

REPUBLIC OF ZAMBIA

# **Ministry of Health**

# REGULATORY IMPACT ASSESSMENT REPORT ON THE TOBACCO CONTROL BILL

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#### 1.0 BACKGROUND

Tobacco is the single most preventable leading cause of death in the world<sup>1</sup>. It contains 7,000 chemicals of which 69 cause cancer<sup>2</sup>. It leads to chronic diseases such as cancer, heart diseases, respiratory diseases, and diabetes, mouth and skin infections<sup>3</sup>. It also contributes to high health costs and economic losses, widens socioeconomic inequalities, and contributes to environmental degradation.

Globally more than 7 million deaths occur as a result of tobacco consumption of which 890,000 deaths are due to exposure to tobacco smoke (passive smoking). Approximately 80% of the deaths occur in low- and middle-income countries including Zambia.

In Africa, 13 million women use tobacco products including smokeless tobacco. According to recent studies, approximately 13% of young adolescent girls use tobacco products. Between 2002 and 2030, tobacco attributable deaths are expected to double in LMICs including Zambia. Approximately two thirds of adult deaths due to second hand smoke are among women (64%)<sup>4</sup>.

In response to the globalization of the tobacco epidemic, the World Health Organisation Framework Convention on Tobacco Control (WHO FCTC) was developed, and is the only public health treaty. The main objective of the WHO FCTC is to protect the present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke. The WHO FCTC provides a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke. The tobacco epidemic is a health and sustainable development issue embedded in the United Nations Sustainable Development Goals in particular Goal 3 which refers to "Health for All ages." Target 3.4 refers to reduction in mortality from Non-Communicable Diseases (NCDs) of which tobacco is a major risk factor. Further, target 3a focuses on strengthening the implementation of the WHO FCTC.

The Government of the Republic of Zambia ratified the WHO FCTC on 23 May, 2008 and as a Party to the Convention, it is legally bound to comply with its requirements. Implementation and enforcement of comprehensive tobacco control measures, based on the WHO FCTC will significantly reduce tobacco consumption and exposure to tobacco smoke. Zambia has an opportunity to scale up tobacco control efforts and honour its commitments to the WHO FCTC and ensure that young people do not become the next generation of smokers.

The WHO FCTC contains demand and supply reduction measures which include: -

# 1.1 Measures relating to the reduction of demand for tobacco

- 1.1.1 Price and tax measures (Article 6)
- 1.1.2 Protection from exposure to tobacco smoke (Article 8)
- 1.1.3 Regulation of contents of tobacco products (Article 9)

<sup>&</sup>lt;sup>1</sup> WHO Report on Tobacco Epidemic, 2008

<sup>&</sup>lt;sup>2</sup> WHO 2019

<sup>&</sup>lt;sup>3</sup> WHO 2018

<sup>&</sup>lt;sup>4</sup> ibid

- 1.1.4 Regulation of tobacco products disclosures (Article 10)
- 1.1.5 Packaging and labelling of tobacco products (Article 11)
- 1.1.6 Education, communication, training and public awareness (Article 12)
- 1.1.7 Tobacco advertising, promotion and sponsorship (Article13)
- 1.1.8 Tobacco dependence and cessation (Article14)

# 1.2 Measures relating to the reduction of the supply of tobacco

- 1.2.1 Elimination of illicit trade in tobacco products (Article 15)
- 1.2.2 Prohibition of sales of tobacco products to and by minors (Article 16)
- 1.2.3 Provision of support for economically viable alternative activities and livelihoods (Article 17)

#### 1.3 Other Measures

- 1.3.1 Protection of the environment and health of the persons (Article 18)
- 1.3.2 Liability (Article 19)
- 1.3.3 Mechanisms for scientific and technical cooperation and exchange of information (Articles 20-22).

#### 2.0 SITUATION ANALYSIS

Non Communicable Diseases (NCDs) are the leading cause deaths globally with 85% of deaths occurring in Low and Middle Income Countries (LMICs)<sup>5</sup>. In Zambia, NCDs are responsible for 29% of all deaths in the country<sup>6</sup>. NCDs are diseases that cannot be transmitted from one person to the other such as diabetes, hypertension, cancers and heart diseases. There are five major risk factors for NCDs and these are tobacco use and exposure to tobacco smoke, air pollution, physical inactivity, alcohol and unhealthy diet. Tobacco is a gateway and a leading preventable risk factor for non-communicable diseases and is also linked to infectious diseases. Tobacco use causes 1 in 6 NCDs.

Addressing NCDs is integral to the 2030 Agenda for Sustainable Development. Sustainable Development Goals (SDG) target 3.4 calls for a one-third reduction in premature mortality from NCDs by 2030. In order to achieve this and universal health coverage (UHC), tobacco control must be a priority for governments and communities worldwide.

Exposure to Tobacco smoke occurs in three forms; first, second and third hand. First hand exposure refers to a primary smoker, second hand refers to a passive exposure to the smoke from the primary smoker while the third hand refers to exposure to residue smoke left on surfaces up to six months following deposition by a primary smoker. Other forms of tobacco use include smokeless tobacco which is either chewed, snuffed or placed between gum and the cheek or lip.

<sup>&</sup>lt;sup>5</sup> WHO Non Communicable Diseases Country Profile; 2018

<sup>&</sup>lt;sup>6</sup> Prevention and Control of Non-Communicable Diseases (NCDs) in Zambia: The Case for Investment, 2019

According to the Zambia STEPS Survey Report of 2017, 24% of adult male and 7.8% of adult female were using tobacco in 2017 indicating that tobacco use is significantly higher among men.

The Zambia Census of Population and Housing 2010 Report, indicates that the youth population comprise approximately 50% of Zambia population. Youth rates of tobacco use are on the increase in Zambia. The Global Youth Tobacco Survey (GYTS) of 13-15 year olds attending school in Lusaka in 2002 showed 22.8% of boys and 22.4% of girls using tobacco products. These figures increased to 25.7% of boys and 25.6% of girls in 2007. Youth use rates were even higher in Chongwe and Luangwa, with 28.7% of boys and 27.7% of girls using a tobacco product in 2007. In Kafue, 30.1% of boys and 27.8% of girls used a tobacco product. The GYTS for Zambia conducted in 2011 showed 24.9% of boys and 25.8% of girls using tobacco products.

The increase in tobacco use especially among adolescents is alarming and currently propelled by exposure to tobacco advertisement as an important risk factor for adolescent smoking in Zambia<sup>7</sup>. Furthermore the increase in tobacco use is attributed to accessible and affordable tobacco products, availability of illicit tobacco products, inadequate legal framework and illicit trade in tobacco and nicotine products. In addition, the knowledge on the harmful effects of tobacco and nicotine use is low<sup>8</sup>.

Tobacco smoking is both addictive and lethal. Tobacco contains over 7,000 chemicals; 69 of which are cancer causing chemicals. The component responsible for addiction is nicotine which is among the top five most addictive substances<sup>9</sup>. Other components of tobacco that are harmful to health are poisonous gases and toxic metals.

Tobacco use causes ischaemic heart disease, cerebrovascular disease, lower respiratory infections, chronic obstructive pulmonary disease, tuberculosis, trachea, bronchus and lung cancers which lead to death. Figure 1 highlights the distribution of Tobacco related deaths by disease in Zambia. Approximately an average of 7,142 early deaths occur from tobacco-related diseases annually<sup>10</sup>.

<sup>&</sup>lt;sup>7</sup> Siziya et al; 'Prevalence and correlates for tobacco smoking among persons aged 25 years or older in Lusaka urban district Zambia,' 2011.

<sup>&</sup>lt;sup>8</sup> ITC Zambia wave 1 and 2 National Report (2012, 2014), ITC Project.org/findings

<sup>&</sup>lt;sup>9</sup> The USA National Institute on Drug Abuse (NIDA) 2016

<sup>&</sup>lt;sup>10</sup> Zambia Tobacco Control Investment Case Report 2019

# Distribution of Tobacco Related Deaths by Disease

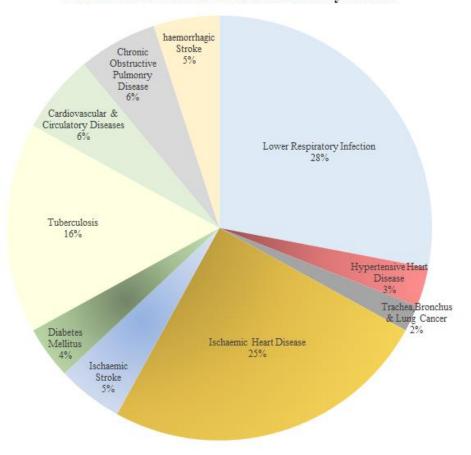


Figure 1 - Distribution of Tobacco related deaths by disease

Management of tobacco related diseases requires huge sums of money. According to the Cancer Diseases Hospital, Government spends an estimated \$3,400 to treat each lung cancer patient among other cancers<sup>11</sup>.

