



**Ethiopian Food, Medicine and Healthcare
Administration and Control Authority**

Tobacco Control Directive

March 2015

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PREAMBLE

WHEREAS, tobacco products have serious health, social, economic and environmental consequences;

WHEREAS, tobacco consumption has been scientifically confirmed to cause serious ailments including cancer, respiratory disease, cardiac and blood vessel diseases; disability as well as death;

WHEREAS, exposure to tobacco smoke causes serious health problems, death, and disability to nonsmokers exposed to the smoke, and its control is found to be necessary;

WHEREAS, in order to control increased consumption of tobacco by children and adolescents in the country, it is found essential to regulate advertising, promotion and sponsorship of tobacco products as these increase demand and consumption;

WHEREAS, in accordance with the WHO Framework Convention on Tobacco Control, government has the responsibility to prevent and reduce nicotine addiction in addition to its regulatory responsibilities to reduce and prevent tobacco use and exposure to tobacco smoke;

WHEREAS, given the moderately low use of tobacco products in the country, and the necessity to effectively sustain current tobacco control efforts, and protection of the public health particularly among non-smokers, children, pregnant and other vulnerable parts of the community, it is found necessary to ban nicotinic and non-nicotinic Electronic Nicotine Delivery Systems despite the claims that use of these products, compared to combustible tobacco, may have reduced harm to tobacco smokers;

WHEREAS, the House of Peoples' Representative mandated the Ethiopian Food, Medicine and Healthcare Administration and Control Authority to take all necessary measures to implement the Framework Convention on Tobacco Control Ratification Proclamation No. 822/2013;

WHEREAS, entrusting certain tobacco control measures to regional governments is found to be a necessary measure to implement the Framework Convention on Tobacco Control Ratification Proclamation No. 822/2013 efficiently and effectively;

NOW, THEREFORE, this directive is issued by the Ethiopian Food, Medicine and Healthcare Administration and Control Authority in accordance with Article 4 of the Framework Convention on Tobacco Control Ratification Proclamation No. 822/2013, Article 55(3) of Proclamation No. 661/2009 and Article 98 of the Council of Ministers Regulation on Food, Medicine and Healthcare Administration and Control.

PART ONE

GENERAL

1. Title

This directive may be cited as the “Tobacco Control Directive No 28/2015”

2. Definition

In this Directive, unless the context otherwise requires:

- 1) “tobacco products” means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing and includes shisha tobacco;
- 2) “electronic nicotine delivery system” means any system which is used to heat nicotinic and non-nicotinic compounds and includes electronic cigarettes;
- 3) “tobacco advertising” means any commercial communication, recommendation or action with the aim, effect or likely effect of directly promoting a tobacco product or tobacco use through mass media, outdoor advertisement, telecom, post, internet, fax and similar other means;
- 4) “tobacco promotion” means any communication, recommendation or action with the aim, effect or likely effect of indirectly promoting a tobacco product or tobacco use through incorporating written, recorded, or graphic tobacco product message with any program; contributions or grants of socially responsible activities, giving promotional materials or equipment, and other similar means;
- 5) “tobacco sponsorship” means any form of contribution to any event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly;
- 6) “health warning” means texts or color pictures prescribed by the Authority to be displayed on tobacco packaging and labeling that convey the health consequences of tobacco use and exposure to tobacco smoke;

- 7) “content or ingredient” include tobacco, components including materials used to manufacture those components, additives, processing aids, residual substances found in tobacco, and substances that migrate from the packaging material into the product;
- 8) “special license” mean an authorization granted by the appropriate health regulatory organ for the purpose of tobacco products import, wholesale, distribution or retail sale;
- 9) “wholesaler” means a person who distributes any tobacco product in more than one region;
- 10) “retailer” means any person who independently holds and sells for retail any tobacco products;
- 11) “second-hand tobacco smoke” means the smoke emitted from the burning end of a cigarette or from other tobacco products usually in combination with the smoke exhaled by the smoker;
- 12) “smoking” means being in possession or control of a lit tobacco product regardless of whether the smoke is being actively inhaled or exhaled;
- 13) “outside packaging” means any packaging used on the retail package of tobacco product;
- 14) “label” means required messages written or affixed on packaging of tobacco products;
- 15) “public place” means any place which is open to the public or any part of the public, or to which members of the public ordinary have access, and includes a work place;
- 16) “indoor or enclosed” means any space covered by a roof or one or more walls or sides, regardless of the type of material used and regardless of whether the structure is permanent or temporary;
- 17) “work place” means any place where one or more persons perform work duties and includes any common area which is used by such persons during the course of their employment or work;
- 18) “open place or outdoor” means any place which is not designated in accordance with this directive;
- 19) “designated room or area” means an area in otherwise smoke-free public places which is intended for use by smokers and made in accordance with this directive;

