco use should be carried out simultaneously with the control of the infectious pathologies.

The monitoring of tobacco use along with the assessment processes in HIV / TB care should include an assessment of the impact of tobacco cessation on HIV and TB outcomes.

### 3.4 Recommendation 4

Conduct follow-up and evaluation of strategy implementation.

Monitoring the integration of tobacco cessation strategies with HIV / AIDS and TB care services and assessing the program's impact make up an essential component of this project. These evaluation steps can help to identify opportunities for improving the interventions, thus contributing to the efficient use of resources.

Accordingly, the proposed evaluation plan aims to assess the extent of implementation of the project, its application, the commitment of HCPs, and the results in the target population.



### A logic model of the key components of the intervention is provided in Figure 2, showing the resources and activities to implement each recommendation, as well as expected outcomes.

Recommendation	Inputs / Resources	Outputs / Activities	Short and Mid-Term Results	Long-Term Results
R1: Conduct a national situation analysis - Implementation of the FCTC - Degree of implementation of the WHO policy on HIV / TB collaborative activities - Situation regarding smoking treatment services - Situation regarding HIV and TB treatment services	Local experts     Local policy-makers     Project experts     Online conferences      Documents:     National situation analysis worksheet     Guidelines for the implementation of Article 14 in the HIV / TB population	1a - Obtain data and perform a preliminary local analysis  1b - Web-based workshop to identify the gaps between the national situation and the recommendations	Partial situation analysis performed  Identification of new information to be obtained for second / third web-based meeting  Identification of gaps between the national situation and the recommendations	Situation analysis performed
R2: Develop and disseminate broad guidelines for treating tobacco use in HIV and TB care	Local experts     Local policy-makers     Project experts     Online conferences      Document:     Implementation plan for the general recommendations      Budget	2a - Perform a SWOT analysis regarding each gap detected  2b - Develop a cessation strategy for policy-makers  2c - Develop clinical practice guidelines and materials for HCPs and patients	Policy-makers aware of the cessation strategy HCPs and patients aware of clinical practice guidelines and materials	Cessation strategy implemented  Clinical practice guidelines widely implemented in health services treating HIV / TB
R3: Carry out comprehensive actions to implement smoking cessation strategies in the population living with HIV / TB	Experts     Local experts     Local policy-makers     HCPs     Drugs for smoking cessation     Funding of the strategy     Other partners and stakeholders	3a - Training activities for HCPs who treat HIV / TB on using the minimal intervention  3b - Specialized cessation services focusing on PLHA and people with TB  3c - Interventions at the population level	HCPs trained in the minimal intervention  Health teams trained in specialized cessation treatment including pharmacological treatment	Users receive integrated treatment for HIV / TB and tobacco use  Decrease in tobacco consumption among people living with HIV / TB
R4: Conduct follow-up and evaluation of strategy implementation	Local referents for strategy implementation     Budget for follow-up and evaluation	4a - Assess degree of elaboration of the cessation strategy  4b - Assess awareness and application of the strategy by the health care providers  4c - Measure achieved changes in target population	Follow-up of the strategy is implemented Short-term evaluation is completed	Improvements based on short-term evaluation are implemented  Long-term evaluation is completed

Figure 2. Logic model of the intervention.

FCTC: Framework Convention on Tobacco Control HCPs: Health Care Providers

HIV: Human Immunodeficiency Virus PLHA: People Living with HIV/AIDS SWOT: Strengths, Weaknesses, Opportunities, and Threats

TB: Tuberculosis

WHO: World Health Organization



### **Implementation Plan for the Recommendations**

### How to design a cessation strategy for this target population

The objective of this section is to elaborate the design process for a tobacco cessation strategy for a HIV / TB population that is adapted to the national context. This strategy should include a timeline of activities; indicators of results; and short, medium, and long-term goals.

It is recommended that an individual or commission be responsible for and in charge of articulating all actions related to the implementation of the approach to smoking cessation in people living with HIV and / or TB.