Considering the magnitude of the consequences of tobacco use and the huge health care cost required and other consequences of tobacco use as highlighted above, it is imperative that Government puts in place multi-sectoral interventions to mitigate the impact of tobacco use and exposure to tobacco smoke.

#### 3.0 BASELINE

Despite efforts in reducing the prevalence of tobacco use and exposure to tobacco smoke, current trends suggest that further interventions are needed. The consequences of inaction will perpetuate increase in the disease burden and health care costs. Figure 2 shows a model of cigarette smoking epidemic in a population<sup>12</sup>.

<sup>&</sup>lt;sup>11</sup> Cancer Diseases Hospital Report, 2019

<sup>&</sup>lt;sup>12</sup>Lopez A.D et al (1994), https://tobaccocontrol.bmj.com/content/tobaccocontrol/3/3/242.full.pdf

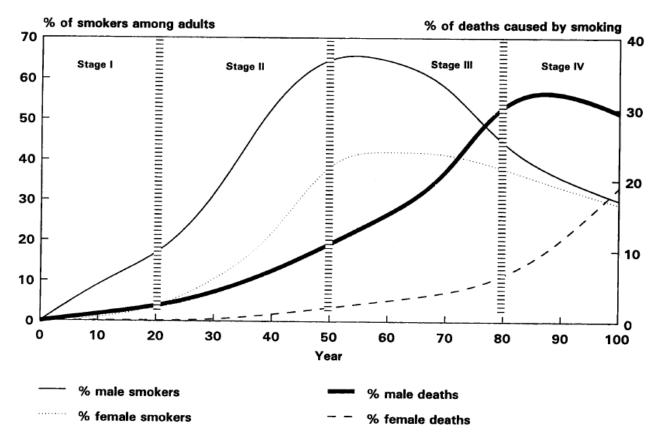


Figure 2: A Model of the Cigarette Epidemic

The model shows that initiation of smoking starts at an early age with tobacco use among males significantly higher than females. The increase in smoking continues up to the age of 50 years, then starts to decline. However, there is approximately a 10 year time lag between smoking initiation and the occurrence of death as shown in stage 1. Stage 2 shows significant increase in both smoking and occurrence of death for both males and females. Stage 3 shows that despite a reduction in smoking, deaths continue to occur for both sexes. Stage 4 shows a decline in male deaths, however deaths continue to occur among the females.

In the case of Zambia, the Global Youth Tobacco Surveys of 2002 and 2007 showed the prevalence of tobacco use among adolescents aged 13 -15 years. In agreement with the model in figure 2, figures 3 and 4 show an increase in the prevalence of tobacco use in both male and female adolescents that used any form of tobacco products.

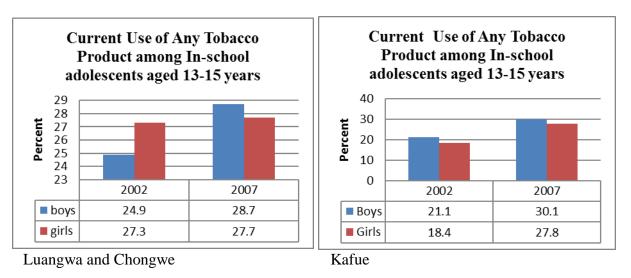


Figure 3 - Tobacco Use among In-school Adolescents (13-15 years)

The trends in tobacco use in both sexes in the age group (13 - 15 years) in figure 3 sampled from Kafue, Luangwa and Chongwe showed a significantly higher prevalence (average above 20% for both boys and girls in 2002 and 2007) of tobacco use than what is depicted in the model figure 2 (average below 10% for both boys and girls).

From this scenario, in the absence of effective interventions, we can deduce that in the next 10 years, there will be an increase in the number of deaths from diseases related to tobacco use. This is a source of concern and hence the need for urgent intervention.

#### 4.0 GENERAL OBJECTIVE

To reduce by 10% tobacco and nicotine use related morbidity and mortality by 2026.

# 4.1 Specific Objectives

The specific objectives are:

- 4.1.1 To implement measures aimed at reducing the demand for tobacco and nicotine products in order to reduce morbidity and mortality by 10% by 2026;
- 4.1.2 To execute measures that aim at reducing access to tobacco and nicotine products by minors in order to reduce initiation of consumption of tobacco and nicotine products by 50% by 2026;
- 4.1.3 To implement 80% of measures aimed at protecting the public places from exposure to tobacco smoke in order to protect public health by 2026; and
- 4.1.4 To lobby for the elimination of illicit trade in tobacco products in order to reduce consumption of tobacco and nicotine products by 2026.

#### 5.0 OPTIONS CONSIDERED IN ADDRESSING THE PROBLEM

# 5.1 Option 1: Maintaining the status quo/no new interventions

Continuing with the existing tobacco control regulatory regime is not a viable option. Increase in tobacco use, especially among young people, and girls in particular, portend perpetuation of high levels of tobacco use resulting in addiction, disease, and death. An intervention can no longer be delayed in light of the clear evidence showing that young people are especially vulnerable to the addictive effects of nicotine and risk both nicotine-caused cognitive harms and tobacco-caused short and long-term health harms. If tobacco and nicotine product use is avoided during adolescence and early adulthood, a person is unlikely to ever become a tobacco user.

Tobacco costs Zambia ZMW2.8 billion every year, equivalent to 1.2% of GDP in 2016 (27% of the total health care costs)<sup>13</sup>. Maintaining the *status quo* entails that illicit trade will continue to flourish and costs of tobacco related illnesses will increase further. In addition, current trends predict that African countries are unlikely to meet the 2025 World Health Assembly 2013 goal of a 30% relative reduction which was identified as the most urgent and immediate priority intervention to reduce NCDs.

Failure to put up tobacco control interventions will lead to the tobacco burden growing from being the 'fly on the wall to the elephant in the room' as reported by the American Cancer Society.

# 5.2 Option 2: Public health awareness and education campaigns

Evidence shows that mass media campaigns can be effective in facilitating behaviour change. However, these campaigns require sufficient funding to enable frequent and widespread exposure to messages over time, as well as message targeting and testing to ensure resonance with specific population groups such as youth.

While public health education and awareness programmes are an important component of a tobacco control strategy, and in fact are required by Article 12 of the WHO FCTC, they must be combined with the entire suite of WHO FCTC-based legal and administrative measures to ensure effective protection.

#### 5.3 Option 3: Enacting a new piece of legislation to domesticate the WHO FCTC

In May 2008, Zambia signed and ratified the WHO FCTC whose Articles are legally binding. Article 5.2(b) of the WHO FCTC mandates Parties to adopt and implement effective legislative and other measures to prevent and reduce tobacco consumption nicotine addiction and exposure to tobacco smoke. Therefore, enacting a piece of legislation and fully implementing and enforcing it shall be in line with the WHO FCTC priority of giving the right of the highest standard of health to all people.

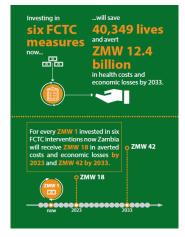
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<sup>&</sup>lt;sup>13</sup> Supra note 10

With full implementation of the WHO FCTC, the country can save ZMW 12.4 billion over 15

years representing averted productivity losses of about ZMW 11.8 billion and ZMW685 million in healthcare expenditure over 15 years. Of this, ZMW 329 million saved in Government Health care expenditure and ZMW188 million saved in out of pocket health care costs; approximately saving 40,349 lives over 15 years<sup>14</sup>.

Passing legislation to control tobacco use and exposure to tobacco smoke has proved to be a significantly effective way of reducing the prevalence of tobacco use. By way of illustration, in the case of Kenya in 2008, 19% of males used tobacco products and in 2014, this number had reduced to 12.8% following its domestication of WHO FCTC<sup>15</sup>.



