Medicine Evaluation and Marketing authorization Lead Executive office

Guideline for regulation of advertisement and promotion of medicines

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Document History

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001	**New guideline**	
002	To update application form and include Authorization Template for promotional and advertisement of medicine To change nomenclature in line with the current structure of the authority To include document number and version	**25.01.2024**

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Definitions

For the purposes of this guideline, the following terms shall apply:

"Applicant" means a person seeking approval to advertise or promote medicines.

"Medicine Promotion": Any activity undertaken by medical representatives who promote directly or indirectly the prescription, supply, sale and/or use of medicines.

"Advertisement" means a form of commercial communication through the media about medicines by an identified sponsor which is used to encourage or persuadean audience (viewers, readers or listeners) to continue with or take some new action.

"Medical Representative": means a person expressly employed by a manufactures or importers or wholesalers and holding a certificate of qualification to promote medicines.

"Healthcare professional" means any health professionals registered by appropriate body including medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, dispense, recommend, purchase, supply or administer a pharmaceutical medicine.

"Certificate of Qualification": The certificate issued directly to Medical Representative to promote medicines by the Authority.

"**Promotional material**": all communications, materials, messages or events created, controlled, disseminated in the form of printed, video, radio and digitalby or on behalf of the manufacturing company that mention, characterize or discuss a medicine approved for marketing, to induce the prescription, recommendation, supply, administration or consumption of its medicines.

"Summary of Product Characteristics (SmPCs)": The document prepared for healthcare professionals as part of the registration dossier, containing the registered/permitted indications of the medicine and minimum information relating to the medicine;

"**Patient information leaflet**: The instructions prepared in accordance with the SmPCs of the medicine, in a manner so that it is comprehensible by patients, for the purpose of informing the patients about the medicine, and which is required to be inserted inside the package of the medicine;

"Prescription medicine": means a medicine which can only be made available to a patient through a written prescription signed by a duly registered and licensed medical practitioner and dispensed by a registered and licensed pharmacist.

"Registration Holder / Pharmaceutical Company": a person in the name of whom a registration/permit has been issued by the EFDA for their medicines;

"Market authorization certificate "is an official document issued by the Authority for the purpose of the marketing or free distribution of a medicine.

"Media": means newspaper, magazine, medical/journal, television, radio, the internet; out of home, vehicle branding, posters, handbills, cinema, point of sale material; online, digital, and social media, any form of projected light and sound recordings or any of such means of communication.

"**Print media"** means any printed material which has a distribution aimed to reach the entire public or a section thereof such as a newspaper, magazine, advertisement book or yellow page, telephone directory or green page

"medicine" means any substance or mixture of substance used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof; used in restoring, correcting or beneficial modification of organic or mental functions in human; or articles other than food, intended to affect the structure or any function of the body of human and it includes articles intended for use as a component of any of the above specified articles;

"**General public"** means a person other than healthcare workers

"Authority" means the Food and Drug Authority

"Person" means a natural or juridical person

Abbreviations

EFDA	Ethiopian Food and Medicine Authority
POM	prescription only medicine
cGMP	Current good manufacturing practices
SmPCs	Summary of Medicine Characteristics
MAH	Market Authorization Holder
PIL	patient information leaflets

1. Introduction

The Ethiopian Food and Drug Authority (EFDA)is established by the definitions of powers and duties of the executive organ's proclamation No.1263/2021 and mandated by the Food and Medicine administration Proclamation No.1112/2019 article 4 to ensure safety, efficacy and quality as well as rational use of medicines including control of medicine advertisement and promotion.

The Food and Medicine Administration Proclamation No 1112/2019, article 59 sub-article 1, 2 and 3 provides the legal basis to regulate and evaluate information used in the promotion, and advertising of medicines. Article 59(1) requires unless subject to exceptions defined under a directive issued by the executive organ, it shall be illegal to advertise any medicine through a means of advertisement dissemination and Articel59(2) states that any direct advertisement or promotion made in-person to a health professional shall be through a medicine promoter who is duly authorized by the executive organ. Furthermore, Article 59(3) requires that unless it falls under the maximum allowable gift or giving as defined by a directive issued to implement this proclamation, it shall be prohibited to offer or give, directly or indirectly, any financial, in-kind or comparable benefit to a health professional in relation to promotion to health professionals.