### 1. National Situation Analysis

To elaborate an effective strategy that can be translated into concrete actions and achieve the proposed objectives, it is necessary to know the national starting point with respect to the following topics:

- TB treatment program: level of implementation and operation of services.
- HIV treatment program: level of implementation and operation of services.
- Collaborative activities within HIV / TB treatment programs.
- Level of implementation of Article 14 of the WHO FCTC.
- Level of implementation of the WHO FCTC, with emphasis on the articles that are synergistic with Article 14 (i.e., Articles 6, 8, 11, 12, and 13).

The person responsible for the coordination of HIV / TB / TOB activities should coordinate the compilation of the most reliable and complete information to carry out the initial analysis.

The data should be provided by those responsible for each issue, be drawn from reliable records, and have the possibility of being monitored to assess the impact of the implemented strategies.

The **National Situation Analysis: HIV / TB / TOB** (Annex 1) tool was created specifically for this project to systematize the evaluation. This tool is based on two published documents: the national situation analysis for the implementation of FCTC Article  $14^{(17)}$  and the WHO guide for monitoring and evaluation of collaborative TB / HIV activities  $^{(18)}$ .

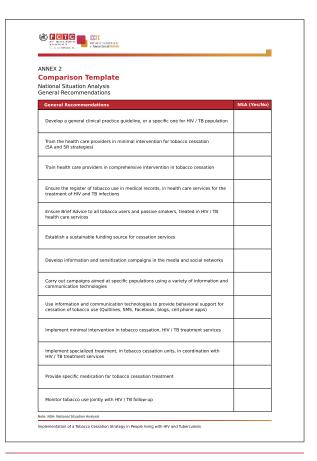
Using these reference documents is recommended to carry out a deeper country situation analysis on each of the issues to be addressed.

### 2. Comparison of the National Situation with the General Recommendations

All the recommendations come from the implementation guidelines for Article 14 of the FCTC. At this stage, it is convenient for you to have read the following in detail:

Articles 14, 6, 8, 11, 12 and 13 of the FCTC as well as the guidelines for implementation of Article 14.

Each of the recommendations should be compared with the data provided by the National Situation Analysis tool to determine at what level of implementation the country is for each recommendation. A list of the measures not yet implemented should then be prepared. Figure 3 provides a template for comparing the recommendations with the data from the National Situation Analysis tool (Annex 2).



**Figure 3.** Recommendations for the implementation of tobacco cessation in the population living with HIV / TB: Table for comparison using the National Situation Analysis tool (Annex 2, Page 21)



### 3. Analysis of the Feasibility of the Implementation of each Recommendation

The gradual implementation of the recommendations requires prioritization. To do this, it is necessary to consider the following points:

- The relevance of the recommendation in terms of its impact on the target population.
- The feasibility of implementing the recommendation within a certain period of time.

To establish the feasibility of implementation, a SWOT analysis for each recommendation should be carried out. This will expand the national scenario provided by the situation analysis (Figure 4, Annex 3).

Considering the circumstances of each country, an ordered list of priorities should be created for the gradual implementation of the recommendations that have not yet been realized. These priorities will determine the specific objectives of the cessation strategy that will be elaborated in the project.

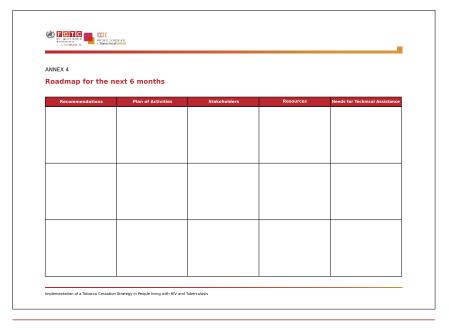
ANNEX 3 SWOT Analysis				
				_
Recommendations	Strengths	Weaknesses	Opportunities	Threats
Ensure screening of tobacco use and second-hand smoke exposure and Brief Advice to all tobacco users and exposed, assisted in HIV / TB care services				

Figure 4. Example template for the SWOT analysis of each recommendation (Annex 3, Page 22)

### 4. Roadmap for each Recommendation

After the necessary interventions have been prioritized to achieve the integration of tobacco cessation into HIV / TB care, a roadmap should be prepared for each intervention to identify the following:

- Activities and tasks.
- The person responsible.
- Material resources.
- Timetable.
- Indicators and goals for their evaluation.