#### 6.0 COMPARISON OF COSTS AND BENEFITS OF OPTIONS

In order to make comparisons of costs and benefits of options, Cost Effectiveness Analysis was used. The reason for choosing this method is that cost effectiveness analysis is used in areas where benefits are difficult to quantify and monetise. This method is applied to sectors such as health, education and security.

Cost-Effectiveness Analysis (CEA) - Estimates Costs and outcomes of Interventions. It is expressed as a ratio where the Denominator is a gain in health (e.g. years of life, premature births averted) and the numerator is the cost associated with the health gain. It compares results with other interventions affecting the same outcome where the lower the ratio is, the better the outcome.

Cost Effectiveness Analysis (CEA).

CEA Formula: Costs (monetised) / Benefits (metric such as lives saved)

#### **Option 1: Maintaining the Status Quo**

Health Benefits - Lives lost<sup>16</sup>

- 7,142 Zambians killed per year
- Loss of 116,427 of healthy years of life per year

# Health Care Costs<sup>17</sup>

- ZMW 154 million in healthcare expenditures per year
- ZMW 2.7 billion in loss productive capacities due to premature mortality, disability and workplace smoking per year

<sup>&</sup>lt;sup>14</sup> Supra note 10

<sup>&</sup>lt;sup>15</sup> Kenya Health Demographics Survey, 2008

<sup>&</sup>lt;sup>16</sup> Supra note 10

<sup>17</sup> Ibid

CEA = 154,000,000 / 7,142 =**ZMW 21,563:1** 

# Option 2: Public health awareness and education campaigns

There is no study undertaken in Zambia to show the relationship between cost of awareness and education campaigns to the number of lives saved. In the same vain, it was difficult to find data within the Sub-Sahara region that demonstrate this relationship. However, a study conducted in  $2012^{18}$  in the USA showed the impact of awareness and education campaigns on the lives of smokers. The study showed that 17,000 people were saved from a premature death on a budget of \$48,000,000 equivalent to ZMW 240,000,000 at ZMW 5 to 1 USD in 2012.

CEA = cost (monetise) / # of lives saved

- Cost = 48,000,000 \* 5 = 240,000,000
- Lives saved = 17,000

CEA = 240,000,000 / 17,000 =**ZMW14, 117.65:1** 

# Option 3: Enacting a new piece of legislation to domesticate the WHO FCTC

Health Benefits – Lives Saved<sup>19</sup>

- Save 40,349 lives from 2018-2033
- Or save 2,690 lives per year

Health Care Costs<sup>20</sup>

- ZMW 122, 800,000 in investments per 5 years
- ZMW 24, 560,000 investments per year

CEA = 24,560,000 / 2,690 = ZMW 9,130:1

#### 7.0 STAKEHOLDER CONSULTATIONS

Zambia became party to the WHO FCTC in May 2008, and commenced the development of Tobacco Control Bill in 2009. The consultation process with various stakeholders started in 2009 and has been ongoing. The Ministry of Health has carried out consultations with stakeholders including line ministries, civil society organizations, tobacco industry and Academia. The methods of engagement included consultative and high level inter-ministerial meetings as well as written correspondence.

Stakeholders consulted include:

<sup>&</sup>lt;sup>18</sup> Xu, Xin, et al "Cost Effectiveness Analysis of the first federally funded Anti-smoking campaign," American Journal of Preventive Medicine, 2014.

<sup>19</sup> ibid

<sup>&</sup>lt;sup>20</sup> ibid

#### 7.1 Government line Ministries

- 7.1.1 Ministry of Agriculture
- 7.1.2 Ministry of Commerce, Trade and Industry
- 7.1.3 Ministry of National Development and Planning
- 7.1.4 Ministry of Finance
- 7.1.5 Ministry of General Education
- 7.1.6 Ministry of National Guidance and Religious Affairs
- 7.1.7 Ministry of Local Government
- 7.1.8 Ministry of Fisheries and Livestock
- 7.1.9 Ministry of Community Development and Social Services
- 7.1.10 Ministry of Labor
- 7.1.11 Ministry of Justice
- 7.1.12 Ministry of Home Affairs
- 7.1.13 Ministry of Chiefs and Traditional Affairs
- 7.1.14 Ministry of Youth, Sport and Child Development
- 7.1.15 Ministry of Information and Broadcasting Services
- 7.1.16 Ministry of Works and Supply
- 7.1.17 Cabinet Office PAC

# **7.2** Government Institutions

- 7.2.1 Zambia Environmental Management Agency (ZEMA)
- 7.2.2 Zambia Revenue Authority (ZRA)
- 7.2.3 Drug Enforcement Commission (DEC)
- 7.2.4 Tobacco Board of Zambia (TBZ)
- 7.2.5 Zambia Law Development Commission (ZLDC)
- 7.2.6 Lusaka City Council (LCC)
- 7.2.7 Zambia National Broadcasting Corporation (ZNBC)
- 7.2.8 Competition and Consumer Protection Commission (CCPC)
- 7.2.9 Zambia Bureau of Standards (ZABS)

# 7.3 Academia

- 7.3.1 University of Zambia School of Medicine (UNZASOM)
- 7.3.2 University of Zambia School of Law (UNZASOL)
- 7.3.3 Centre for Advocacy and Research in Tobacco Control in Zambia (CARTOCOZA)
- 7.3.4 Zambia Agriculture Research Institute (ZARI)
- 7.3.5 Centre for Primary Care Research (CPCR)

# 7.4 Civil Society

- 7.4.1 Non-Governmental Organization Coordinating Committee (NGOCC)
- 7.4.2 Zambia Consumer Association (ZACA)
- 7.4.3 Zambia Tobacco Control Consortium (ZTCC)
- 7.4.4 Tobacco Free Association of Zambia (TOFAZA)

- 7.4.5 Anti-Alcohol & Drug Abuse (ADAZA)
- 7.4.6 Zambia Heart and Stroke Foundation (ZAHESFO)
- 7.4.7 Mental Health User Network of Zambia (MHUNZA)
- 7.4.8 Center for Trade Policy Development (CTPD)

#### 7.5 Other stakeholders

- 7.5.1 Members of Parliament (MPs)
- 7.5.2 World Health Organization (WHO)
- 7.5.3 United National Development Program (UNDP)
- 7.5.4 Campaign for Tobacco Free Kids (CTFK)
- 7.5.5 International Labour Organisation (ILO)
- 7.5.6 Food Agriculture Organisation (FAO)
- 7.5.7 Centre for Tobacco Control in Africa (CTCA)

# 8.0 SUMMARY OF CONSULTATIONS UNDERTAKEN

In coming up with the final draft for tobacco control Bill, a number of consultations were made with key stakeholders who expressed a lot of interest in the Bill. The consultations involved either face to face discussion, focus group discussions, presentations of the Bill or review of the Bill section by section. The following is an illustration of the various consultative meetings held:

- 8.1.1 Conceptual Meeting held at Chainama National Mental Health Resource Centre on 24<sup>th</sup> August 2009 which involved 8 participants. *Minutes attached as annex 1*.
- 8.1.2 Meeting held at Lillo Lodge in Kafue held from  $21^{st} 25^{th}$  September 2015 which involved approximately 33 participants. *Report attached as annex 2*.
- 8.1.3 Meeting held at Mika Convention Centre held from  $19^{th} 20^{th}$  April 2017 which involved 25 participants. *Minutes and report collectively attached as annex 3*.
- 8.1.4 Meeting held at Ndozo Lodge held from 20<sup>th</sup> 22nd June, 2018 which involved 46 participants. *Report attached as annex 4.*
- 8.1.5 Parliamentary engagement meeting with Members of Parliament held on 27<sup>th</sup> June 2018 at Parliament Building. *Report attached as annex 5*.
- 8.1.6 Inter-ministerial engagement meeting on the status of tobacco held on 24<sup>th</sup> July 2018 Cabinet office, which involved 17 participants. *Minutes attached as annex* 6.

