



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

**Tobacco Control Directive
Number 771/2021**

March, 2021
Addis Ababa

Preamble

WHEREAS, scientifically proved that using tobacco is a risk factor for disease such as cancer, respiratory disease, heart disease, stroke and non-communicable disease as well as resulted to physical injury and death;

WHEREAS, the number of tobacco users in Ethiopia and youth is high that unless the youth protected from exposure and appropriately regulated, high prevalence in tobacco users would inevitably increase even more causing health problems for citizens escalating their medical expense, the country's expense to import medicine and foreign exchange; it will also decrease productivity and impose heavy burden on the economy by creating other such damages;

WHEREAS, in addition to the direct users, tobacco will hurt people exposed to the smoke that necessitate strengthening enforcement in order to make smoke free public and work places from tobacco smoke

NOW, THEREFORE, the Ethiopian Food, Medicine and Health Care Administration and Control Authority issued this directive in accordance with article 71 sub-article (2) of the Food and Medicine Administration Proclamation No.1112/1019.

PART ONE GENERAL Provisions

1. Title

This Directive may be cited as the "Tobacco Control Directive No.771/2021."

2. Definition

In this Directive,

- 1) "**Proclamation**" means the Food and Medicine Administration Proclamation No 1112/2019;
- 2) "**Special license**" means a license that the Authority gives to a person engaged on tobacco product or raw material manufacturing, importing, exporting, or wholesaler based on regulatory system and requirements.
- 3) "**content**" includes tobacco, any input used to manufacture a tobacco product or those used to manufacture the input, additives, processing aids, residual substances found in tobacco, and substances that migrate from the packaging material into the product;

- 4) "**smoking**" means being in possession or control of a lit tobacco product regardless of whether the smoke is being actively inhaled or exhaled;
- 5) "**Authority**" means the Ethiopian Food, Medicine and Health Care Administration and Control Authority;
- 6) The definition provided under the Proclamation and the regulation to be issued shall apply to words and phrases whose meaning is provided under the Proclamation and regulation and used in this Directive.

3. Function of the Authority

- 1) The function of the Authority shall be to:-
 - a) Regulate and issue, suspend or revoke a special license for manufacturing, importing, wholesaling and exporting of tobacco products and raw materials;
 - b) Regulate tobacco smoking, using and sale prohibition in place and services controlled by the federal government;
 - c) Enforce tobacco control laws applicable on institutions and services mentioned under letter (a) and (b) of this article
- 2) Notwithstanding sub-article (1) of this Article, the Authority shall provide the necessary support to regions to strengthen regions` conduct of tobacco control activities and collaborate on tobacco control works.

PART TWO

ISSUANCE OF TOBACCO PRODUCT SPECIAL LICENSE

4. Issuance of special license

- 1) The Authority shall issue tobacco product special license in accordance with this directive.
- 2) Any person prior to engaging in business of tobacco product or raw material manufacturing, import, export or wholesale must obtain a special license from the Authority.
- 3) Any person to obtain a special license from the Authority shall fulfill the criteria provided under this Directive.
- 4) A special license shall be issued on bases of business type separately for manufacturing, import, wholesale, and export. This condition shall not be applicable for manufacturer to distribute a product it manufactured to wholesalers.
- 5) A person who wants to undertake two or more business type of tobacco product shall obtain special license in manner of sub-article (4) of this article. However, the special license may be given altogether in a single certificate.