**Figure 5.** Example template for developing a roadmap for the implementation of each recommendation within a certain period (for example, 6 months) (Annex 4, Page 23)



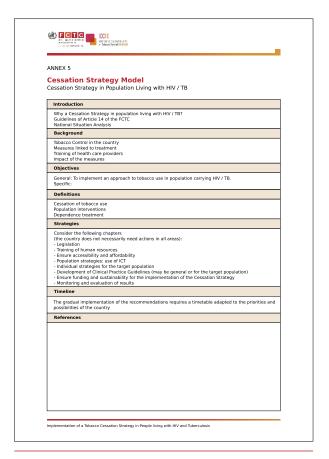
### 5. Final Product: Cessation Strategy

The development of the roadmaps for the specific objectives identified will allow the drafting of a document that will be the basis of the cessation strategy for tobacco use in the population living with HIV / TB.

This document should later be expanded with the involvement of all those involved in its implementation. Chapters about background, legislation, and the development process, as well as other chapters considered necessary for the document to be understandable and adoptable should be included.

To ensure the implementation of the cessation strategy, the following points are essential:

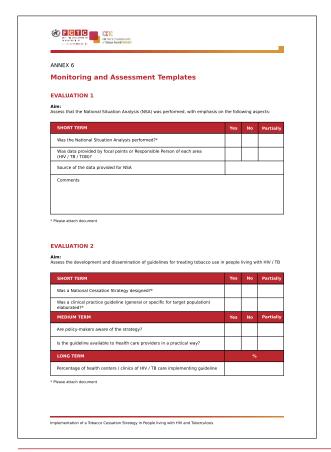
- The strategy must have political support, especially from the health authorities.
- The strategy must have the approval of the technicians who will implement the different actions.
- Financing sources must be defined for each stage proposed in the strategy.
- Intermediate evaluations must be carried out to recalibrate aspects of the strategy that are not achieved as planned.

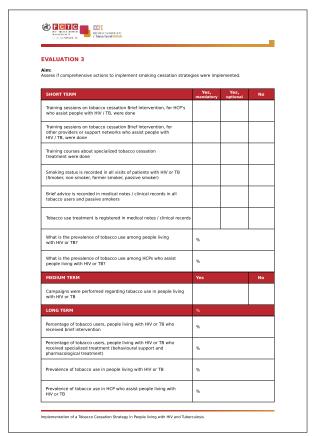


**Figure 6.** Example structure of a cessation strategy for a specific population (Annex 5, Page 24)

### **Monitoring and Assessment**

An assessment is proposed for each of the recommendations regarding the elaboration of a cessation strategy based on a national situation analysis, the implementation of this strategy, and achievements reached among HCPs and the target population.





Figures 7 / 8. Example template of Monitoring and Assessment. (Annex 6, Pages 25 and 26)