- 8.1.7 Country common position paper over tobacco meeting held on 17<sup>th</sup> September 2018 at Government Complex which involved 13 participants from the line Ministries. *Report and position paper collectively attached as annex 7.*
- 8.1.8 Meeting held at Waterfalls Lodge from 19<sup>th</sup> 21<sup>st</sup> November 2018 which involved 44 participants. *Report attached as annex 8*.
- 8.1.9 Parliamentary engagement meeting with 48 Members of Parliament held in February 2019 at Parliament Building. *Report attached as annex 9.*
- 8.1.10 High level meeting held in June 2019 with various Permanent Secretaries from Ministry of Agriculture, Commerce, Justice, Finance, Labour, Planning and Local Government. This was chaired by Secretary to the Cabinet. *Report attached as annex 10.*
- 8.1.11 High level meeting held from  $10^{th} 13^{th}$  September, 2019 with various Directors and Assistant Directors from Ministry of Agriculture, Commerce, Trade and Industry, Justice, Finance, National Planning and Development which involved 30 participants. *Report attached as annex 11*.
- 8.1.12 Meeting held at Waterfalls from 16<sup>th</sup> -17<sup>th</sup> December, 2019 which involved approximately 40 participants. *Minutes and report collectively attached as annex* 12.

Following the above consultations with key stakeholders including but not limited to line ministries, industry, civil society organisations and academia, the observations are summarised below:

Clause	Proposed provision	Comments from stakeholders	Response from MoH
No.			
	Objects of the Bill  a) provide for the protection of present and future generations from the devastating, health, social, environmental and economic consequences of tobacco consumption, nicotine addiction, and exposure to the harmful emissions of tobacco products, tobacco devices, nicotine products and nicotine devices;  b) prevent use initiation, continually and substantially reduce consumption of tobacco and nicotine products and encourage quitting; c) domesticate the World Health Organisation Framework Convention on Tobacco Control; and d) Provide for matters incidental to, and in connection with, the foregoing.	supported the Bill d) Some stakeholders felt that there is need to dispel the rumours that	MoH is not stopping industry from production but looking at protecting the health of the public and potential consumers.  MoH has a mandate to protect public health especially the young people who currently cover 50% of Zambia population.  The domestication of WHO FCTC will not kill the tobacco industry. Currently, There are 32 countries in Africa that have ratified and domesticated the WHO FCTC in their respective laws and the tobacco industry still operates within the set regulated environment.  In line with Health in All Policies and one government approach to health and the attainment of the SDGs,

Clause No.	Proposed provision	Co	omments from stakeholders	Response from MoH
				Zambia as a party to the FCTC is obligated to domesticate the WHO FCTC.
	II: THE TOBACCO PRODUCTS AND NICOT	INE P	RODUCTS CONTROL COMMI	TTEE
3.	Establishment and composition of Tobacco Products and Nicotine Products Control Committee	a)	Stakeholders did not object to the establishment of the committee. However, there were concerns on the appointing authority and the partiality of the committee.	The Tobacco Control Bill is a preserve of the Ministry of Health whose portfolio function is good health for all citizens of the Republic. It follows that the jurisdiction to appoint the committee created under the Bill belongs to the Minister of Health.
				Notwithstanding the above, even though power to appoint the committee is vested in the Minister of Health, the composition of the committee is multisectoral and inclusive.
			The Tobacco Industry was of the view that penalties are excessive.	Penalties are applied according to the gravity of the offence and in consultation with other laws in the country.
		c)	Tobacco Industry wanted to find out who would be responsible for enforcement.	Authorised officers from various government departments and agencies will be responsible for enforcement.
		d)	Tobacco industry was concerned about the implementation of the WHO FCTC when it is a guiding document and what would happen when comes to an end	The notion that the FCTC is <i>only</i> a guiding document is incorrect, it is an internationally binding legal instrument which Zambia has already ratified. This is the reason why Zambia is developing the legal framework in order to domesticate WHO FCTC into the national context.
4.	Prohibition of members of committee from	a)	Tobacco industry stated that this	The tenure of the WHO FCTC is not based on an agreed term of years. International documents like the FCTC are subject of perpetual existence but can be amended from time to time.  MoA, MoF and MCTI are not affiliated to TI. These

Clause No.	Proposed provision	Comments from stakeholders	Response from MoH
No.	affiliation to tobacco industry	would mean MOA, MOF and MCTI will not be included.	provide policy to govern the conduct of the Tobacco industry. And as such is in contact with the TI as part of execution of their individual portfolio functions.
		b) The Tobacco industry stated that the Private Sector does not include TI. On this provision, there will be no industry included when there are issues that relate directly to the TI. Need experts from the TI.	This is in line with the guidance provide in the WHO FCTC under Article 5.3 to prevent conflict of interest and interference in public health policies from the TI.
5.	Director, staff and secretariat of the Committee	The Tobacco industry stated that committee should not sit in the MOH but sit somewhere else where it is independent of the Ministries to allow other Ministries to freely submit concerns; The proposal should sit in cabinet office so that there is neutrality.	The MOH under its portfolio functions is mandated to ensure good health for all citizens. It follows that this Bill is sponsored by MOH. Any agency or committee established under a MOH Bill become a statutory body or committee of the MOH.
	II: SMOKE FREE ENVIRONMENTS		
5.	Protection from exposure to tobacco smoke and other emissions	Most stakeholders were in agreement with the provisions in Part Three. The distance between the smoker and non- smoker was suggested by stakeholders	
		The Tobacco industry asked in relation to Page 18 what constituted enclosed space defined with one wall? too broad	"enclosed" means any space covered by a roof or roof-like structure with one or more walls or sides, regardless of the type of material used and regardless of whether the structure is permanent or temporary.
		Tobacco industry asked in relation to Page 17 on enclosed workplace; the problems you are trying to	The problem being addressed is clear and it relates to protection of the public from exposure to tobacco smoke. Evidence shows that tobacco smoke particles can move up to 25 meters radius. Further there is no

CI.	D 1 ''		D e M H
Clause No.	Proposed provision	Comments from stakeholders	Response from MoH
No.		adduces moved be seem along	and a level of any accurate taken and ample
		address must be very clear	safe level of exposure to tobacco smoke.
			In Africa, 10 countries have banned smoking in all or
			virtually all indoor public places (Burkina Faso, Chad,
			Congo, Ethiopia, Gambia, Madagascar, Mauritania,
			Namibia, Seychelles, Seychelles, and Uganda)
PART I	V: ADVERTISING, PROMOTION AND SPONS		
	Comprehensive ban on advertising, promotion	Generally all stakeholders including	
	and sponsorship	tobacco industry were in support	
		with this provision. Tobacco industry	
		further emphasized on the need to	
		urgently ratify elimination of illicit	
		trade in tobacco protocol as those	
		involved in advertising are illicit	
		traders.	
11.		The Tobacco industry in relation to	This creates an opportunity for a company to present
		Corporate Social Responsibility on	itself as socially responsible, regardless of social,
		page 25 stated that as a Chamber of	health and environmental harms it may perpetrate.
		Commerce, TI has a responsibility to	This ambiguity has allowed tobacco companies to
		uphold its image through corporate	develop CSR programmes even though tobacco use is
		social responsibility	the world's leading cause of preventable death.
			Tobacco-related deaths are projected to rise to 8.3
			million people in 2030 (from 5.4 million in 2005) as
			the activities of multinational tobacco companies
			spread the smoking epidemic to developing
			countries <sup>21</sup>
			The tobacco industry conducts activities described as
			socially responsible to distance its image from the
			lethal nature of the product it produces and sells or to
			interfere with the setting and implementation of public
			health policies. Activities that are described as
			nearth poheres. Activities that are described as

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<sup>&</sup>lt;sup>21</sup> G. Fooks, A. Gilmore, J. Collin et al., The limits of corporate social responsibility: techniques of neutralization, stakeholder management and political CSR, J Bus Ethics, 2013;112(2):283-299, doi: 10.1007/s10551-012-1250-5

Clause	Proposed provision	Comments from stakeholders	Response from MoH
Clause No.	Proposed provision	The Tobacco industry stated that the TI is not allowed to advertise even internationally and it is not TI's responsibility.  The tobacco industry corporate companies, police themselves more than what is in the document.  The current display of tobacco products in many communities are proliferated by illicit traders. There is need to bear in mind that there are legitimate players and illegitimate players. The law is for legal players. We cannot regulate illegal market. Do not reinvent the will, laws are to be drafted in consultation and review of other existing laws to ensure there is harmonization.	"socially responsible" by the tobacco industry, aiming at the promotion of tobacco consumption, is a marketing as well as a public relations strategy that falls within the Convention's definition of advertising, promotion and sponsorship.  Total ban on advertising, promotion and sponsorship is required. According to TI, International standards prohibit advertising of tobacco products.  Tobacco Advertising, Promotion and Sponsorship (TAPS) is the main channel through which the TI attracts young people to initiate smoking and also retain its customers. Comprehensive ban on TAPS has been proven to reduce the consumption of tobacco products. An international review based on data from 102 countries found that per capita consumption in countries with comprehensive TAPS decreased by 8% <sup>22</sup> . OECD countries with comprehensive bans experienced a 7.4% reduction smoking and a 5.4%
		is narmonization.	reduction in overall tobacco consumption. Approximately 48 countries ban all forms of direct and indirect tobacco advertising, promotion and
			sponsorship. In Africa, 15 countries have comprehensive TAPS bans including retail product display bans e.g. Chad, Eritrea, Ethiopia, Gambia,