5. Applying for a special license and conditions need to be fulfilled

- 1) Any person to obtain a special license from the authority shall submit a request in accordance with request system set by the Authority.
- 2) Any person who submitted request in accordance to sub-article (1) of this article shall fulfill the following information:
 - a) Name and address of the applicant;
 - b) Name and address of the manager of the business;
 - c) The type of special license permit requested which means manufacturing, or importation, or wholesale or export;
 - d) Date of application; and
 - e) Other information that may be required as per the request system.
- 3) An application request made in accordance with sub-article (1) of this Article shall be accompanied by:-
 - a) Copy of an identity card or passport for sole proprietor; copy of establishment document for a business organization ;
 - b) A proof of ownership, if the work is carried out at the location that belongs to special license requester or a copy of valid contract if the place is rented;
 - c) A receipt confirming the required service fee has been paid;
 - d) A document that shows permission or consent given by the monopoly right possessor, if the request is submitted while tobacco business is being operated by monopoly;
 - e) Verified copy of monopoly right agreement, if the applicant is a monopoly right possessor; and
 - f) Other documents that may be required as per request system.
- 4) Any person who submitted request in accordance to sub-article (1) of this article shall fulfill the following.
 - a) adequate store,
 - b) documentation system that enables to document information to be submitted in accordance with this directive to the Authority regularly or upon request by the Authority, and
 - c) a work place and store that fulfill environmental protection requirements set by the relevant law.

6. Special license certificate

- 1) The Authority shall issue a special license certificate conforming the criteria have been fulfilled by evaluating the application for the special license.
- 2) A certificate issued in accordance with sub-article (1) of this article shall include the following:
 - a) Name and address of the business that the special license issued for;
 - b) The type of business the special license issued for;
 - c) Date of the special license issued;
 - d) Date of expiry of the special license; and

- e) Name and signature of the official who approved the special license.
- 3) The special license issued by the Authority shall be displayed in the work place of the business organization.

7. Renewal of special license

- 1) A special license issued in accordance with Article 6 of this Directive shall be renewed annually.
- 2) Renewal of a special license shall be made within the last two months period of the license to expire. .
- 3) A special license shall be renewed when:
 - a) the licensee submits a request,
 - b) the licensee presents all the information required by the Authority,
 - c) the conditions provided under sub-article (4) of article 5 of this article maintained, and
 - d) the required service fee is paid.
- 4) A special license not renewed within time frame provided under sub-article (2) of this Article may be renewed with fine determined by a regulation within two months period of time after expiry of the special license.
- 5) A special license that is not renewed per sub-article (4) of this Article shall be considered as revoked.
- 6) It is prohibited to conduct any tobacco products business activity whilst it is in the renewal period with penalty or revoked as mentioned under sub-article (4) of this Article.
- 7) Anyone whose special license is revoked in accordance with sub-article (5) of this Article may not engage in any tobacco business within one year starting from the last day of renewal with fine. .

8. Tobacco product content and related information disclosure

- 1) Every manufacturer or importer of tobacco products shall submit the required information as to the content of its tobacco product, the type of each tobacco product and its single product, and ingredients used to produce each brand product that are under the main brand in accordance with Annex 1 of this Directive.
- 2) Without prejudice to sub-article (1) of this Article, the Authority may require manufacturers, importers, wholesalers and exporters to provide additional information regarding the company profile, tobacco products and their emissions, sales data, and information on product composition, chemicals, hazardous properties, and brand elements.
- 3) The content of a tobacco product presented in accordance with sub-article (1) and (2) of this Article, especially the product composition, hazardous properties, and amount of nicotine

chemicals, shall be confirmed by acceptable third party laboratory.

9. Content and limits on emission

- 1) A tobacco product's content and level of emission shall not be more than the limits provided by the Authority.
- 2) The Authority shall give reasonable transition period for implementers to enforce tobacco product content and emission limit.

10. Sample collection and testing

- 1) The Authority may take samples of tobacco products from manufacturing sites, at a port of entry, place of selling, storing or a location and person the product is placed with legally or illegally when it finds it necessary to issue a special license or for inspection purposes.
- 2) Samples of tobacco products gathered by the Authority in accordance with sub-article (1) of this Article or samples submitted to apply for a special license may be tested and measured by the Authority or it may have the samples tested by an accredited third party laboratory.
- 3) If it is confirmed that the content is not what is permitted or it is more than the amount allowed, the owner of the product shall cover the expense. In other circumstances, the Authority may require the owner of the product to cover the expense for the laboratory testing as necessary.