- 20) “public conveyance” means any form of transportation that carries members of the public, whether locally or internationally, and includes conveyances for employees’ transportation;
- 21) “Authority” means the Ethiopian Food, Medicine and Health Care Administration and Control Authority;
- 22) “region” means the states establishes in accordance with Article 47 of the Constitution of the Federal Democratic Republic of Ethiopia and includes the administration of the Addis Ababa and Dire Dawa Cities;
- 23) “city administration” means an organ having the delegation by law or relevant government body to exercise city administration functions;
- 24) “appropriate organ” means the federal and regional government organ in charge of activities, including health, trade, education, transport, culture and tourism, customs and revenue, or advertisement, and other government organ responsible to execute regulated activities under this directive;
- 25) “person” includes any natural and legal person;
- 26) any expression in the masculine gender includes the feminine.

3. Objective

The objective of this directive shall be to protect public health from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke and, as appropriate, to give effect to Ethiopia’s obligations undertaken under the WHO Framework Convention for Tobacco Control and its implementing guidelines and protocols.

4. Scope of application and division of functions

- 1) The directive shall be applicable to all tobacco products that are imported, distributed and sold in Ethiopia.
- 2) Responsibilities described in part 2 and 3 of this directive pertaining to licensing of tobacco product importers and wholesalers; packaging and labeling; product content;

health warnings; sample collection and testing; and tobacco advertising and promotion, and tobacco sponsorship shall be carried out by the Authority.

- 3) Tobacco products distribution, sales, tobacco advertising and promotion, and sponsorship that are limited within one region shall be regulated by the appropriate regional organ.

5. General prohibition

Manufacturing, importing, distributing, selling or in any other way introducing Electronic Nicotine Delivery Systems in to Ethiopia shall be prohibited.

PART TWO

SPECIAL LICENSE REQUIRMENTS

6. Special license

- 1) No person may be involved in commercial import, wholesale or distribution of tobacco products without having special license issued by the Authority.
- 2) Special license requirements for tobacco product wholesale, distribution or retail sale within a region shall be in accordance with requirements set by the appropriate regional government organ.

7. Renewal and amendment of special license

- 1) A special license granted in accordance with Article 6 shall be valid for a period of one year and subject to annual renewal during the first month of Ethiopian budget year (Hamle 1- Hamle 30).
- 2) If the special license granted in accordance with Article 6 is not renewed within one month of the start of the Ethiopian budget year (Hamle 1- Hamle30), a 100 % additional licensing fee per month shall be charged to renew within the next two consecutive months.

- 3) If the special license is not renewed within three months from the start of the Ethiopian budget year, it shall be considered cancelled and any tobacco business operation thereafter shall be deemed to be carried out without a permit.
- 4) A special license shall be amended if an importer or wholesaler wishes to introduce a new tobacco product other than those declared during application for initial license.

8. Outside packaging, labeling and health warning requirements

- 1) Misleading statement and other signs on the outside packaging and labeling of tobacco products with the likely effect to create an erroneous impression about the product's characteristics, health effects, hazards or emissions shall be prohibited.
- 2) Statements on any tobacco product including "low tar", "light", "ultra light", or "mild", "extra", and "ultra" and similar terms in any language are prohibited.
- 3) Any figure or statements about the quantitative emissions of tobacco products on the product, its outside packaging, and inside the product shall be prohibited.
- 4) It shall be prohibited to display expiry dates on packaging and labeling of tobacco products.
- 5) Any outside packaging and labeling of tobacco products shall have a health warning. The health warning shall be displayed on not less than 30 % of each principal display area of the packaging.
- 6) The outside packaging shall not be made in such a way that normal opening of the package would permanently damage, conceal, obscure, or otherwise hamper the visibility of any portion of the health warning.
- 7) The health warning shall not be obstructed by other required packaging and labeling markings or by anything put on the package by the manufacturer, importer, wholesaler or any other seller.
- 8) Health warnings on tobacco products shall be large, clear, visible and legible and be placed on the upper portion of the principal display areas, which constitute the front and back of rectangular-shaped outside packaging.
- 9) Health warning shall be in two contrasting colors that would enhance its noticeability.