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<sup>&</sup>lt;sup>22</sup> SafferH. Tobacco Advertising and Promotion, In: Jha PChaploupka F,editors. Tobacco Control in Developing Countries (2000)

Clause	Proposed provision	Comments from stakeholders	Response from MoH
No.			Ghana, Guinea, Kenya, Mauritius, Mauritania, Namibia, Niger, Senegal, Seychelles, Madagascar, Togo and Uganda.  A study was conducted by Muula and Siziya et al entitled prevalence and determinants of ever smoked cigarettes among school going adolescents in Lusaka. Richard Zulu also did a study on association of advertisement promotion sponsorship related factors with current cigarette smoking among ins school adolescents in Zambia concluded that TV advertisements, promotion sponsorships was positively associated with smoking.
PART V	V: PACKAGING AND LABELLING		
13.	Health warnings and other information required on tobacco products and tobacco device packaging and labelling	Generally the stakeholders were of the view that the size of health warnings on tobacco packs were inadequate if it was to protect the lives of individuals. Thus provisions under this part were acceptable.  The tobacco industry stated that many statements were open and there was need for a bare minimum	
		of what we wanted which had to be very clear and so did not have to be left open.  In relation to the phrase "to be prescribed" the TI stated that there should be a bare minimum prescribed in the document not all left to the Minister.	The word Prescription is used because we want to invoke the SI at any time as need arises and Bill should not be bulky; certainty will be provided for in the Statutory Instrument where specific conditions will be set out.

Clause	Proposed provision	Comments from stakeholders	Response from MoH
No.	2.10 Poseda P.10 (2010)	0 0 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
		There will be compliance issues with	
		this section that is very prescriptive.	
16.	Packaging and labelling during rotation period	The tobacco industry stated that	1 1 1 1
		MOH has been written to	ministry
		complaining about the proliferation	
		of illicit traders and feedback has not	
		been provided yet.	
		The display of pictures was not	Scientific studies demonstrate that large pictorial
		, , , , , , , , , , , , , , , , , , ,	health warnings on tobacco product packaging are
			more effective than smaller text only warnings. This is
		regulation but it was not being	borne out, for example, in the reduced smoking
		observed.	prevalence rates in Canada of between 2.9 and 4.7%
			resulting from the introduction of pictorial warnings
		Packaging had no effect on smoking	
		prevention as it would never stop	Australia the on-going downward trajectory in
		anyone from smoking.	smoking prevalence showed a further decline, from
			15.1% to 12.8% in 2013, with the introduction of
			plain packaging displaying large pictorial health warnings. <sup>24</sup>
			warmings.

<sup>23</sup> Azagba S, Sharaf MF. The effect of graphic cigarette warning labels on smoking behavior: evidence from the Canadian experience. Nicotine Tob Res 2013; 15(3): 708-17.

<sup>&</sup>lt;sup>24</sup> Wakefeld, M. A., Hayes, L., Durkin, S., & Borland, R. (2013). Introduction effects of the Australian plain packaging policy on adult smokers: a cross-sectional study. *BMJ Open*, 3(7), 1–10. doi:10.1136/bmjopen-2013-003175.

Clause	Proposed provision	Comments from stakeholders	Response from MoH
No.			
			91 countries require large (≥50%) pictorial health
			warnings with all appropriate characteristics; 19
			countries and 1 jurisdiction require pictorial health
			warnings health warnings covering $\geq 50\%$ of principal
			display areas (Gambia (75%), Benin (75%),
			Cameroon (70%), Chad (70), Ethiopia (70),

Clause No.	Proposed provision	Comments from stakeholders	Response from MoH
			Mauritania (70%), Senegal (70%), Zanzibar (70%), Cote d'Ivoire (70%), Mauritius (65%), Uganda (65%), Gabon (62.5%), Burkina Faso (60%), Ghana (55%), Namibia (55%), Burundi (50%), Democratic Republic of Congo (50%), Madagascar (50%), Niger (50%), Nigeria (50%), and Seychelles (50%));
17.	Second and subsequent rotations	The tobacco industry stated that there are production costs incurred and therefore rotation periods must be prescribed with caution and be practical	This is noted but it is worth noting that 8 countries in Africa are already implementing rotations on an annual basis and therefore compliant
PART V	VI: PRODUCT SALES		
21.	Regulation of sale of a tobacco product, tobacco device, nicotine product or nicotine device	18 years is what is common. We cannot pass a law that is in violation of what the constitution states. This is vulnerable to litigation  A stakeholder indicated that if we were to treat the minimum age for tobacco and alcohol differently, then we would be confusing things as there should be standard rules as to who was an adult.  A representative of the Industry indicated that we needed to be careful so that we did not open cases for litigation as some of those things looked small but they were sensitive.	You define different age ranges depending on the subject matter Proposed 21 years had nothing to do with adulthood but brain development and addiction propensity. The propensity starts to come down at 21, and at 26 it is better thus at 21, the person's brain is mature enough for them to decide whether to smoke or not. This is evidence based.  The American Lung Association has advocated for increasing the age of sale for tobacco products from 18 to 21 because it will help save lives. In December, 2019, the legislation was included in the federal year-end legislative package and passed by both houses of Congress. President Trump signed the Bill into law on December 20, 2019 and it immediately took effect. In March 2015, a report from the National Academy of Medicine revealed that Tobacco 21 could prevent 223,000 deaths among people born between 2000 and 2019, including reducing lung cancer deaths by 50,000.
24.	Requirement of intact package	What is being described in the Bill is vague. The Zambia Cigarette	In Africa, 10 countries have banned single cigarette stick sales (Benin, Burkina Faso, Ethiopia, Kenya,

Clause	Proposed provision	Comments from stakeholders	Response from MoH
PART V	VII: PRODUCT REGULATION AND REPORTION Regulation of ingredients and emissions	Adult smokers have an option and	Mali, Mauritius, Nigeria, Togo, and Uganda); However, the relevant provision on intact packaging of tobacco product or nicotine product will be subject to the Standards Act.  Flavours are meant to appeal to young people,
	28 (1) A person shall not manufacture, import, or sell a tobacco product or nicotine product that— (b) contains any additive with properties associated or likely to be associated with energy or vitality, a health benefit, or reduced health risk, such as but not limited to, amino acids, caffeine,	are at liberty to choose the type of cigarette to smoke. Characterizing flavours are not meant for young people and this part should be deleted entirely.	especially children because of the substances used such as chocolate, strawberry, banana etc. In Africa, 6 countries have banned flavoured tobacco products (Ethiopia, Mauritania, Niger, Nigeria, Senegal, and Uganda).
	taurine and other stimulants, vitamins, and minerals, or is represented or suggested as containing any such additives or having such properties;  (e) is represented or suggested, including through words, images, pictures, symbols, smells,		This is the reason why we were advocating that smokers be protected as we did not know what substances were coming out of burning of substances such as chocolate and the like, as they may be exposing themselves to more harm.
	colours, or other signs or signals, as being a flavoured product, or as having any of the additives or properties described in paragraphs (b)-(d).		In the case of BAT Uganda Limited v The Attorney General <sup>25</sup> The TI in Uganda provided the same argument about liberty to smoke coined the 'Right to Smoke". The TI lost in litigation that there was no such right that's exists.
			Further in relation to the same case, on 28 May 2019, a five-judge bench of the Constitutional Court of Uganda unanimously rejected a legal challenge brought by British American Tobacco (BAT) against the Tobacco Control Act 2015 of Uganda. In doing so, the court affirmed that the Tobacco Control Act was enacted in order for the state to meet its obligations to protect the fundamental rights to life, health, and a