### References

- 1. World Health Organization. WHO Framework Convention on Tobacco Control. Geneva; 2004.
- 2. World Health Organization. WHO Framework Convention on Tobacco Control: Guidelines for Implementation of Article 5.3, Articles 8 to 14. 2013.
- 3. Zumla A, Malon P, Henderson J, Grange JM. Impact of HIV infection on tuberculosis. Postgrad Med J. 2000;76(895):259–68.
- 4. World Health Organization. WHO Policy on Collaborative TB/HIV Activities: Guidelines for National Programmes and Other Stakeholders. Geneva: World Health Organization; 2012.
- 5. Organización Mundial de la Salud. Tuberculosis. Datos y Cifras. [Internet]. 2018. Available from: <a href="https://www.who.int/es/news-room/fact-sheets/detail/tuberculosis">https://www.who.int/es/news-room/fact-sheets/detail/tuberculosis</a>. Accessed June 2019.
- 6. Organización Mundial de la Salud. Una Monografía de la OMS y la Unión sobre Control del Tabaco y de la Tuberculosis. Unir esfuerzos para controlar dos epidemias mundiales relacionadas. [Internet]. 2012. Available from: <a href="http://apps.who.int/tobacco/publications/health\_effects/tb\_tobacco\_mono\_sp.pdf">http://apps.who.int/tobacco/publications/health\_effects/tb\_tobacco\_mono\_sp.pdf</a>. Accessed June 2019.
- 7. Organización Mundial de la Salud VIH/SIDA. Datos y Cifras. [Internet]. 2019. Available from: <a href="https://www.who.int/es/news-room/fact-sheets/detail/hiv-aids">https://www.who.int/es/news-room/fact-sheets/detail/hiv-aids</a>. Accessed June 2019.
- 8. Montaner JSG. Treinta años después: amplia cobertura con HAART, la clave para el control global del VIH y el sida. Actual en SIDA 19. 2011;73:85–91.
- 9. Organización Mundial de la Salud. Tabaco. Datos y Cifras. [Internet]. 2019. Available from: https://www.who.int/es/news-room/fact-sheets/detail/tobacco. Accessed June 2019.
- 10. Feldman DN, Feldman JG, Greenblatt R, Anastos K, Pearce L, Cohen M, et al. CYP1A1 genotype modifies the impact of smoking on effectiveness of HAART among women. AIDS Educ Prev. 2009;21(Suppl 3):81–93.
- 11. Shuter J, Bernstein SL. Cigarette smoking is an independent predictor of nonadherence in HIV-infected individuals receiving highly active antiretroviral therapy. Nicotine Tob Res. 2008;10(4):731–6.
- 12. Helleberg M, Afzal S, Kronborg G, Larsen CS, Pedersen G, Pedersen C, et al. Mortality attributable to smoking among HIV-1-infected individuals: a nationwide, population-based cohort study. Clin Infect Dis. 2012;56(5):727–34.
- 13. Pacek LR, Rass O, Johnson MW. Positive smoking cessation-related interactions with HIV care providers increase the likelihood of interest in cessation among HIV-positive cigarette smokers. AIDS Care. 2017;29(10):1309–14.
- 14. Mdege ND, Shah S, Ayo-Yusuf OA, Hakim J, Siddiqi K. Tobacco use among people living with HIV: analysis of data from Demographic and Health Surveys from 28 low-income and middle-income countries. Lancet Glob Heal. 2017;5(6):e578–92.
- 15. Siddiqi K, Khan A, Ahmad M, Dogar O, Kanaan M, Newell JN, et al. Action to stop smoking in suspected tuberculosis (ASSIST) in Pakistan: a cluster randomized, controlled trial. Ann Intern Med. 2013, 158(9): 667-75.
- 16. West R, Raw M, McNeill A, Stead L, Aveyard P, Bitton J, et al. Health-care interventions to promote and assist tobacco cessation: a review of efficacy, effectiveness and affordability for use in national guideline development. Addiction. [Internet]. 2015;110(9):1388–403. Available from: <a href="https://doi.org/10.1111/add.12998">https://doi.org/10.1111/add.12998</a>. Accessed June 2019.
- 17. Raw M, McRobbie H, West R, McNeill A. National Situation Analysis. Tools to promote implementation of FCTC Article 14 on tobacco cessation [Internet]. 2015. Available from <a href="https://www.treatobacco.net">www.treatobacco.net</a>. Accessed June 2019.
- 18. World Health Organization. Guide to Monitoring and Evaluation for Collaborative TB/HIV Activities-2015 Update. World Health Organization; 2015.



### **Annexes**

- 1. National Situation Analysis of HIV / TB / Tobacco
- 2. Comparison Template: National Situation Analysis General Recommendations
- 3. Swot Analysis for Recommendations to Implement
- 4. Roadmap for Implementing Recommendations in 6 months Term
- 5. Cessation Strategy Model
- 6. Monitoring and Assessment Templates
- 7. Pilot Plan



### National Situation Analysis of HIV / TB / TOB

### Introduction

This document is an adaptation of "National Situation Analysis" Version 1, elaborated by Raw et al. as part of a Toolkit to promote the implementation of Article 14 of the Framework Convention on Tobacco Control (FCTC) about cessation of tobacco use. It is based on the FCTC and the guidelines on Article 14 and should be used together with those documents.