The Control of promotion and advertisement of medicines aims at ensuring that public and healthcare professionals receive the correct information about the medicine to help them make an informed decision on the choices and use of medicines. It also includes protecting from false, misleading or deceptive information that would create erroneous impression for users. Unethical advertisements and promotion may affect the lives of the consumers.

Therefore, this guideline has been developed to provide necessary information on the current minimum requirements for advertisement and promotion of medicines. The guideline stipulates, among other things, contents of advertisement and promotion, general conditions and requirements, restrictions therein, basic requirements and the procedures for submission of application and approval to advertise and promote medicines in Ethiopia.

2. Purpose of the guideline

The guideline is to

- review and regulate all advertisement and promotion information communicated to health care professionals and the general public is accurate, current, factual and not misleading.
- Certify the qualified medical representatives to promote medicines.
- Promote ethical advertisement and promotion practice of medicines.
- Provide guidance to manufacturers, importers, wholesalers, medical representative, advertising agent, and other concerned bodies aimed at ensuring the rational use of medicines.
- Provide requirements, content and format of advertisement and promotion of medicines to approve and regulate promotional materials and practice.

3. Scope

The scope of this guideline applies to all advertisements and/or promotion of medicines by manufacturers, importers, wholesales and other concerned bodies in Ethiopia. In addition, the guideline applies to advertising agents and medical representatives.

Advertising and promotional that are subject to the guidelines include:

a) Promotion of medicines to healthcare professionals and pharmacists, provision of information provided directly or indirectly to the general public, about the medical-scientific features of medicines.

b) Advertisement of medicinal with published in journals, magazines, and newspapers, displays on posters and notices, photographs, film, broadcast material, video recording, electronic transmissions and material posted on the internet

c) All activities of medicines promotion representatives, including the use of promotional materials and verbal promotion.

d) Advertisements to be placed on medical and professional books and journals.

e) Advertisements made via direct mailing or by using the electronic environment; announcements made through printed and visual media or via other communication media.

f) Company sponsored activities and company activities conducted by using digital environment and social media.

g) Materials and activities involving reminder promotion.

h) Distribution of free samples.

i) Direct or indirect organization (via another establishment) or sponsorship including the organization or sponsorship of scientific, educational and promotional meetings attended by healthcare professionals, payment of relevant travel, accommodation costs and congress registration fees.

j) Promotion intended for those executing their profession in Ethiopia in international meetings

k) Participation in fairs and exhibitions, use of audio cassettes, films, records, tapes and video recordings; use of promotional materials such as radio, television, internet, electronic media, interactive data systems, audio or video CDs, DVDs, flash disks and the like.

l) Programs and materials intended for patient education

This guideline does not apply to the advertisement and promotion of traditional medicines not registered by the EFDA

This guideline does not apply to summary of medicine characteristics (SmPCs) and Labeling on medicines and patient information leaflets.

4. General requirements for promotion and advertisement applications

1. The advertisement or promotion of any medicines shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners.
2. Promotion of a medicine shall be consistent with the approved products information and data contained in such medicine's current SmPCs.

3. Ensure that all advertised information is correct and truthful. Any claims relating to a particular medicine must be aligned with the approved uses of the medicine or label recommendations, as well as with any prevailing guidance for that category of medicine.
4. Any advertisement or promotion should encourage rational use of medicines of the medicine by presenting it objectively and without exaggerating its qualities; and an advertisement must encourage the correct and proper use of a medicine; this is a positive obligation. This might include when a medicine should be taken, how much should be taken, the route of administration, by whom it should be taken and special precautions.
5. Where the promotion involves the use of a documentation prepared by utilizing citations, tables or other visual materials from medical journals or other scientific publications, such materials shall be authentically reproduced, providing full reference to relevant sources.
6. Promotion and advertising shall not be made through use of misleading, exaggerated or unproven information which can encourage unnecessary use of a human medicine or lead to unexpected risks, or through use of alluring visuals not directly related with the medicine.
7. No benefits, whether in cash or in kind, may be provided, or even offered or promised during promotion of human medicines to physicians, dentists and pharmacists. Likewise, the aforesaid healthcare professionals are prohibited from accepting or requesting any inducement during the course of such promotional activities directed at them.
8. Statements, illustrations or pictures used in an advertisement shall not mislead directly or by implication
9. Healthcare professionals shall disclose any sponsorship received from registration/permit holders:
10. Advertisements should not be presented to suggest that the use of medicine will improve normal good health or vice versa.
11. Where the medicine launch is for prescription only medicines, claims made for medicine shall be published in medical or scientific journals only.

