

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

Tobacco Products Pictorial Health Warning and Labeling Directive

October 2019

PREAMBLE

WHEREAS, the health risk and addictiveness of tobacco products and exposure to tobacco smoke must be communicated to all people using the most effective means;

WHEREAS, pictorial health warnings are found to be a proven instrument to effectively implement tobacco products packaging and labeling requirements provided under the WHO Framework Convention on Tobacco Control;

WHEREAS, Article 57 of the Food and Medicine Administration Proclamation No. 1112/2011 provides that the packaging of any tobacco product shall contain rotating health warning and that messages as set by the executive organ;

WHEREAS, Article 4(16) of Proclamation No. 1112/2011 mandates the Ethiopian Food, Medicine, and Healthcare Administration and Control Authority to regulate the packaging and labeling of tobacco products in line with the WHO Framework Convention on Tobacco Control and its implementing guideline;

WHEREAS, the Authority is convinced that additional packaging and labeling requirements recommended under the Implementing Guideline to Article 11 of the WHO Framework Convention on Tobacco Control and included under this directive would strengthen the attainment of Ethiopia's tobacco control policies;

WHEREAS, it is necessary to provide the detailed requirements and implementation of the health warning and packaging requirements in a directive;

NOW, THEREFORE, per Article 71 (2) of the Food and Medicine Administration Proclamation 1112/2019, the Authority issued this directive.

PART ONE

GENERAL

1. Title

This directive may be cited as “Tobacco Products Pictorial Health Warning and Labeling Directive No. 44/2019.”

2. Definition

In this Directive, unless the context otherwise requires:

- 1) “Health warning” means texts and color pictures prescribed by the Authority to be printed on tobacco products packaging and labeling that convey the health consequences of tobacco products use, exposure to tobacco smoke and other relevant messages;
- 2) “outside packaging” means the covering, wrapper, or container that has direct contact with the tobacco product intended for retail sale;
- 3) “Authority” means the Ethiopian Food, Medicine, and Healthcare Administration and Control Authority;
- 4) “color” means prescribed colors to be used to implement health warning under this directive;
- 5) “Proclamation” means the Food and Medicine Administration Proclamation 1112/2019;
- 6) Words and phrases defined under Article 2 of the Proclamation and used in this directive shall have the meaning provided in the proclamation.
- 7) Any expression in the masculine includes the feminine.

PART TWO

LABELING AND PACKAGING REQUIREMENTS

3. General

No person shall manufacture, import, distribute, or sell any tobacco product unless the package contains health warnings and other messages as provided under the Proclamation and this Directive.

4. Size, Location, and Manner of Placement of Health Warnings

- 1) Every tobacco product shall contain health warnings and messages printed on 70% of the front and back of the principal display areas of its package, not counting the space taken up by the black frame, which shall surround the health warning. The width of the frame used to surround the health warning shall be 1mm.
- 2) Health warnings on tobacco products shall be large, clear, visible, and legible and constitute the front and back of rectangular-shaped outside packaging. If the packaging has a flip-top design the front health warning shall be placed starting from the immediate field below flip-top. If the packaging design does not have flip-top the health warning shall be placed on the upper part of the outside packaging.
- 3) The health warnings on tobacco products shall be permanently printed on the outside packaging and labeling of the product and any 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.
- 4) The health warnings shall not be obstructed by other legally required packaging and labeling markings, including tax stamps.

5. Color and Rotation Requirement

- 1) The health warnings and messages shall be comprised of combined text and full-color pictures as per the Annex to this Directive or, as appropriate, as prescribed by the Authority in a letter, and shall rotate per requirements set under this Directive.
- 2) The pictorial health warning shall comply with requirements provided under the Proclamation and this Directive. It shall also be as per the color requirements as prescribed by the Authority and the text of the health warning shall be as per this Directive.
- 3) Health warnings prescribed for one rotation period shall only be valid for not more than twenty-four months.
- 4) Once a rotation period referred under sub-article (3) of this Article expires has ended, the next set of prescribed health warnings shall replace the warnings from the previous set. The Authority shall, through a letter, notify regulated persons of the new health warnings one

hundred twenty days before the expiration date.