Questions related to a specific population, people living with Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome (HIV / AIDS) and Tuberculosis (TB) were added to the original document. This part of the evaluation is also based on the World Health Organization Guide for the monitoring and evaluation of TB / HIV collaborative activities.

### **Basic Data**

Q1. Country				
World Bank income level	Low	Medium Low	Medium High	High
WHO Region				
Population				
Q2. Tobacco use				
	Male	Fen	nale	Total
2a – Prevalence (%)				
Smokers (any smoked tobacco)				
Smokeless tobacco				
Youths				
2b – Estimated total number of tobacco users				
			•	

Q3. HIV Infection			
	Male	Female	Total
3a – Prevalence (%)			
Adults			
Children (0 to 14 years old)			
3b – Estimated total number of people living with HIV / AIDS			
3c – Estimated total number of people with HAART (Highly Active Antiretroviral Therapy)			

Q4. Tuberculosis			
	Male	Female	Total
4a – Prevalence (%)			
4b – Estimated total number of people with diagnosed TB			
4c – Estimated total number of people with TB under treatment			



### Tobacco control policies and their impact

Q5. Synergistic articles of Article 14 of the FCTC		
	Yes	No
5a – Article 6. Do you have policies on prices and taxes in place?		
5b – Article 8. Do you have effective smoke-free legislation in place?		
5c – Article 11. Do you have appropriate tobacco packaging and labelling including clear, large health warnings on tobacco products?		
5d – Article 12. Do you have education and communication measures, including campaigns that warn of the dangers of tobacco use and benefits of quitting?		
5e – Article 13. Do you have a ban on tobacco advertising and sponsorship?		

### **Infrastructure**

Q6. Health systems and other resources to offer TB treatment	
6a – Number of establishments that perform TB diagnostic tests	
6b – Number of facilities for people with TB	

Q7. Health systems and other resources to offer treatment to people living with HIV / AIDS	
7a – Number of establishments that perform HIV diagnostic tests	
7b – Number of facilities for people with HIV / AIDS	

Q8. What health care systems and resources do you have that can help provide wide access to cessation support, including brief advice?		
	Yes	No
8a – Primary health care system		
8b – Specialized cessation services		
8c – TB services		
8d – HIV / AIDS services		
8e – Community services		
8f – Home Nurses		
8g – Dental services		
8h – Pharmacies		
8i – Work places		
8j – Others		



Q9. Information - Communication Technology infrastructure data			
9a – Proportion of households with fixed line phones:			
9b – Proportion of population with cellphones:			
9c – Proportion of households with internet access:			
9d – Other/comments:			
Q10. Which individuals, institutions, organizations and groups in your coun partnership with to achieve your goal of integrating tobacco cessation man care programs?			
Q11. Financial resources for tobacco control. Do you have sustainable fund cessation support?	ing for		
	Yes	No	
11a – Professional training			
11b – Campaigns to raise awareness among the target population			
11c – Development of tobacco treatment programs			
Q12. Financial resources for addressing HIV / TB. Do you have sustainable f HIV and TB care?	unding for Yes	No	
12a – Professional training			
12b – Campaigns to raise awareness among the target population			
12c – Development of HIV and TB treatment programs			
12d – HIV / TB collaborative activities proposed by WHO			
Tobacco cessation support infrastructure			
Q13. Is there an officially identified person in government (or hired by gove for tobacco dependence treatment?	ernment) res	ponsible	
Yes			
No			
Q14. Is it mandatory to record tobacco use in the clinical history / medical no	otes?		
Yes			
No			
Q15. Is brief cessation advice integrated at all levels of health care, including specific areas such as tuberculosis treatment, HIV / AIDS and others?			
Yes			
No			