- 10) Outside packaging of tobacco products may not contain any information other than brand name, product name and/or manufacture's name, contact details, the quantity of product in the packaging and other information acceptable to the Authority.
- 11) Health warning shall be in Amharic or English language.
- 12) The Authority may require various health warnings to be applied on a rotating schedule.
- 13) The Authority shall require the text of the health warning to include the following messages: tobacco smoking is addictive; tobacco smoking causes pulmonary disease, cancer, bronchitis, cardiac disease; tobacco smoking can harm your fetus; tobacco smoking can harm your child; tobacco smoking cause diseases in non-smokers around you; tobacco use causes premature death; and quitting smoking now greatly reduces serious risk to your health
- 14) The warnings required by the Authority, in accordance with this article, shall run for a period of not more than 12 months, after which they shall be replaced with the next set of required health warnings and the Authority shall, through letter, notify regulated persons three months in advance.
- 15) Health warnings shall be placed on an equal number in each brand family or within each variant within a brand family as required by the Authority.
- 16) It shall be prohibited to use different packaging except as permitted under the law.

9. Tobacco product content and disclosure requirements

- 1) Modifications or any changes to tobacco product ingredients shall be notified to the Authority by the manufacturer or the importer, as appropriate.
- 2) The Authority may prescribe other information that manufacturers and importers shall provide including, but not limited to, company profile, other information on tobacco products and their emissions, sales data and information on product composition, ingredients, hazardous properties and brand elements.

10. Prohibitions

- 1) No person shall import, wholesale, distribute, sell or offer for sale any flavored tobacco products.
- 2) No person shall import, wholesale, distribute, sell or offer for sale any tobacco products containing any content or ingredient used to create an impression that a tobacco product has health benefits or reduced health hazards, including but not limited to, vitamins, fruits and vegetables, amino acids, and essential fatty acids and stimulant compounds that are associated with energy and vitality.
- 3) “Flavored tobacco products” means any tobacco product that contains any content or ingredient, singly or in combination with other contents and ingredients, that in an un-combusted state or upon combustion or pyrolysis imparts a distinguishable taste or aroma, other than the taste or aroma of tobacco, including, but not limited to, tastes or aromas of fruit, chocolate, vanilla, honey, candy, cocoa, menthol, mint, alcoholic beverage, herb or spice.

11. Sample collection and testing

- 1) The Authority may take samples of tobacco products from manufacturing sites, during inspection at port of entry, or when it is necessary during licensing and inspection procedures. Any sample taken in accordance with this article shall only be used for the purpose of investigation or testing.
- 2) The Authority may require testing and measuring of tobacco products to be performed by an accredited laboratory. The Authority may require the owner of the product to pay for testing of the product performed in accordance with this article.

PART THREE

TOBACCO ADVERTISING, PROMOTION AND SPONSORSHIP

12. General prohibitions

- 1) All tobacco advertising, promotion, and sponsorship activities shall be prohibited.
- 2) Without prejudice to the complete ban on tobacco advertising, promotion and sponsorship of tobacco products the following acts and related activities shall be prohibited:
 - a) communication through audio, visual or audiovisual means: print, films, DVDs, videos and CDs, games, other digital communication and theatre or other live performance;
 - b) provision of gifts or items like key rings, T-shirts, hats, and cigarette lighters and related promotional activities with the purchase of tobacco products;
 - c) supply of free samples of tobacco products, including in conjunction with marketing surveys and taste testing;
 - d) promotion of discounted products;
 - e) incentive promotions or loyalty schemes including redeemable coupons provided with purchase of tobacco products;
 - f) connecting a brand name, emblem, trademark, logo or trade insignia or any other distinctive feature of a tobacco product with non-tobacco product or services, or a non-tobacco products or services with a tobacco product in such a way that two are likely to be associated;
 - g) direct targeting of individuals with promotional (including informational) material, such as direct mail, telemarketing, “consumer surveys” or “research”;
 - h) payments or other contributions to any person who sale tobacco product to encourage or induce them to sell products, including retail incentive programs like rewards to tobacco product sellers for achieving certain sales volumes;
 - i) sale, supply, placement and display of products at educational establishments, health institution, hospitality, sporting, entertainment, music, dance and social venues or events; and

- j) the manufacture, import, sell or offer for sale any tobacco product that resemble toys, sweet products, and any other products.
- 3) Any person who in any way participates in the dissemination of tobacco advertising, promotion and sponsorship activities mentioned under sub-article (2) of this article and is in a position to control the activity shall stop or take all necessary measures in order to limit accessibility of the prohibited dissemination or activity.