11. Importing tobacco product

- 1) Only a person who has a special license in accordance with this directive shall import tobacco product or raw materials.
- 2) Tobacco product or raw material importation may be allowed when:-
 - a) The license provided certificate of special license,
 - b) the product fulfilled applicable requirement of graphic health, labeling, content criteria and other criteria required by the law,
 - c) Country of origin, size and related information submitted and
 - d) The product shall in conformity with documents submitted in accordance with this sub-article.
- 3) Importing tobacco product for personal use shall be allowed only an amount determined by the Custom Commission.
- 4) Importing electronic nicotine delivery system or other related cigarette resembling technology product for personal use shall be permitted only a single product. A product with more than one quantity shall be presumed for trade as provided under sub-article (2) of article 46 of the proclamation.

- 5) It is prohibited to import Shisha as well as its device in any quantity as provided under article 49 sub-article (5) of the proclamation.
- 6) A product imported contrary to sub-article (3), (4) and (5) of this article shall be confiscated and disposed. The violator shall be subject to penalty with appropriate law.

12. Controlling illegal tobacco product

- 1) The Authority shall regularly notify to regulatory bodies the names of legal products.
- 2) It is prohibited to manufacture, import, distribute, sell, store, transport or be found in possession of a tobacco product whose details such as its trade name, brand or trade mark has not been disclosed to the Authority in accordance with Article 8 and 13 of this Directive.
- 3) The Authority shall regularly notify stakeholders about illegal products; take the necessary administrative measure; as appropriate support the concerned body for taking administrative measure and criminally liable.
- 4) In collaboration with the appropriate body, the Authority shall put in place a technological system that can distinguish legal from illegal tobacco products.

13. Disclosure of tobacco product and change

- 1) Any manufacturer or importer of a tobacco product shall disclose to the Authority the content, brand name and trade mark of the product manufacture or imports.
- 2) Any person who has been issued a special license shall notify and request permission of the Authority before making any changes to the name, trade mark, content, shape, packaging or any other accepted information of the tobacco product disclosed.
- 3) A person who has been issued a special license shall notify the Authority before manufacturing or importing a tobacco product with new product identity.
- 4) The Authority shall decide application made for change in accordance with this article by ensuring that the change doesn't contradict criteria set by the law.

PART THREE

ADVERTISING, PROMOTION, AND SPONSORSHIP OF TOBACCO and tobacco industry

14. Advertising and promoting tobacco

- 1) The comprehensive ban on direct and indirect advertising of tobacco products introduced under Article 61 of the Proclamation shall include the following.
 - a) Communication through audio, visual or films: print, image or any means that transmits message about tobacco; writing,

- showing, describing or indicating tobacco, tobacco industry or related issues;
- b) showing, describing or indicting tobacco, tobacco industry or related issues through television, radio, telephone, social media page, internet or similar communication means;
 - c) displaying any tobacco product picture, sign, image of tobacco or distinctive feature of a tobacco product or tobacco industry at a retail outlet, public or work place or service;
 - d) announcing there is price discount;
 - e) associating a brand name, emblem, trademark, logo or trade insignia or any other distinctive feature of a tobacco product or tobacco industry with non-tobacco product or services, or indicating or describing non-tobacco products or services having association with a tobacco product.
- 2) The comprehensive ban on direct and indirect promotion of tobacco products introduced under Article 61 of the Proclamation shall include the following.
- a) providing a gift with or without tobacco product items such as key ring, T-shirts, hats, lighters or any other item with logo, symbol, name, or comparable message about the industry or the product, or
 - b) providing or distributing any material that has direct or indirect association with tobacco whether or not the material contains the organization's logo mark or symbol of tobacco;
 - c) giving or providing financial or material gift;
 - d) the supply of free tobacco products, including samples;
 - e) incentive promotions or loyalty schemes including redeemable coupons provided with the purchase of tobacco products;
 - f) including information in relation to tobacco product advertisement or promotional material messaging or sending mail regarding tobacco product or tobacco industry through targeting individuals or to the whole community or certain community members;
 - g) Conducting consumer survey or market research or similar approach in a way it promotes tobacco product, tobacco industry or tobacco consumption.
- 3) It is prohibited to advertise or promote tobacco product or tobacco industry under the guise of illicit trade prevention or any other legal matters.
- 4) it is prohibited providing payments or other contributions to any person who sells tobacco product to encourage or induce them to sell products, including retail incentive programs like rewards to tobacco product sellers for achieving specific sales volumes; and