5. Specific requirements

5.1. Requirements to certify medical representatives

1. Promotional certification for medical representatives will be granted for professionals who have qualification in pharmacy with three years of experience and should be Ethiopian.
2. A Promotional certification may be issued upon submission of their degree, experience, medicine promotion representative identification card given by company of employment and professional license.
3. Letter of declaration that the applicant has not a mental illness or physical disability that prevents him from performing his professional duties, or is not addicted to alcohol, narcotic and psychotropic medicines and other medicines;
4. Abel to provide resign letter from the previous office he/she worked;
5. If he/she has already issued a promotional certificate in his name before, proof of returned this certificate.
6. Promotional certification shall be valid for two calendar year and medical representatives should renew their certification before expiry.
7. Medical representative should be registered or listed in the data base of EFDA with format prepared for this purpose.
8. Promotional license content issued in accordance with this guideline should contain the following: -
   a. Name and address of medical representative;
   b. Name and address of the pharmaceutical company or MAH;
   c. Promotion license issued date, renewal and expiration date;
   d. Promotion license number;
   e. Signature and seal of the official;
9. Promotional license should be renewed within the first two consecutive months of end of fiscal year after the promotion license is issued and with pay of appropriate service rate of service fees regulation.
10. If the promotion license is not renewed within the stated period, it will be considered as canceled.

11. The medical representative may request replacement of promotion license provided that
    a) If the promotion license is damaged; when returning a damaged Promotional License;
    b) If the promotion license has been lost or burned, when he submits a confirmation from a judicial body stating that the promotion license has been lost or burned;
    c) On payment of the required service charge.

5.2. Application for medical representative certificate

1. Application should be submitted as per the format prepared for this purpose
2. Complete the form with the required information and submit the form (Application form for medicine promotion representative certificate)
3. Attach and submit professional license, professional qualification, experience and identification card given by company of employmentand other documents required by the EFDA, pertinent to promotional activities,
4. Upon successful submission of an application, an acknowledgement with an application number will be generated.
5. The processing time for each application is 15 working days, excluding time taken by applicant to make required changes.
6. If application required further information, the assessors may request to fulfil the requirements
7. If the application is fulfilling the requirements and approved, a permit number will be issued with an endorsed copy of the approved specimen i.e., 'MAHPXXYYYY', where MAH=Market authorization holder name, yyyy_year of application and XX month of application.

5.3. Requirements to certify Advertising and Promotional Materials

1. Content of promotional materials must clearly contain the possible side effects and precautions taken.

2. The content of promotional material information must be clear, up to date, accurate, balanced, fair, objective, verifiable and sufficiently complete and consistent with information approved during registration of the medicine to enable the recipient to form their own opinion of the value of the medicine concerned.

3. If new information is discovered about the medicine that was not disclosed at the time of registration, the information must be reviewed and approved by the authority before being introduced to the health professional.
4. The promotional material should specify the situation in which the medicine should not be used and if there are any sections of the society that cannot use it.
5. Any medicines promotional materials should not use language(s) that brings fear or distress to health professionals or the public.
6. The content of promotional materials should not prevent the public from getting medical services and advice.
7. The content of promotional materials should not imply that a medicine has been selected and recommended by a scientific study or a well-known health professional or other famous person.
8. The content of Promotional materials (including pictorial diagrams) for medicines promotion should not be against the culture and good values of the Ethiopian people.
9. Promotional materials refer to any material used in promotion or advertising, directly via medicine promotion representatives and distributed in the meetings directed at healthcare professionals, including but not exclusive of the following:
    a) Printed materials such as booklets, medical journals, leaflets, and advertisements, providing sufficient and necessary information only about a medicine and relevant diseases;
    b) Audio-visual materials with an educational or informative purpose, presented in storage media such as flash disks and CDs/DVDs;
    c) Audio-visual materials such as films, slides, video shoots, databanks and electronic media including the Internet;
    d) Any type of publications and materials that may be used as a source of information/data/reference by relevant circles;
    e) Free samples in reduced package quantity;

f) Pens and notepads which may be distributed by companies only in the meetings organized by them;
g) Programs and materials intended for patient education;