13. Permitted communications

The following communications shall be allowed even if they have or are likely to have an incidental promotional effect:-

- 1) a plain black-and-white only price list made available where tobacco products are legally sold, provided the list contains nothing more than the tobacco product brand name, package quantity, price, and any government-required or authorized information;
- 2) display of the brand name, product name, manufacturer's name and other acceptable information on tobacco product packaging and labelling, in accordance with any legal requirements, restrictions, or prohibitions;
- 3) depictions of tobacco products or tobacco use in media where the depiction is purely incidental or is justified by reasons of historical accuracy or legitimate journalistic or artistic expression, or where the depiction is required for educational purposes; provided no payment or other consideration was offered or made by a tobacco manufacturer or seller, or any person acting on their behalf. Presentation of this kind of artistic or journalistic works shall contain a message advising that use of a tobacco product is dangerous for health or other comparable message before the start of the presentation;
- 4) genuine political, social, or scientific commentary about tobacco products or tobacco use; provided no payment or other consideration was offered or made by a tobacco manufacturer or seller, or any person acting on their behalf;

- 5) dissemination or reporting of information on tobacco companies' practices characterized as or likely to be perceived as socially responsible practices, such as sustainable environmental practices or good employment practices, that do not involve contributions to other parties; provided this information is necessary for business administration or for required corporate reporting;
- 6) product information made accessible to persons within the tobacco trade who need the information for trading decisions, and only to the extent access is limited to those persons; and
- 7) tobacco manufacturers' newsletters destined for and distributed only to the manufacturer's employees, contractors, suppliers, and other tobacco-related business partners, and only to the extent their distribution is limited to such persons. Commercial communication between a manufacturer, importer or wholesaler and its buyers, business partner, employees or shareholders may not contain any information except for factual information about the tobacco product, its characteristics, its availability or price, picture of the products, the component parts and their packaging.

PART FOUR

PROTECTION FROM EXPOSURE TO TOBACCO SMOKE AND SALES OF TOBACCO PRODUCTS

14. Places where smoking is prohibited

- 1) It shall be prohibited to smoke in any part of indoor public places, indoor work places, and on public conveyances.
- 2) Without prejudice to the generality of sub-article (1) of this article, smoking shall be prohibited in the following indoor work places and public places:-
 - a) health and education institutions;
 - b) restaurants, hotels and other eating places; bars, night clubs, cafes, and recreational clubs;
 - c) prisons, police stations, and any government offices;

- d) corridors, reception areas, lifts, stairwells, toilets and laundries of offices and work places;
 - e) factories and shopping malls;
 - f) cinema, theatre and video houses and concert halls, and such other halls or places of performance, or any other entertainment;
 - g) sites of attraction and sport places; and
 - h) railway stations, airports and bus stations.
- 3) Even if the place is not indoor as defined under sub-article (2) of this Article, no person may smoke anywhere within the outside premises any place that provides services primarily to children or youth under the age 18 including playgrounds, kindergartens, education facilities, other places where children congregate, and youth centers.
- 4) No person may smoke in any public conveyances including buses, taxis, rails, air transport, ambulances or other vehicles intended for public service.

15. Smoking designated rooms and areas

- 1) With the exception of places that provide services primarily to children or youth under the age 18, government offices, rooms of education and healthcare service, tobacco may be smoked if the owners of the prohibited public or work places provide a designated room for smoking.
- 2) A smoking room designated in accordance with sub-article (1) of this article shall be equipped with a separate ventilation, and
- a) in order to decrease the air from the smoking room that may be re-circulated or drift to other areas within the smoking prohibited place, the ventilation shall be able to directly exhaust air from the smoking room to the outside;
 - b) the smoking room shall be properly enclosed and sealed from its floor to the ceiling or roof, and shall have a suitable door to increase the amount of smoke to be exhausted through the ventilation; and

- c) the smoking room may not be placed or created in a manner that requires nonsmokers to pass, cross or in any other way enter the area for any service or purpose.
- 3) Smoking in the outdoor premises of universities, colleges and other higher education facilities, and public transport stations shall be only allowed in a smoking designated area.
- 4) Unless intended for customers who want to smoke, provision of smoking designated room as a primary business may not be allowed.