- 5) Any person who in any way participates in the dissemination of tobacco advertising, promotion and sponsorship activities and is in a position to control the activity shall stop or take all necessary measures to limit the accessibility of the prohibited dissemination or activity.

15. Permitted communications

- 1) Notwithstanding the prohibitions stated under Article 14 of this Directive, the following communications shall be considered legitimate:
 - a) Displaying the trademark, brand name, product name, manufacturer's name and other acceptable information on tobacco product packaging and labeling, per relevant law criteria, and restrictions;
 - b) Provided that no payment or other consideration was offered or made by a tobacco manufacturer, importer, wholesaler, seller, or any person acting on their behalf; messaging on mass media regarding tobacco product or using tobacco purely in incidental or is justified by reasons of historical accuracy or legitimate journalistic or artistic expression, or where the depiction is required for educational purposes;
 - c) Genuine political, social, or scientific commentary about tobacco products or tobacco use; provided no payment or another consideration was offered or made by a tobacco manufacturer importer, wholesaler seller, or any person acting on their behalf;
 - d) Providing required information or report by the tobacco industry to relevant bodies for business regulation or corporate responsibility to report on a matter such as environmental protection, employer and employee relation or other similar issues required by law;
 - e) Information is given to tobacco trader to enable to make a trading decision; and
 - f) Tobacco manufacturers' newsletters 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. Newsletter of this manner should not be given to these people more than personal use and may not be distributed to third parties.
- 2) Newsletter prepared in accordance with letter (f) and 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 whereabouts or price, picture of the products, the component parts, and their packaging.

- 3) A depiction made in accordance to (1) (c) of this Article shall contain a message that describes the use of a tobacco product is dangerous for health or another comparable message before the start of the presentation;

PART FOUR

PROTECTION FROM EXPOSURE TO TOBACCO SMOKE AND SALES OF TOBACCO PRODUCTS

16. Smoke-free environment

- 1) In accordance with Article 48 of the Proclamation, as appropriate in collaboration with regional health regulators, the Authority shall follow up the implementation of the prohibition of smoking and tobacco use in public and work places and services as well as provide support to regional state as necessary.
- 2) Notwithstanding the measures the Authority takes when an organization violates its duty provided in the Proclamation to maintain a smoke free environment, the Authority shall provide the necessary information to the body that administers the organization so it can take the appropriate measure.
- 3) It is prohibited to establish designated areas for smoking or using tobacco in places, institutions and service providing places where smoking or using tobacco is prohibited.

17. Obligations to ensure compliance

- 1) The person who has the duty to enforce tobacco smoke-free provision under Article 50 of the Proclamation shall:
 - a) Post in a visible manner a smoking is prohibited notice corresponding with colored sign at indoor public or work place or service to prevent tobacco smoking or using as provided under article 48 sub-article (1) of the proclamation and stop people who try to use tobacco in violation of the prohibition;
 - b) Post in a visible manner a smoking is prohibited notice corresponding with colored in outdoor public or work place within ten meters of any door way, operable window, or air intake mechanism of such places to prevent tobacco smoking or using as provided under article 48 sub-article (2) of the proclamation and stop people who try to use tobacco in violation of the prohibition;
 - c) Post in a visible manner a smoking is prohibited notice corresponding with colored in relevant spot in indoor place, premises and gets of places where smoking or using tobacco prohibited under article 48 sub-article (3) of the proclamation and stop people who try to use tobacco in violation of the prohibition;