- 5) Relevant products in packaging already in circulation with the health warnings from the previous rotation period may continue to be sold for a transitional period of no longer than 90 days from the first day of the new rotation period. It shall be illegal to sale non-complying tobacco product after the ninetieth day.
- 6) Health warnings prescribed for one rotation period shall be placed on an equal number in each brand family or within each variant within a brand family as required by the Authority. It shall be illegal to place uneven number of health warnings contrary to this provision.
- 7) The health warning pictures and its corresponding text message shall be as per the Annex to this Directive. Health warning pictures and corresponding text messages required for the next rotations, it shall comply with requirements prescribed by the Authority.

6. Messages and Language

- 1) Health warning text for the front side of the outside packaging shall be in Amharic and the backside may be in English language or another Ethiopian local language. The content of the English or other local language shall be equivalent to the Amharic message.
- 2) The text health warning on the front and back panels shall bear, a marker word, the word “WARNING” in Amharic, and English language or another Ethiopian local language on its backside.
- 3) The word “WARNING” referred under sub-article (2) of this article shall
 - a. constitute 10 percent of the 70 percent space designated to the health warning;
 - b. be printed in red with white background;
 - c. be written only with one language on each side;
 - d. not be paraphrased;
 - e. be written in bold and clearly; and
 - f. The font type for Amharic shall be in Power Geez and be Arial for English.
- 4) The text health warning on the outside packaging shall
 - a. constitute 10 percent of the 70 percent space designated to the health warning;
 - b. be written either in white letters on black background or black letters on white background;

- c. be written only with one language on each side;
 - d. not be paraphrased;
 - e. be written in bold and clearly;
 - f. the font type for English shall be Arial and Power Geez for Amharic; and
 - g. the font type for Amharic shall be in Power Geez and be Arial for English.
 - h. Eighty percent of the 70 percent space designated for the health warning shall be used for the pictorial health warning. The font size for other local language replacing English shall be in Arial.
- 5) Placement of the pictorial health warning, which shall constitute eighty percent of the 70 percent space designated for the health warning, shall be as per the Annex to this Directive.
 - 6) It is prohibited to change, improve, or alter in any other way the health warning picture as well as the message prescribed by the Authority.
 - 7) For the purpose of this Directive “front side” means the tobacco products packaging that is visible when the user regularly opens the package.
 - 8) For the purpose of this Directive “back side” means the tobacco products packaging that is opposite to its front side when the user regularly opens the package.

7. Information on Constituents and Emissions of Tobacco Products

- 1) Any figure or statements about the quantitative emissions of tobacco products on the product, its outside packaging, and inside the product shall be prohibited.
- 2) It shall be prohibited to display expiry dates or messages stating “better to consume before” on packaging and labeling of tobacco products.

8. Misleading Packaging and Permissible Information

- 1) Any misleading statement or presentation 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, or any expression or presentation purporting to signify one tobacco product has lesser harm compared to other tobacco

product shall be prohibited.

- 2) The prohibition in clause (1) includes using any term, descriptor, trademark, figurative, whether or not part of the brand name, and any color, number, shape, or other sign of any kind in whole or in part that directly or indirectly creates or is likely to create the impression that a particular tobacco product is less harmful than others, including by using terms such as “low tar”, “light”, “ultra-light” or “mild”, “smooth”, “natural”, “organic”, “extra”, “ultra”, “flavored”, any flavor descriptors such as “menthol”, or “smoke-free” and other terms in any language that are likely to mislead consumers, including when used as part of a brand name or trademark.
- 3) Outside packaging of tobacco products may not contain any information other than the brand name, trademark, product name and/or manufacture's name, contact details, required tax stamp, the quantity of the product in the package, and other information that is, upon request, approved by the Authority.
- 4) Information other than those provided under sub-article (3) of this Article may only be provided on the exterior or inside of the product packaging upon notification and approval by the Authority.

9. Duty to Provide Sample

- 1) Any person, who shall implement health warnings, shall have the responsibility to submit health warnings sample to the Authority before its implementation. The sample must be prepared in the package intended to be used for the product and has to be the final version.
- 2) The Authority shall ensure compliance of the sample with the law and approve compliant samples within ten working days from the date of submission of the sample.