 $<sup>^{25}</sup>$  Constitutional Petition in the Constitutional Court of Uganda No.46 of 2016  $\,$ 

Clause	Proposed provision	Comments from stakeholders	Response from MoH
No.			clean and healthy environment. It also strongly criticised the litigation as part of a global strategy by tobacco companies to undermine public health legislation in order to increase their profits at the expense of public health  This is also one of the arguments that the TI advances
		With respect to some of the Clauses like (b) and (e), there was need to consider the fact that there were issues to do with Intellectual Property and so it was a broader discussion and they were going to state it in their written submission.	about the protection of intellectual property. The protection of intellectual property is a common theme in many legal challenges brought against WHO FCTC measures. Many of these challenges will cite the Agreement on Trade-Related Aspects of Intellectual Property Rights (or 'TRIPS' Agreement), a WTO agreement that sets out minimum standards of intellectual property protection that WTO member states agree to implement into domestic law.
			These arguments generally suffer from a number of misconceptions regarding the nature of the obligations under TRIPS. In particular:  • there is no right to use a trademark under international law, so a measure implementing the WHO FCTC cannot infringe that right  • TRIPS article 20 only prohibits encumbrances that are 'by special requirements' and 'unjustifiable' TRIPS must be interpreted in line with its general principles and objectives, which affirm that TRIPS obligations should be interpreted with regard to public health goals.
			Therefore, there is no infringement of property rights. There is prohibition of manufacturing of flavoured products and advertising; there should be no concern with patent. On the issue of trademarks, any brands

Clause No.	Proposed provision	Comments from stakeholders	Response from MoH
NO.			specifically related to flavouring are prohibited for the
			Zambian market, but does not infringe the trademark
			registration.
	VIII: INFORMATION, EDUCATION AND COM		
29.	Government to undertake information, education and communication	Looking at Part 8, starting with number 1, where it stated that the government shall promote public awareness about health related	Tobacco is harmful to health regardless of whether it is legitimate or illegitimately traded.
		issues, it was noted that the focus	
		was on the dangers of smoking	
		cigarettes, but noted as one of the	
		contributing factors to proliferation	
		of Illicit tobacco on the Zambian	
		market was ignorance or lack of awareness by government on	
30.	Ministry responsible for education to integrate	Stakeholders enquired what would	Government has adopted the Health in All Policies
	tobacco matters into syllabuses	happen if ministry of education does	which will ensure that health related issues including
		not do this.	tobacco matters are addressed in all government
			policies.
	X: PROTECTION OF TOBACCO CONTROL F CCO INDUSTRY	POLICIES FROM THE COMMERCI	AL AND OTHER VESTED INTERESTS OF THE
102.10		Some stakeholders were in agreement with Article 5.3 and felt	The tobacco control Bill focuses on consumption of tobacco products and not on growing of tobacco.
		that protecting public health policies was clear but there seemed to be a contradiction among different line	Therefore, there is no contradiction amongst line ministries; each Ministry has its portfolio
		ministries that are in support of	
		tobacco growing for the purposes of	
		generating revenue for the	
22		government.	
33	Limitation on interactions between Government		
	and the tobacco industry: transparency	the whole PART which limits	the WHO Framework Convention on Tobacco Control
		interactions between Government	on the protection of public health policies with respect

Clause	Proposed provision	Comments from stakeholders	Response from MoH
No.		and the TI. Further the Law should not state that interaction of the industry and the government shall be limited as this was seen as over regulation	to tobacco control from commercial and other vested interests of the tobacco industry have articulated the aspect on vested interests. This has been an argument in the implementation of this article of the WHO FCTC hence, the WHO saw the need to create these guidelines. There two important principles are that — 1. There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests. The tobacco industry produces and promotes a product that has been proven scientifically to be addictive, to cause disease and death and to give rise to a variety of social ills, including increased poverty. Therefore, Parties should protect the formulation and implementation of public health policies for tobacco control from the tobacco industry to the greatest extent possible.
			2. Parties, when dealing with the tobacco industry or those working to further its interests, should be accountable and transparent. Parties should ensure that any interaction with the tobacco industry on matters related to tobacco control or public health is accountable and transparent.
36.	Reports on tobacco industry activities and practices	The TI stated that this is not feasible. This is not the MOH mandate. It is not practiced anywhere worldwide.	The provision was misunderstood as to the contents that would be required for the report submitted to the Minister of Health. The contents of this report would differ from other reports submitted by the TI to the Ministry of Commerce and other relevant authorities thus, there would be no conflict. The report being referred to in the proposed law is in relation to compliance of requirements of the proposed law. These are the requirements that would be prescribed which shall be requirements within the jurisdiction of the Minister of Health.

Clause No.	Proposed provision	Comments from stakeholders	Response from MoH
		TI also stated that the Minister does not prescribe and so there is need to be specific and should not be left blank	The prescription referred to in section 36 (1) is in relation to the information required to be submitted to the Minister. The provision is mandatory for the submission of the report.
PART 2	X: LICENCING		
		The TI indicated that, that part should be left to be led by the Ministry of Commerce, Trade and Industry and should not be left in the Law.	Noted and this is what the Bill states.  It is common practice to make reference to any other relevant ministry or institution as being in charge of a specific function.
		A Representative from the Industry stated that the Law should state where there was Ministry of Commerce, Ministry of Finance and so on, as regards their	
DART	 XI: PREVENTION AND CONTROL OF ILLICI	responsibilities.	
45.	Measures to reduce trade in illicit tobacco	The TI said there is a specific health message for Zambia "Tobacco is harmful to health" which shows that this product should be sold in Zambia only; changing the provision will be costly	This should be sustained and operate as a tracking and tracing system against illicit trade in tobacco products
		Ministry of Finance stated that section 45 (1) could be taken care of through the issuance of regulations that prohibit sale and importation of tobacco products under the Control of Goods Act	One of the intentions of the FCTC is to control Illicit trade of tobacco therefore this section must be maintained. The Control of Goods Act section 2 and 3 refer to a schedule which is located as an annex to the Act. Under that list number 29 -31m refers to types of tobacco, of which this bill has no interest, the bill is interested in tobacco and nicotine products. It follows that the seemingly general provision of the Control of

Clause No.	Proposed provision	Comments from stakeholders	Response from MoH
140.			Goods Act defining goods as "anything capable of being exported and imported" is subject to the specified goods as defined in the regulations.
46.	Prevention of illicit trade of tobacco products, tobacco devices, nicotine product or nicotine device	This section should not be in this Act. It should be left with the Ministry of Commerce.  Every section of the Document	This section is correctly in the proposed and sites the correct Ministry with this portfolio. It is not wrong or irregular for laws to cross reference as has been done in this manner.
		should clearly indicate the Ministry responsibility for that section	
PART 2	XII: ENFORCEMENT		
47.	Appointment of Authorized officer	The TI stated that the definition of the Authorized Officer is not inclusive (narrow).	The provision in the Bill is sufficient.
		The TI requested for guidance on how the Minister would appoint authorized officers.	Usually, the substantive provision of appointing authorised officer is couched in the manner the Bill has reflected. How the appointment is done is an administrative procedure that is not reflected in the substantive Law.
48.	Powers of entry of authorized officer	The TI asked whether they were guidelines on what amounts to "reasonable grounds";	This is standard language in legislation and can be seen in all legislation that has provisions that relate to authorized officers
		The TI asked where the Ministry shall get the capacity for enforcement of the proposed law	That is why the definition of authorised officer is multi-sectoral and covers a lot of different cadres (such as police officers and public health officers who are already in existence) that may be used to enforce the provision of the proposed Law.
	XIII: TOBACCO PRODUCTS AND NICOTINE		
55	Establishment of the Tobacco Products and Nicotine Products Control Fund	Generally under this part, the Ministry of Finance stated that it is the only ministry mandated to manage public monies and	The recommendation is supported.