- d) Post in a visible manner smoking or using tobacco is prohibited notice inside the room if the place where smoking or using tobacco prohibited provides bed service and stop people who try to use tobacco in violation of the prohibition;
 - e) Discontinue service and make the person leave the place after mentioning that smoking is prohibited by the law and the business and the smoker may penalized, if the person trying to use tobacco refuses to stop when asked in accordance with letter (a)-(d) of this sub-article.
 - f) Inform to the Authority, any regulatory or police if the person persisted after he discontinue the service and requested to leave the place in accordance to letter (e) of this sub-article.
 - g) ensure that no ashtray or any similar smoking-related items are available;
 - h) Prevent tobacco advertising, promotion and sale and remove anything that may have advertisement or promotional effect in the institution or service.
- 2) Inspector of the Authority or responsible health regulator body personnel shall ensure the person who has responsibility in accordance with article 50 of the proclamation is undertaking his responsibility in accordance with sub-article (1) of this article. Particularly ensure that the place and service provided under article 48 of the proclamation has no-smoking notice, no tobacco sale, free from tobacco product or industry advertisement or promotion, free from lighter, ashtray or similar item, free from tobacco odor and other similar tobacco control activities.
 - 3) For the purpose of this article `**indoor**` means including verandah any space covered by a roof or enclosed by one or more walls or sides, regardless of the type of material used for the roof, wall or sides, and regardless of whether the structure is permanent or temporary.
 - 4) The ten meters provided under sub-article (1) letter (b) of this article shall be measured from edge of indoor to outdoor space.

18. Sale of tobacco product

- 1) The prohibition of the sale of tobacco products by and to any person under the age of 21, which is provided under Article 49(1) of the Proclamations, shall be implemented by checking the physical appearance or identity card of the buyer or seller.
- 2) In accordance with sub-article (1) whereby the age of a buyer or seller can be determined by looking at the physical appearance and no doubt for any regular person to perceive him as an age of 2.

- 3) If it is difficult to determine the age by looking at physical appearance the age must be confirmed by checking his identity card.

19. Tobacco product packaging and product shape

Whilst tobacco product contains graphic health warning picture and message in its primary package issued routinely by the Authority: -

- 1) It is prohibited to manufacture, import, wholesale or sell a tobacco products using single label name or brand but in different colors, names or shapes.
- 2) Notwithstanding the provision of sub-article (1) of this article, different colors may be used for single label or brand with permission of the Authority. The Authority shall not permit if the use of colors have effect of contradicting the purpose of sub-article (3) and (4) of article 57 and sub-article (1) of article 61 of the proclamation. The Authority may revoke permission and using is prohibited if the using of colors permitted in accordance with this sub-article gradually created effect of contradicting the purpose of these provisions of the proclamation.
- 3) Anyone who wants to use colors in accordance with sub-article (2) of this article prior to use shall submit actual sample and get permission from the Authority.
- 4) Anyone who wants to change physical shape of tobacco product or its packaging prior to use shall submit actual sample and obtain approval from the Authority. While it review the request, the Authority should take into consideration effect of changes in being attractive and promoting consumption.
- 5) The Authority shall respond within reasonable time for request submitted in accordance with this article.

20. Protection against tobacco industry interference

- 1) Any communication between government and the tobacco industry shall be in writing and done in a way that respects the limitations and prohibitions provided by law.
- 2) Even in permissible situation, any communication between the government and tobacco industry shall be not in a manner it advertises or promotes tobacco or tobacco industry or encourages consumption
- 3) Without prejudice of matters prohibited by law to disclose, any communication between the government and tobacco industry shall be open to any interested citizen and shall be given copy of such record upon request by anyone or the Authority.
- 4) Members of the National Tobacco Control Alliance have a duty to present the information they have regarding the communication of their respective organization with the tobacco industry.