PART THREE MISCELLANEOUS

10. Duty to Comply

- 1) It shall be the responsibility of tobacco products manufacturer, importers, and distributors to ensure compliance of all packaging and labeling requirements of this Directive and the proclamation.
- 2) The authority shall have the duty to take administrative measures and ensure appropriate measures are taken by other law on person and tobacco products that non-complying to the requirements of packaging and labeling.

11. Annexes

- 1) The Annex to this Directive providing requirements of pictorial health warning shall be considered part of the Directive.
- 2) Without causing any disparity to rotation time provided under Article 5 of this Directive, the Authority may change or modify the annex giving sequence, with proper notification to regulated person, without amending or repealing the Directive.

12. Repealed Directive

Tobacco Control Directive No. 28/2015, with respect to matters provided for by this directive is hereby repealed.

13. Effective Date

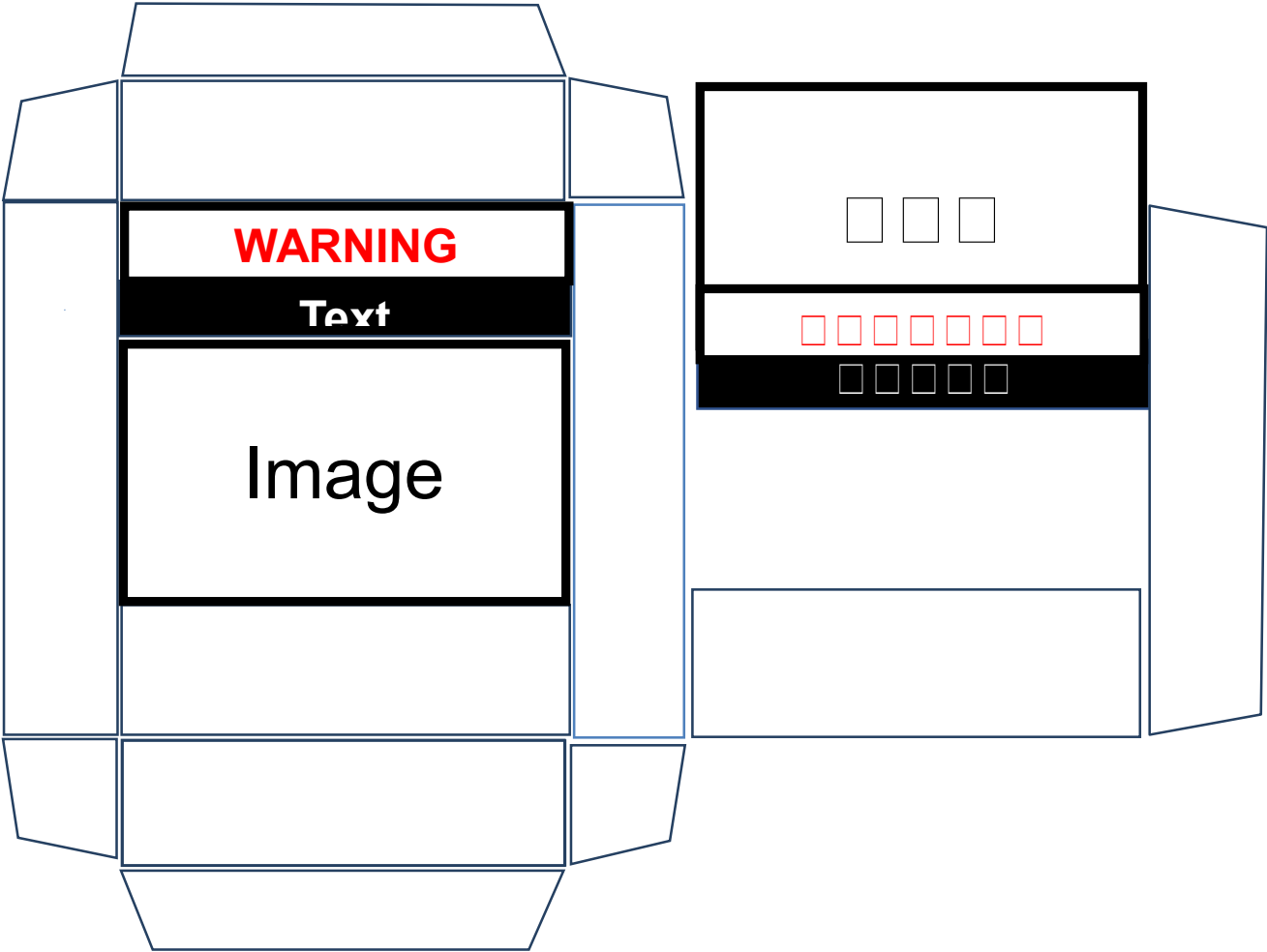
This Directive shall enter into force on October 8, 2019.