Clause No.	Proposed provision	Comments from stakeholders	Response from MoH
	XIV: TAXATION	establishing a fund would be inconsistent with the powers vested in it to manage public resources with the Ministry of Finance.	
		Some stakeholders felt that the current tax rate was substantial for tobacco.	38 countries tax tobacco products at rates that amount to at least 75% of the retail price. According to the International Agency for Research on Cancer and numerous other leading authorities, an increase in tobacco taxes to achieve a 10% increase in price will decrease tobacco consumption by about 6% in lowand middle- income countries.  A review of best practices from Australia, Kenya and South Africa (all of whom have domesticated the WHO FCTC) reveals that effective implementation of tobacco control legislation and policies significantly decreases tobacco consumption. A common thread among these countries has been the implementation of an increase in excise tax on tobacco to meet the WHO recommended benchmark of a 70 percent excise duties. This has resulted in increased revenue for the respective countries and a decline in tobacco consumption due to inaccessibility of the products on account of the higher taxes. Australia specifically, is expected to raise over USD 4 Billion by the end of 2020 through tobacco taxation. This, coupled with a decline in tobacco consumption has eased the burden on the health sector.
		Ministry of Finance stated that excise duty is principally a sin tax that is generally used to discourage consumption of certain goods with	The recommendation is not supported as a general review of other statutes gives general reference to relevant taxes and does not give specific reference to the name of the tax. The current provision in the bill

Clause No.	Proposed provision	Comments from stakeholders	Response from MoH
		negative externalities on health and	does not take away from the power of the Minister of
		the environment. Therefore,	Finance to allow for the imposition of any kind of tax
		proposed an amendment to the said	in relation to tobacco control irrespective of whether a
		section	specific name is given to that tax or not.
PART Y	XV: NEW TOBACCO PRODUCT, TOBACCO D	EVICE, NICOTINE PRODUCT OR	NICOTINE DEVICE
61.	Regulation of a tobacco product, tobacco device,	The tobacco industry suggested that	
	nicotine product or nicotine device new to the	this provision be deleted as it was	market. The general public may not even be aware
	Zambian market	crossing over.	that these are tobacco products. Examples of these
			products are shisha, e-cigarettes, heated tobacco
			products and electronic nicotine devices. It is
			important that these and future devices are regulated.
PART Y	XVI: GENERAL PROVISIONS		
62.	General penalties	The tobacco industry stated that this	Penalty units were arrived at following the gravity of
		section is a bit excessive. How are	the offence. This was also done in consultation with
		the fee units arrived at?	other laws in the country and the region.
68.	Regulations	The tobacco industry state that this	Harmonization of what is required to be prescribed by
		section touches on other ministries	SI will be done by Ministry of Justice during the
		and their mandates.	drafting stage.

#### 9.0 SELECTING THE BEST OPTION AND MAKING RECOMMENDATIONS

Based on the comparisons of costs and benefits of options and the input from stakeholders, option 3 is the best option to address the problem. Option 3, enacting a new piece of legislation to domesticate the WHO FCTC has the lowest ratio of **ZMW 9,130** compared to the other two options.

Cost effectiveness analysis was used to compare the benefits derived from each of the three options. The aforementioned option provided highest benefits compared to the others. Considering the seriousness of tobacco and nicotine use and the commercial interest, the need for law enforcement is the best option.

Existing tobacco control regulations contain wide gaps, do not meet WHO FCTC requirements and fail to provide effective protection. In addition, the timing of the draft Bill allows it to maximise the opportunity to address the more recent tobacco product innovations in the forms of e-cigarettes (nicotine products) and heated tobacco products. These products present new regulatory challenges for governments which were unforeseen decades ago.

By adopting the Tobacco Control Bill, the Government would invest in the health of the nation, saving lives and generating productivity gains that would boost the economy.

# 10.0 IMPLEMENTATION AND MONITORING PLAN

		Y	r 1 l	by	7	Yea		by	Y	ear		by		ar 4	-	Y	ear		у	
Strategic Objectives	Strategic Objectives	1	tr. 3	4	1	$\frac{Q}{\square 2}$	)tr.	4	1	$\frac{Q}{2}$	tr. 3	4	1	Qtr 2	3 4	1	Q <sub>1</sub>	3	4	Responsible Department
1. To implement measures aimed at reducing the demand for tobacco and nicotine products in order to reduce morbidity and mortality by 10% by 2026	Quarterly coordination meetings with line ministries and CSOs to map stakeholders(Collaborate with asthma, diabetes and adolescent health programs/associations to holistically approach chronic disease management and tobacco prevention)																ı			MOH, Line Ministries, Academia, CSOs, WHO, World Bank, UNDP,
	Curriculum and extra curriculum based activities (Debates, clubs, drama, essay competitions), Educational broadcasts on tobacco control (TV/Radio)																			MOGE, MOH, Line Ministries, Academia, CSOs, WHO, World Bank (WB), UNDP,
	Development and distribution of Educational materials on tobacco control e.g. booklets, posters, brochures, educational magazines and other IEC materials etc.																			MOH, MNDP, MOGE, MYSCD, DEC, WHO, UNODC, WB, UNDP,
	Develop an advocacy and Social Behaviour Change communication Plan ( addressing different target audiences)																			MOH, Line Ministries, Academia, CSOs, WHO, WB, UNDP,
	Establish a toll free line/quit line																			MOH, MNDP, MOGE, MYSCD, DEC, WHO, UNODC, WB, UNDP,
	Establish functional anti-tobacco clubs in all public and private primary, secondary and tertiary schools (youth empowerment initiatives)																			MOH, MOGE, MOHE, DEC, MYSCD, MCD,MNDP, WHO, UNDP,
	Public awareness campaigns (Educate for tobacco-free environments for all (school, work, home, public)																			MOH, MOGE, MLSS, DEC, WB, WHO, UNDP, UNICEF,
	Update regulations on content and emissions, and disclosure of contents and emission tobacco products																			MOH, MOGE, MOJ, MYSCD, MOCTI, MLG, MLSS, ZEMA,ZRA, ZABS, WHO, UNDP
	Training of enforcement and public health																			MOH, MOF, MYSCD, MCTI, MNDP, MOGE, MLSS, MLG,