Q16. Are tobacco control and tobacco cessation incorporated into the trelevant pre and post-qualification courses?	raining curricula of
Yes	
No	
	,
Q17. Does all health personnel receive training to provide brief advice, attempts and refer tobacco users to specialized cessation support serv	
Yes	
No	
Q18. Which training resources exist in your country that can train in to If there are none, or they are very limited, which organizations or cour international level that can be accessed?	
Q19. Does your country have an official national strategy to promote to provide treatment for tobacco dependence?	obacco cessation and
Yes	
No	
Q20. Does your country have clinical practice guidelines for the treatm dependence?	ent of tobacco
Yes	
No	
	·
Q21. Does your country have a toll-free tobacco helpline?	
Yes	
No	
Yes, but the coverage is not national, or not free of charge	
	l



	Yes	No
Nicotine replacement treatments (NRT)		
Bupropion		
Varenicline		
Cytisine		
Nortriptyline and / or clonidine		
Others:		

Q23. Are the following medications easily accessible and affordable for all tobacco users in your country?								
	Yes	No						
Nicotine replacement treatments (NRT)								
Bupropion								
Varenicline								
Cytisine								
Nortriptilyne and / or clonidine								
Others:								

Additional comments about	medications or treatment o	ptions	

### References

Raw M, McRobbie H, West R, McNeill A. National Situation Analysis. Tools to promote implementation of FCTC Article 14 on tobacco cessation [Internet]. 2015. Available from <a href="https://www.treatobacco.net">www.treatobacco.net</a>. Accessed June 2019.

World Health Organization. Guide to Monitoring and Evaluation for Collaborative TB/HIV Activities - 2015 Update. World Health Organization; 2015.



**Comparison Template** National Situation Analysis **General Recommendations** 

General Recommendations	NSA (Yes/No)
Develop a general clinical practice guideline, or a specific one for HIV / TB population	
Train the health care providers in minimal intervention for tobacco cessation (5A and 5R strategies)	
Train health care providers in comprehensive intervention in tobacco cessation	
Ensure the register of tobacco use in medical records, in health care services for the treatment of HIV and TB infections	
Ensure Brief Advice to all tobacco users and passive smokers, treated in HIV / TB health care services	
Establish a sustainable funding source for cessation services	
Develop information and sensitization campaigns in the media and social networks	
Carry out campaigns aimed at specific populations using a variety of information and communication technologies	
Use information and communication technologies to provide behavioral support for cessation of tobacco use (Quitlines, SMS, Facebook, blogs, cell phone apps)	
Implement minimal intervention in tobacco cessation, HIV / TB treatment services	
Implement specialized treatment, in tobacco cessation units, in coordination with HIV / TB treatment services	
Provide specific medication for tobacco cessation treatment	
Monitor tobacco use jointly with HIV / TB follow-up	

Note: NSA: National Situation Analysis

# **SWOT Analysis**

Recommendations	Strengths	Weaknesses	Opportunities	Threats
Ensure screening of tobacco use and second-hand smoke exposure and Brief Advice to all tobacco users and exposed, assisted in HIV / TB care services				



# Roadmap for the next 6 months

4)		
Needs for Technical Assistance		
Resources		
Stakeholders		
Plan of Activities		
Recommendations		



### **Cessation Strategy Model**

Cessation Strategy in Population Living with HIV / TB

### Introduction

Why a Cessation Strategy in population living with HIV / TB? Guidelines of Article 14 of the FCTC National Situation Analysis  $\frac{1}{2}$ 

### **Background**

Tobacco Control in the country Measures linked to treatment Training of health care providers Impact of the measures

### **Objectives**

General: To implement an approach to to bacco use in population carrying  $\ensuremath{\mathsf{HIV}}$  /  $\ensuremath{\mathsf{TB}}.$  Specific:

### **Definitions**

Cessation of tobacco use Population interventions Dependence treatment

### **Strategies**

Consider the following chapters

(the country does not necessarily need actions in all areas):