Heran Gerba

Director-General

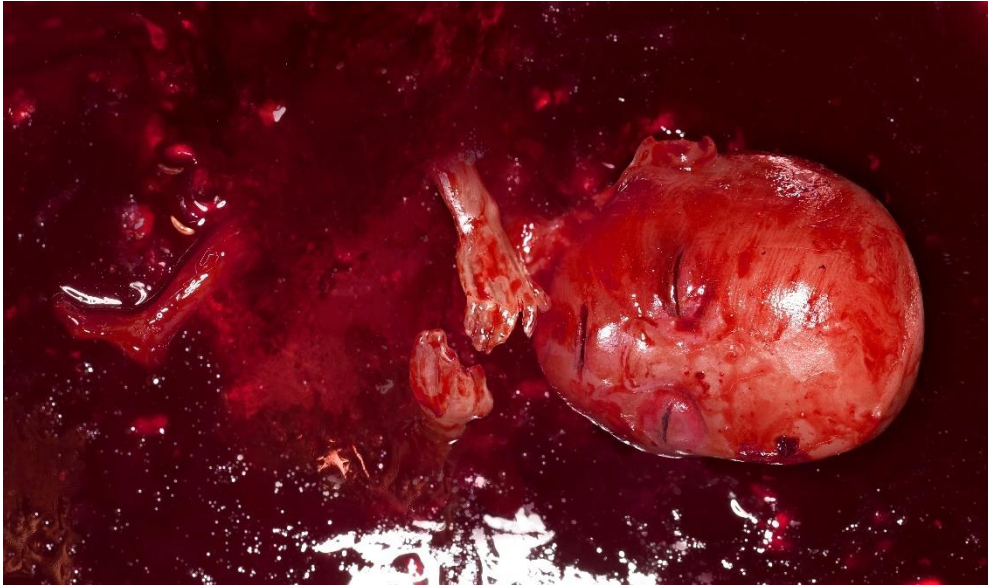
The Ethiopian Food, Medicine, and Healthcare Administration and Control Authority

Annex One

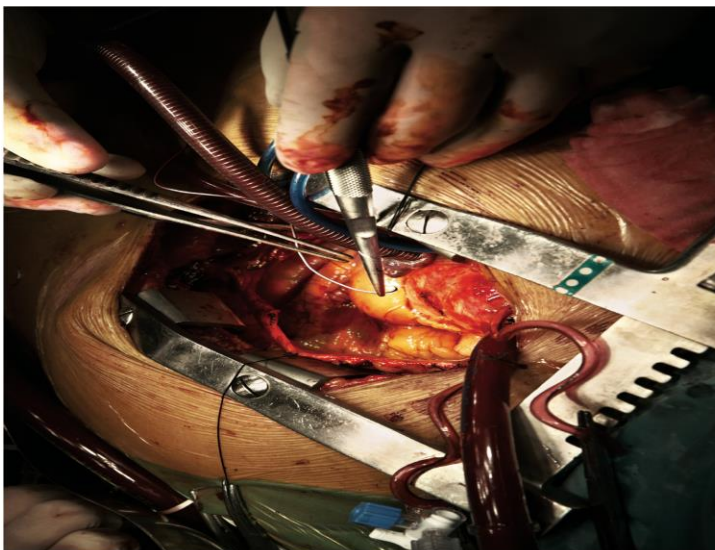


ANNEX 2
TEXT AND PICTORIAL HEALTH WARNING

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Smoking causes miscarriage



2. □□□□ □□□ □□□ □□□ □□□□□□
Smoking causes heart disease



3. □□□□ □□□ □□□ □□□□ □□□□□□
Smoking causes oral cancer



4. □□□□ □□□ □□□□ □□□□ □□□□□□
Smoking causes lung cancer