- 5) The Authority, with the exception of trade information protected by law, shall provide relevant information as necessary to the public regarding the activities of the tobacco industry.
- 6) Except for legally required fees, any financial or material gift from the tobacco industry to the government is prohibited.
- 7) The tobacco industry is prohibited from making any financial or material contribution in any form of fulfilling a corporate social responsibility, and providing financial and material support or assigning an expert for the organization of an event, meeting, training or for any other similar occasion.

21. Protection against conflict of interest

- 1) Any government employee who engaged either directly or indirectly in any tobacco trade shall not participate in any kind of tobacco control activity.
- 2) No government employee shall participate in a research or evaluation of research which is directly or indirectly supported by the tobacco industry.
- 3) Where government employee is found in violation of the provisions of this Article, the Authority and the regional health regulator shall provide the necessary support to the concerned institution and justice organ to take the appropriate measure.

22. Reporting

- 1) Every tobacco industry shall submit an annual report to the Authority regarding its activities.
- 2) A report to be submitted per sub-article (1) of this Article shall contain based on type of business the special license where issued:
 - a) The total amount of manufactured tobacco product or/and raw material in the reporting year, in general;
 - b) Manufactured tobacco product within the reporting period containing data amount, disaggregated brand and product type;
 - c) Imported tobacco product within the reporting period containing disaggregated data by amount, brand and product type;
 - d) Exported tobacco product within the reporting period containing disaggregated data by amount, brand and product type;
 - e) Type and amount of raw materials imported and obtained locally used for the production or remain unused within the reporting period;
 - f) The number of wholesalers, and the total amount of product each wholesaler procured from the manufacturer or importer within the reporting period;

- g) The total amount of product in stock at the time the industry submitted its report;
 - h) The price of each product the manufacturer or importer or exporter used to sell in their type and brand; and
 - i) In case of wholesaler the total amount of product obtained from manufacturer and importer and selling price in product type and brand, amount in stock.
- 3) A report to be submitted in accordance with this Article shall be presented at the end of the Ethiopian fiscal year from June 15 to 30.

PART FIVE
ADMINISTRATIVE MEASURES

23. General

- 1) The prohibitions included under this directive shall be viewed perspective to article 62(7) of the Proclamation; and the manner of implementation of administrative measures shall be in accordance with Article 65 of the Proclamation, this Directive and other appropriate laws.
- 2) Administrative measure shall be taken by considering the gravity violation, the manner it was committed and the damage it caused or it could have caused.

24. Administrative Measures

- 1) The administrative measure to be taken on a violation of a prohibition or duty provided in the Proclamation, the Regulation or this Directive, where the act does not constitute a criminal offence in any law, shall be:-
 - a) For the first time, a written warning;
 - b) For the second time, a written warning and a fine that shall be determined by a regulation;
 - c) For the third time, suspending the special license for up to one year;
 - d) For the fourth time, revoking the license.
- 2) Where the violation of prohibition or duty provided in the Proclamation, Regulation or this Directive constitutes a criminal offence in any law and the punishment is simple imprisonment, the special license shall be suspended for up to one year.
- 3) Where the person whose special license had been suspended in accordance with sub-article (2) of this article commits the act provided under sub-article (1), his special license shall be suspended for up to two years and pay the fine provided in the regulation.
- 4) Where the violation of prohibition or duty provided in the Proclamation, Regulation or this Directive is an act

constituting a criminal offence in any law and the punishment is rigorous imprisonment, or the special license had been suspended, special license shall be revoked.