- Legislation
- Training of human resources
- Ensure accessibility and affordability
- Population strategies: use of ICT
- Individual strategies for the target population
- Development of Clinical Practice Guidelines (may be general or for the target population)
- Ensure funding and sustainability for the implementation of the Cessation Strategy
- Monitoring and evaluation of results

### Timeline

The gradual implementation of the recommendations requires a timetable adapted to the priorities and possibilities of the country

### References



### **Monitoring and Assessment Templates**

### **EVALUATION 1**

### Aim:

Assess that the National Situation Analysis (NSA) was performed, with emphasis on the following aspects:

SHORT TERM	Yes	No	Partially
Was the National Situation Analysis performed?*			
Was data provided by focal points or Responsible Person of each area (HIV / TB / TOB)?			
Source of the data provided for NSA			
Comments			

<sup>\*</sup> Please attach document.

### **EVALUATION 2**

### Aim:

Assess the development and dissemination of guidelines for treating tobacco use in people living with HIV / TB

SHORT TERM	Yes	No	Partially
Was a National Cessation Strategy designed?*			
Was a clinical practice guideline (general or specific for target population) elaborated?*			
MEDIUM TERM	Yes	No	Partially
Are policy-makers aware of the strategy?			
Is the guideline available to Health care providers in a practical way?			
LONG TERM		%	
Percentage of health centers / clinics of HIV / TB care implementing guideline			

<sup>\*</sup> Please attach document.



### **EVALUATION 3**

### Aim:

 $Assess\ if\ comprehensive\ actions\ to\ implement\ smoking\ cessation\ strategies\ were\ implemented.$ 

SHORT TERM	Yes, mandatory						
Training sessions on tobacco cessation Brief Intervention, for HCP's who assist people with HIV / TB, were done							
Training sessions on tobacco cessation Brief Intervention, for other providers or support networks who assist people with HIV / TB, were done							
Training courses about specialized tobacco cessation treatment were done							
Smoking status is recorded in all visits of patients with HIV or TB (Smoker, non-smoker, former smoker, passive smoker)							
Brief advice is recorded in medical notes / clinical records in all tobacco users and passive smokers							
Tobacco use treatment is registered in medical notes / clinical records	ment is registered in medical notes / clinical records						
What is the prevalence of tobacco use among people living with HIV or TB?	%						
What is the prevalence of tobacco use among HCPs who assist people living with HIV or TB?	%						
MEDIUM TERM	Yes		No				
Campaigns were performed regarding tobacco use in people living with HIV or TB							
LONG TERM	%	%					
Percentage of tobacco users, people living with HIV or TB who received brief intervention	%						
Percentage of tobacco users, people living with HIV or TB who received specialized treatment (behavioural support and pharmacological treatment)	%						
Prevalence of tobacco use in people living with HIV or TB	%						
Prevalence of tobacco use in HCP who assist people living with HIV or TB	%						



### **Pilot Plan**

The cooperation activities to be developed by the International Cooperation Center for Tobacco Control (ICCTC) and each country (COUNTRY), as Pilot of this Implementation Plan with the objective of preparing a Cessation Strategy of tobacco use in the HIV / TB population adapted to the national situation, are described below with a schedule of activities, indicators of results and short, medium and long-term goals.

In total, we will work together for 18 weeks. There will be 4 virtual workshops of 2 hours each and a communication channel will be maintained for the exchange of information, experiences and knowledge.

### Contact of counterparts

The effectiveness of the South-South and Triangular cooperation activities depends to a large extent on the adequate selection of the participants.

ICCTC: the most experienced people in cooperation for the implementation of Art. 14 have been selected, with extensive experience in the approach to tobacco use at all levels of intervention and experts have been contacted worldwide, who have contributed with their experience in the approach of tobacco use in the target population.

COUNTRY: For this activity it will be necessary to have at least two people with different technical profiles:

- a health professional involved in the treatment of HIV / AIDS and TB, or with practical knowledge of the functioning of the treatment programs of those infections. Ideally with knowledge of the tobacco cessation treatment although it is not a priority condition.
- another professional, with knowledge of the organization of the health system of the country, with decision-making capacity, who can make the necessary changes for the implementation of the Strategy that they are going to develop.