Strategic Objectives  Officers in line ministries and key government departments and agencies  Training of key influencers ( media, religious leaders, chiefs, teachers ) to educate about emerging tobacco products including electronic nicotine delivery devices, as youth may be experimenting with and regularly using these products that can go easily undetexted  Advocate for 75% graphic/pictorial health warnings on tobacco product packaging and labelling  Development and dissemination of packaging and labelling guidelines and monitoring checklists on all tobacco products  Engagement with manufacturers, traders and distributors of tobacco and nicotine products, on packaging and labelling  Provide evidence and best practices on contents and emissions of tobacco products  Train programment and dissemination of packaging and labelling  Provide evidence and best practices on contents and emissions of tobacco products  Engagement with manufacturers, traders and distributors of tobacco and nicotine products, on packaging and labelling  Provide evidence and best practices on contents and emissions of tobacco products  Train key stakeholders on minimum standards  Set up a licensing system  Integrate tobacco control program into other national programmes and plans in line sectors,			Y		· 1 b	у	Yea		•	Y	ear		by	Y		4 b	y	Y	ear		by	
officers in line ministries and key government departments and agencies Training of key influencers ( media, religious leaders, chiefs, teachers ) to educate about emerging tobacco products including electronic nicotine delivery devices, as youth may be experimenting with and regularly using these products that can go easily undetected Advocate for 75% graphic/pictorial health warnings on tobacco product packaging Develop comprehensive regulations on packaging and labelling guidelines and monitoring checklists on all tobacco products (including smokeless tobacco products) Engagement with manufacturers, traders and distributors of tobacco and nicotine products, on packaging and labelling Provide evidence and best practices on contents and emissions of tobacco Train key stakeholders on minimum standards on packaging and labelling of all tobacco products Develop a comprehensive M & E system to ensure compliance with set standards Set up a licensing system  MOH, MOCTI, MENR, ZABS, WHO  MOH, MOCTI, MENR, ZABS, ZEMA, WHO, UNDP, Academia  Train key stakeholders on minimum standards on packaging and labelling of all tobacco products  Develop a comprehensive M & E system to ensure compliance with set standards  Set up a licensing system  MOH, MOCT, MENR, CIY, Councilis MOH, MOCT, MENR, CIY, Councilis MOGE, MYSCD, WHO  Integrat tobacco control program into other national programmes and plans in line sectors,	Strategic Objectives	Strategic Objectives						Qtr.	,	<u> </u>	Q	tr.										
Training of key influencers (media, religious leaders, chiefs, teachers) to educate about emerging tobacco products including electronic incotine delivery devices, as youth may be experimenting with and regularly using these products that can go easily undetected Advocate for 75% graphic/pictorial health warnings on tobacco product packaging and labelling Development and dissemination of packaging and labelling guidelines and monitoring checklists on all tobacco products (including smokeless tobacco products (including smokeless tobacco products)  Engagement with manufacturers, traders and distributors of tobacco and nicotine products, on packaging and labelling Provide evidence and best practices on contents and emissions of tobacco  Train key stakeholders on minimum standards on packaging and labelling of all tobacco products  Develop on comprehensive regulations on packaging and labelling products, on packaging and labelling products, on packaging and labelling products, on packaging and labelling products of tobacco and nicotine products, on packaging and labelling products of tobacco and nicotine products, on packaging and labelling products, on packaging and labelling products, on packaging and labelling products.  Engagement with manufacturers, traders and distributors of tobacco and nicotine products, on packaging and labelling products.  Engagement with manufacturers, traders and distributors of tobacco and nicotine products.  Engagement with manufacturers, traders and distributors of tobacco and nicotine products.  Engagement with manufacturers, traders and minimum standards and packaging and labelling of all tobacco products.  Engagement with manufacturers, traders and minimum standards and packaging and labelling of all tobacco products.  Engagement with manufacturers, traders and monitorine products, on packaging and labelling of all tobacco products.  Engagement with manufacturers, traders and monitorine products, on packaging and labelling of all tobacco products.  Engagement with manufacturers,			1	2	3	4	1	2 3	3 4	1	2	3	4	1	2	3	4	1	2	3	4	
Training of key influencers (media, religious leaders, chiefs, teachers ) to educate about emerging tobacco products including electronic nicotine delivery devices, as youth may be experimenting with and regularly using these products that can go easily undetected  Advocate for 75% graphic/pictorial health warnings on tobacco product packaging  Develop comprehensive regulations on packaging and labelling guidelines and monitoring checklists on all tobacco products (including smokeless tobacco products (including smokeless tobacco products (including smokeless tobacco products on packaging and labelling guidelines and monitorine products, on packaging and labelling products on packaging and labelling																						ZRA, ZABS, WHO
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Strategie Objectives	Strategie Objectives	1	3	4	1	2	3	4	1		3	4	1	2 3	3 4	1	2	3	4	Responsible Bepartment
	Hold multi-sectoral meetings for consensus building and development of advocacy roadmap and materials to increase taxes on tobacco products and nicotine products to 75%																			MOH, MOF, MNDP, ZRA, MOCTI, WHO
	Engagement of Parliamentarians on awareness creation, tax restructuring and earmarking funds for tobacco control programmes																			MOH, MOF, MNDP, ZRA, MOCTI, WHO
	Advocate for complete ban on the importation of snuff and smokeless tobacco and nicotine products																			MOH, MOGE, ZRA, MOF, WHO
	Develop guidelines on scope of TAPS, violation, sanctions and seizures																			MOH, MOGE, MOJ, MOCTI, MLG, MLSS, MENR, MLSS, MLG, ZEMA, ZRA, ZABS, WHO, UNDP
	Training staff involved in de-addiction and cessation programmes																			MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Incorporate de-addiction and cessation programmes in the pre-service curriculum of all health workers																			MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Conduct behavioural therapy based on intensive counselling																			MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Produce smokers guidelines on quitting with a directory of available services																			MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Conduct KAP surveys on youth/public/grower's and other special groups perceptions on tobacco use, second hand smoke, quitting, etc.																			MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Train counsellors, community health workers on helping smokers to quit  Conduct Midterm Review of the tobacco																			MOH, WHO, UNDP  MOH, MENR, MLSS, MLG,

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	control program																_				_	MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
To Protect the public from exposure to Tobacco smoke (Article 8)	Awareness creation on harms of exposure to tobacco smoke and the need for smoke-free environments  Develop and review enforcement manual																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP MOH, MENR, MLSS, MLG,
																						MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP MOH, MENR, MLSS, MLG,
	Train legal enforcement officers																					MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Legal enforcement of the smoke-free environment																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Institute tobacco free/smoke free zones (Educate state-level school stakeholder organizations and local school administrators and policymakers on the importance of completely tobacco free school, including ENDS, environments including passing resolutions and policies supporting completely tobacco free school campuses																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Draft regulations on smoke free environments																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Conduct random inspections in institutions																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
To lobby for the elimination of all forms of illicit trade in tobacco and nicotine products	Review policies and legislation that needs to be amended or reviewed/enacted in order to domesticate the Protocol																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP

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(Article 15)	Initiate process of domestication by enactment of salient aspects of protocol in existing legislation	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3 4		1 2	3	3 4	MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Set up licensing and enforcement procedures																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Introduction of import tax																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Institute public awareness programs on illicit trade among state and non-state actors																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Develop and implement a tracking and tracing mechanism for all tobacco and nicotine products																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Training of authorised officers																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
To implement measures that aim at reducing access to tobacco and nicotine products by minors in order to reduce	Review and strengthen the SI 163 of 1992 (The Public Health (Tobacco) Regulations 1992) to include regulations related to:																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
initiation of consumption of tobacco and nicotine products by 50% by 2026(Article 16)	• Selling of tobacco single sticks or small packets/quantities or other tobacco products (OTP) such as little cigars and cigarillos																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Selling of tobacco products by and to minors																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Distribution of free tobacco products																				MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP

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Strategic Objectives	Strategic Objectives		Qı				Q	tr.				tr.			Qt				Qt			Responsible Department
	Total ban of tobacco vending machines	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	• Total ban of sale of tobacco products on store shelves																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Monitor manufacturing, importation and sale of sweets, bubble gums, snacks, toys or any other subjects/flavoured tobacco products which appeal to minors																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Increase the age limit from 16 years to 18 years to harmonize with the regulation on alcohol																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Review/update regulations on access to tobacco products by minors																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Hold sensitization meetings/trainings on new regulations on the sale of tobacco products to and by minors																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Hold quarterly multi-stakeholder dialogue meeting to monitor adherence to regulations.																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Activate and integrate tobacco prevention and cessation programmes through youth friendly services																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP
	Community engagement on 'Nsunko' and other smokeless and emerging tobacco products																					MOH, MENR, MLSS, MLG, MOGE, MOJ, MOCTI, MLG, MLSS, ZEMA, ZRA, ZABS, WHO, UNDP

#### 11.0 ANNEXES

Conceptual Meeting held at Chainama National Mental Health Resource Centre on 24<sup>th</sup> August 2009 which involved 8 participants. *Minutes attached as annex 1*.

Meeting held at Lillo Lodge in Kafue held from  $21^{st} - 25^{th}$  September 2015 which involved approximately 33 participants. *Report attached as annex 2.* 

Meeting held at Mika Convention Centre held from  $19^{th} - 20^{th}$  April 2017 which involved 25 participants. *Minutes and report collectively attached as annex 3*.

Meeting held at Ndozo Lodge held from 20<sup>th</sup> - 22nd June, 2018 which involved 46 participants. *Report attached as annex 4*.

Parliamentary engagement meeting with Members of Parliament held on 27<sup>th</sup> June 2018 at Parliament Building. *Report attached as annex 5*.

Inter-ministerial engagement meeting on the status of tobacco held on 24<sup>th</sup> July 2018 Cabinet office, which involved 17 participants. *Minutes attached as annex* 6.

Country common position paper over tobacco meeting held on 17<sup>th</sup> September 2018 at Government Complex which involved 13 participants from the line Ministries. *Report and position paper collectively attached as annex 7.* 

Meeting held at Waterfalls Lodge from  $19^{th} - 21^{st}$  November 2018 which involved 44 participants. **Report attached as annex 8.** 

Parliamentary engagement meeting with 48 Members of Parliament held in February 2019 at Parliament Building. *Report attached as annex 9.* 

High level meeting held in June 2019 with various Permanent Secretaries from Ministry of Agriculture, Commerce, Justice, Finance, Labour, Planning and Local Government. This was chaired by Secretary to the Cabinet. *Report attached as annex 10.* 

High level meeting held from  $10^{th} - 13^{th}$  September, 2019 with various Directors and Assistant Directors from Ministry of Agriculture, Commerce, Trade and

Industry, Justice, Finance, National Planning and Development which involved 30 participants. *Report attached as annex 11*.

Consultative Meeting with the Tobacco industry and other stakeholders on the tobacco and Nicotine products Control Bill held at Waterfalls from 16<sup>th</sup> -17<sup>th</sup> December, 2019 which involved approximately 40 participants. *Minutes and report collectively attached as annex 12*.