- 5) Without prejudice to the measures to be taken in accordance with sub-article (1)-(4) of this Article, measure may be taken against the tobacco product as appropriate seizing, confiscating or disposing.
- 6) Without prejudice to the general statement provided under sub-article (5) of this article a tobacco product or raw material:
 - a) sale of which is prohibited;
 - b) which has no applicable health warning;
 - c) which has prohibited content;
 - d) manufactured, stored, transported, marketed or in any way made available by a person with no special license or an expired special license;
 - e) found in the hands of a person whose special license has been suspended, unless the product was in his possession legally before his license was suspended;
 - f) Manufactured, imported, stored, transported or marketed illicitly shall be confiscated and disposed.
- 7) A product possessed legally before suspension or revocation of special license, with supervision of the Authority, may be transferred, or sold to a person who have special license or disposed by the owner.

25. Seizing tobacco product

- 1) Any health regulator shall seize a tobacco product or raw material if he has sufficient ground to suspect that the product was illegally manufactured, imported, marketed, stored, transported; or does not fulfill requirement of health warnings or other criteria; or found in the hands of a person with no special license or expired or suspended special license.
- 2) A product seized in accordance with sub-article (1) shall be kept until appropriate decision given.

26. Confiscation

- 1) The Authority shall decide, as appropriate, to confiscate a product if an administrative measure has been taken against the tobacco product in accordance with Article 24 of this Directive or if it is seized per Article 25 or if it illegal tobacco product without an owner.
- 2) The Authority should give the opportunity to a person who claim that he has right on the product to submit his opinion and evidence before making decision in accordance with sub-article (1) of this Article.

27. Disposing

- 1) A product confiscated in accordance with Article 25 of this Directive shall be disposed of.
- 2) The Authority shall make sure the confiscated product is disposed in a manner that it doesn't cause damage to the environment and used again.

28. Causing for criminal liabilities

Where a violation of any provision of this Directive constitutes a criminal offense in the appropriate law, the Authority, in addition to taking administrative measures, shall provide appropriate information to the organization entrusted with power of investigating or prosecuting criminal offence.

PART SIX

TOBACCO CONTROL NATIONAL COORDINATING BODY

29. Establishment

- 1) The Ethiopian Tobacco Control National Coordinating Body (hereinafter called National Alliance) hereby established by this Directive in accordance with sub-article (15) of Article 4 of the Proclamation.
- 2) The National Alliance shall be accountable to the Director-General of the Authority.

30. Objective

The objectives of the National Alliance:

- 1) To coordinate the implementation of the WHO Framework Convention on Tobacco Control, its implementing guidelines, and applicable tobacco control laws at the federal level;
- 2) To monitor effectiveness of implementation of tobacco control in the federal government institutions; and
- 3) To strengthen tobacco control collaborative activities and coordination among federal government institutions, partners and stakeholders.

31. Members of the National Alliance

- 1) Members of the National Alliance shall be:-
 1. The Ethiopia Food, Medicine and Health Care Administration and Control Authority,
 2. The Office of the Prime minister,
 3. The Ministry of Health,
 4. The Ministry of Culture and Tourism,
 5. The Office of Federal Attorney General,
 6. The Ministry of Trade and Industry,
 7. The Ministry of Finance;
 8. The Ministry of Revenue;
 9. The Ministry of Women, Children and Youth;
 10. The Ministry of Agriculture;
 11. The Ministry of Science and Higher Education;
 12. The Ministry of Education;

13. The Ministry of Transport;
 14. The Ministry of labor and social affair;
 15. The FDRE civil service commission;
 16. Customs commission;
 17. The FDRE police commission;
 18. Addis Ababa police commission;
 19. The Ethiopian public health institute;
 20. The Environment, forest and climate change commission;
 21. The World Health Organization Ethiopian Country Office;
 22. Mathiwos Wendu YeEthiopia Cancer Society;
 23. Mequamia Community Development Organization;
 24. Health Development and Anti-malaria Association, and
 25. Other organization selected by the Authority.
- 2) The Authority shall conduct the necessary follow up and provide support to make sure members of the Alliance properly participate.
 - 3) Any person participating in the Alliance representing member listed under sub-article (1) of this article shall not engaged or engage directly or indirectly in tobacco product, have no any interest tie and smoke or use tobacco.