16. Obligations to ensure compliance

- 1) It shall be the duty of the owner or other responsible person of the public place or conveyance, or, in the case of a workplace the employer or other appropriate person to take all reasonable steps to enforce or ensure compliance with the smoking prohibition provisions of this directive.
- 2) The reasonable steps to be taken under sub-article (1) of this article shall include, but are not limited to, a duty to:
 - a) post clear signs at entrances and other appropriate locations indicating that smoking is not permitted by law;
 - b) supervise the observance of regulations; and
 - c) ask the person to stop smoking, ask the person to leave the premise or public conveyance, discontinue services if appropriate, and notify law enforcement agents.
- 3) The owner or other appropriate person in charge of the public place and public conveyance, or in the case of a workplace the employer or other appropriate person may not permit placement of ashtrays in any place under his control.
- 4) The owner or other responsible person of the public place or conveyance, or, in the case of a workplace the employer or other appropriate person, shall post clear and prominent notices in Amharic or English, or in the Region's local language and in Amharic, stating that smoking is prohibited by law.

17. Protection of minors from tobacco products

- 1) No person may directly or indirectly give, provide or sell any tobacco product to a person under the age of 18.
- 2) If the buyer appears to be a minor to any person who sale tobacco product, he may confirm age of the buyer by requiring passport, driving license or residence identification card.
- 3) Any means of facilitating the sale of tobacco products where the buyer and seller are not physically in the same place including though internet shall be prohibited.

18. Prohibition of unit sale of cigarette

- 1) It shall be prohibited to sale cigarette sticks unit by unit.
- 2) Tobacco products may only be sold in intact packages containing, as applicable, the specified number of sticks or consisting of the specified weight, and shall have the required health warning in accordance with this directive.
- 3) For the purpose of this article “unit” means single cigarette contained in a cigarette package.

PART FIVE

ENFORCEMENT

19. Administrative measures

- 1) In accordance with the Directive on Administrative Measure Taking and Complaint Handling, the Authority, depending on the severity of the violation, shall take one or more administrative measures on non-complying institution and/or tobacco products.
- 2) The Authority may give warning, suspend or revoke a special license or take other appropriate measure on the product or regulated person if a manufacturer, importer or wholesaler’s products introduced in the market is found to be non-complying with

provisions regarding packaging and labeling, and content and disclosure information supplied or declared to the Authority at the time of initial licensing.

- 3) The Authority, when it has sufficient reason to support administrative measure-taking, may seize and **cause the** disposal of non-complying tobacco products held by manufactures, importers, and wholesalers.
- 4) In relation to the retail trade of tobacco products and other activities regulated by regions, the appropriate regional government organ may, as appropriate, seize and dispose non-complying tobacco products, give a warning, suspend or revoke a special license, or take such other appropriate administrative measure.

20. Criminal responsibilities

Where violation of any provision of this directive by any regulated person constitutes criminal offence in accordance with the Ethiopian criminal code, the Food, Medicine and Healthcare Administration and Control Proclamation No.661/2009 or any other appropriate public health laws, the violating person shall be held criminally responsible.

PART SIX

MISCELLANEOUS

21. Illicit trade in tobacco products

- 1) No person may participate in illicit tobacco product import, distribution, storage, sale, hold of such products, or illegally introduce tobacco products in the market.
- 2) The appropriate government organs shall maintain information, and monitor activities regarding illicit trade in tobacco products and other tobacco product trades.
- 3) Seized tobacco products and any proceeds and income associated with illicit tobacco trade shall, in accordance with applicable laws, be confiscated by the appropriate government organ.
- 4) All appropriate government organs shall cooperate to control illicit trade in tobacco products.

22. Duty to cooperate

The concerned federal and regional bodies, private institutions and individuals shall have the duty to cooperate to assist all appropriate organs to effectively execute their responsibilities given in accordance with this directive.

23. Trade chain

Manufacturers and importers of tobacco products may only supply products to a wholesaler having a valid special license granted by the appropriate organ.

24. Disposal of tobacco products

- 1) Non-compliant tobacco products, manufacturing equipment and related articles may only be disposed of in such a manner that doesn't harm public health or contaminate the environment.
- 2) Disposal of tobacco products shall be notified to the appropriate government organ and it shall be performed in accordance with applicable directive or guideline.

25. Service fee

Any person who is provided with regulatory service under this directive may be required to pay an applicable service fee as determined by the appropriate government organ.

26. Inapplicable laws

Any directive, circular or customary practice which is inconsistent with this directive may not be applicable with respect to those matters provided for in this directive.

27. Effective date

- 1) Provisions of part two of this directive including packaging, labeling, content and emission requirements of tobacco products shall enter into force six months after the entry in to force of this directive.
- 2) All provisions, with the exception of part two of this directive, shall come in to force one month after the entry into force of this directive.
- 3) This directive shall enter into force on the date of 21 March 2015.

Yehulu Denekew

Director General

Ethiopian Food, Medicine and Healthcare Administration and Control Authority