Both technicians with the availability of time to participate in this activity that will include: periodic contacts with us and analysis work, planning, preparation of documents and then implementation of the planned actions.

### Preparatory activities

When the COUNTRY has constituted the work team, documents and instructions for the preparatory activities will be sent. This will be the starting point of the timetable.

ICCTC – To know general data of the Country: politicaleconomic organization, literacy level, health system organization, relevant cultural data.

COUNTRY - To deepen their knowledge of the FCTC,

especially Articles: 6, 8, 11, 12, 13 and 14. Guidelines Art. 14. To carry out a National HIV / TB / TAB Situation Analysis using the template provided by the ICCTC for this purpose.

The National Situation Analysis will take between 3 and 4 weeks, in order to be done with reliable and documented information.

### Workshop 1 - National Situation Analysis

Objective: to work on the Comparison of NSA with the General Recommendations provided by the ICCTC.

After the presentation of the COUNTRY and the people who will participate in the cooperation activities, each recommendation and its level of implementation in the COUNTRY will be analyzed.

At the end of the workshop, the COUNTRY will have a list of recommendations to implement.

### Workshop 2 – SWOT Analysis

Objective: SWOT analysis of the Recommendation considered as a priority, to be implemented in 6 months.

During the workshop, the implementation of the recommendation that the COUNTRY defined as the first activity will be analyzed.

If possible, advance the following priority recommendations:

- Ensure the registration of tobacco use in medical records and Brief Advice to all tobacco users and passive smokers, in health care services for the treatment of HIV and TB infections.
- Train the health team on minimal intervention in tobacco cessation (5A and 5R).

### After-workshop tasks:

### COUNTRY:

- 1 COUNTRY should complete a SWOT analysis of each of the recommendations that the COUNTRY decides to implement.
- 2 Then COUNTRY will establish a list of recommendations ordered according to their implementation priority, based on the SWOT analysis, including the necessary political support, which has been achieved in this period.

The ICCTC will be available for consultation during this work.

### Workshop 3 – Roadmap

Objective: to prepare a Roadmap for the implementation of the Recommendation that has been defined as a priority. The methodology applied will be repeated for each of the recommendations that the COUNTRY decided to implement in the short term.



After-workshop tasks:

The COUNTRY must complete the Roadmaps for each of the recommendations that will be implemented in the medium and long term.

At the end of this stage, the COUNTRY must have the necessary information to be able to plan in a realistic manner the gradual implementation of all the recommendations contained in Art. 14.

### Workshop 4 - Cessation Strategy

Objective: To elaborate a first draft of a Cessation Strategy.

It will be based on each recommendation that the COUNTRY decided to implement and its prioritization, as specific objectives of the Strategy.

For each objective they will define: activities and tasks, need of material and financial resources, responsible for the tasks, a timetable for the implementation, indicators and goals to be met.

This information will be obtained from the Roadmap of each recommendation.

In the joint work, opinions on improvements to the initial proposals will be exchanged and a model of Strategy as a guide to facilitate its development will be provided.

At the end of the workshop, the COUNTRY will have a first draft of a Cessation Strategy for the target population, which it should continue working on during the following weeks.

A Commitment to Change will be completed, with goals measurable to 6 months.

It is expected that the final product can be elaborated in 2 or 3 weeks. It is important that the final document has the approval of the authorities, to begin the implementation process.

The cooperation work will end with a first evaluation of the Cessation Strategy for the HIV/TB carrier population.

### Schedule of activities

	W	eek																
Activities	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Documents and instructions for the preparatory activities																		
Preparatory activity. NSA																		
Workshop 1 – comparison NSA - recommendations																		
Workshop 2 – SWOT																		
Complete SWOT analysis																		
Workshop 3 – Roadmap																		
Complete the Roadmap of all the recommendations to be implemented																		
Workshop 4 – Cessation Strategy																		
Cessation Strategy completed																		
Evaluation of the implementation of the short-term activities																		



Implementation of a Tobacco Cessation Strategy in People living with HIV and Tuberculosis