32. Power and function

The National Alliance shall have the following functions:

- 1) follow-up and evaluate the implementation of tobacco control legal frameworks, propose solutions to challenges faced, submit recommendation to the Authority;
- 2) follow-up and evaluate the implementation of tobacco control activities by members of the Alliance and conduct experience sharing;
- 3) conduct site visits as appropriate to monitor the implementation of applicable laws;
- 4) Organize and establish sub-committees that are necessary for the implementation of its functions;
- 5) Cause social mobilizations to create deep understanding of harmful effect of tobacco and prohibition and to enable their participation in the prevention ;
- 6) Provide support to regional tobacco control coordinating body;
- 7) Undertake other activities assigned by the Director-General.

33. National Alliance Structure

The National Alliance has;

- 1) A chairperson to be appointed by the Authority;
- 2) Secretariat;
- 3) Members and
- 4) As necessary, sub-committees.

34. Responsibility of the chairperson, Secretariat, and members

- 1) The chairperson shall lead the activities of the Alliance, preside over meetings, and oversee the preparation of annual plans and implementation when endorsed by the members and approved by the Authority.
- 2) The Secretariat shall set the agenda of the meeting, record minutes, and communicate decisions to members.
- 3) Members of the Alliance shall take every possible effort to enable the Alliance to achieve its objective and coordinate the implementation of tobacco control activities within their respective institutions.
- 4) Sub-committees established by the Alliances perform tasks they are set for and report to the Alliance.
- 5) The Alliance may enact working internal procedures for itself and sub-committee established.

35. Meetings of the National Alliance

- 1) The National Alliance shall have a regular meeting every three months. However, the chairperson may call a meeting at any time, as appropriate.
- 2) There shall be a quorum where more than half members of the National Alliance are present.
- 3) The National Alliance shall pass a decision with a majority vote. In case of a tie, the chairperson shall have a casting vote.
- 4) Without prejudice to provisions of this Article, the National Alliance may issue internal meeting procedure code.
- 5) Unless the situation requires otherwise, a meeting of the National Alliance shall be conducted at the Authority's headquarters.

36. Source of Budget

The Authority and partners shall cover the necessary operating cost of the National Alliance.

PART SEVEN

MISCELLANEOUS PROVISIONS

37. Trade chain

- 1) It is only possible in domestic to sell or buy tobacco product or raw material to or from a person who has valid special license given from the Authority.
- 2) Import of tobacco product or raw material shall be from legal source.

38. Service fee

To obtain a service which requires payment of fee shall be paid and receipt provided to the Authority prior to obtaining the service.

39. Repealed law and cases partly excluded

- 1) Tobacco Control Directive No. 28/2015 is hereby repealed.

- 2) Regarding graphic health warning and labeling and content of tobacco product, this directive and directive No. 45/2019 are not applicable to tobacco products imported from tax free through special way for diplomatic community and other privileged persons in accordance to Geneva Convention if it is provided to allowed person and available only in permitted place.
- 3) The Authority may permit import of tobacco products for purpose of this article sub-article (2) with graphic health warning of country of origin.

40. Effective date

This Directive shall enter into force on the date of 13 April 2021.

Heran Gerba
Director General
Ethiopian Food and Drug Authority

Annex 1

Tobacco Product content disclosure form

Company Name:

The Company's special license number:

Date of the license issued

Type of tobacco business engaged in _____ (Manufacture, Import, Export, Wholesale)

- The product type and content shall be disclosed under the following table

Product type	Brand type	Ingredient type and amount in the product	Harmful ingredients in the product	Source of the product (manufactured locally or imported)	Remark
Cigarette					
Cigar					
Cigarillos					
Pippa (tobacco product smoked using a pipe)					
Suret					
Another tobacco product					

The _____ person or section who prepared the data: _____

Signature _____

Date _____

Approved by: _____

Signature: _____

Date _____