10. All printed promotional material, including advertisements should contain below information:
    a) The name of the medicine (normally the brand name);
    b) The active ingredients, using approved names where they exist;
    c) The name and address of the pharmaceutical company or its MAH responsible for marketing the medicine;
    d) date of medicine on of the advertisement; and
    e) "Abbreviated prescribing information" which should include an approved indication or indications
    f) For use together with the dosage and method of use; and a succinct statement of the
    g) Contraindications, precautions, and side-effects.
11. The advertisement or promotional materials on the medicine shall be authenticated by the quality assurance department head of the company sponsoring the medicine advertisement.
12. Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies, organizations or individuals, in a way that is likely to mislead or confuse.
13. Where applicable, appropriate limitations to the use of the medicine should be pointed out.
14. Proof of up-to-date certificate of competence or registration license of the company that wishes to advertise from relevant body;
15. All advertisement or promotional materials including scripts, storyboards, artwork, radio scripts and any other promotional material as may be required by the EFDA shall be submitted along with an application.
16. If a registration/permit holder wishes to announce the launch of a medicine to healthcare professionals through a press release, a genuine copy of the announcement will be sent to the EFDA for approval. A press release may be published only once.

17. Promotional materials used continuously shall be re-approved at least once every two years to ensure that their content continues to conform with registration status.
18. Subsequent advertisement or promotion applications shall be valid for two (2) years/ provided no alteration is made and conditions of renewal approval remain the same.

5.4. Application for advertisement and promotion permit

1. Application should be submitted as per the format
2. Complete the application form with the required information and submit (Application form for advertising and promotional materials approval)
3. An application submitted by manufacturer, importer, wholesaler, or the sponsor of the advert shall contain the following information:
    a) the brand name of the medicine (if any);
    b) the generic name of the medicine;
    c) the dosage forms available where applicable;
    d) the place of importation or local manufacturer;
    e) the name and location address of the manufacturer;
    f) the name and location address of the local distributor;
    g) the name and location address of the advertising company;
    h) the date of first introduction of the medicine to the Ethiopia market;
    i) any previous advertisement of the medicine in Ethiopia;
    j) a copy of the old script (if any);
    k) the proposed media for the advertisement;
    l) a copy of the registration certificate of the medicine;
    m) a copy of the registration certificate of the premises of the sponsors;
    n) scripts and recording,
    o) justification for any special claims on the medicine.
4. Attach and submit all information and document required by the EFDA, pertinent to promotional activities,
5. Upon successful submission of an application, an acknowledgement with an application number will be generated.

6. The application number is not a permit number. You may use the application number for enquiry before the approval of the application.
7. The processing time for each application is 14 working days, excluding time taken by applicant to make required changes.
8. If application required further information, the assessors may request to fulfil the requirements
9. If the application is approved, a permit number will be issued with an endorsed copy of the approved specimen i.e., 'MAHPMXXYYYY', where MAH=Market authorization holder name, PM=Promotional material, yyyy _year of application and XX month of application.
10. On payment of the required service charge.

5.5. Promotional free sample

Free samples may be distributed or use only to physicians, dentists, or pharmacists provided that the following conditions are fulfilled:

1. Registration/permit holders shall set up and appoint qualified persons for an adequate system of records and control, for the importation, and distribution of free promotional samples, to safely withdraw them where necessary. Upon demand, these records shall be submitted to EFDA electronically or in hardcopy in the format designated by the EFDA
2. Registration/permit holders shall establish a system and formulate a process to enable the safe withdrawal of free samples where necessary.
3. A copy of the PIL and/or SmPC, shall always be provided, where available, along with the promotional sample.
4. A free sample can be used as a sample only if it is a medicine registered by the authority or when it is presented to the authority and evaluated and approved in case of special circumstances;
5. The statement, "Free promotional sample – "Not for sale" or "Free sample not for sale," will discernibly appear on the outer packaging of promotional samples on at least one surface should be clearly written in English or Amharic or in both languages

. The same statements shall be printed also on the inner package, where this is possible.

6. A copy of the SmPCs and the PIL, where available, shall be provided with the promotional sample.
7. Samples may not be provided or distributed of medicines containing psychotropic or narcotic substances, covered under medicines subject to national control.
8. In principle, there shall be no barcode/datamatrix on the packaging of promotional samples. If their inclusion is mandatory, permission will be requested from the EFDA, offering sufficient justification, and their sale shall be blocked in the EFDA medicine Tracking System. Registration/marketing holders shall establish a system to enable safe withdrawal of free samples where necessary.
9. Free samples of medicinal medicines for human use may be distributed up to 5% of the total annual sales upon monitoring the monthly sales in the first calendar year as of the introduction date, and in the second calendar year up to 5% of total annual sales generated the preceding year, and in the third, fourth and fifth calendar years up to 3% of total sales generated the preceding year, and after the fifth calendar year, up to 1% of total sales generated the preceding year.
10. Promotional samples may not be used as an investigational medicine during a clinical trial.
11. Free sample medication is only provided to healthcare professionals;
12. If allowed in circumstances by the authority to promote narcotic and psychotropic medicines, use of free medicine samples to promote narcotic and psychotropic and precursor medicines is not allowed.
13. The pharmaceutical company should have its own secure room or place to store promotional free sample medicines;
14. Should not be used for treat, cure or prevent a disease or restore, correct or modify physiological functions
15. Only provide modest quantities (One full dose/cycle) of free samples of legally available prescription medicines to prescribers if requested.
16. Samples shall not be distributed for the purpose of patient treatment
17. Promotional samples may not be used as a research medicine in clinical trials.

18. Physicians should provide these samples “free” of charge to their patients for a small duration, in order to determine if the patient tolerates the medication.

5.6. Prohibition for advertising and/or promotion

The applicants shall adhere to the general requirements for promotion and advertisement of medicines. He/she shall not be allowed to:

- Cannot engage in any medicines advertising without obtaining an advertising license or permission from the relevant body
- Advertise or promote an unregistered medicine
- Medicines which contain psychotropic or narcotic substances cannot be advertised to the general public.
- Advertise or promote an unregistered indication of a registered medicines
- Make any false or misleading claims or representations
- Target advertising material at children under 18 years old.
- Make claims that mislead by emphasis, contrast or omission with regard to the safety, quality or efficacy of the therapeutic product.
- Make claims that give rise to any unrealistic expectations with regard to the effectiveness of the therapeutic product.
- Make claims that cause fear, alarm or distress to the public.
- Encourage inappropriate or excessive use.
- Suggest guaranteed results without side effects.
- Encourage incorrect use or self-treatment of serious diseases and discourage from seeking a medical professional's advice.
- Use the names or logos of the Authority and any of our professional groups.
- Offer refunds, in full or partial amounts, to users of the product.
- Promote medicines for non-authorized or not licensed establishments or personnel.
- It is prohibited the approval of any advertisement wholly or mainly directed to the general public which is likely to lead to the use of a prescription only medicine (POM) and non-prescription medicines (NPM). But in some circumstances, it is allowed to advertise ORS, condoms, birth control, vaccines such as polio vaccine, measles, tuberculosis, PCV, pentavalent, BCG, tetanus toxin;

- There is an exemption from the prohibition on advertising unlicensed medicines in certain public health emergencies including in response to the suspected or confirmed spread of pathogenic MAHs, toxins, chemical MAHs, or nuclear radiation.
- Advertisements for a licensed vaccine medicine that have been approved by Health Ministers as part of a government-controlled vaccination campaign are exempt from this prohibition
- Promotional information available for self-medication should not in any way put the vulnerable groups at risk e.g., use of medicines during pregnancy.
- Medicine should not be launched for medicines unless approval/clearance has been obtained from the EFDA.
- Medicine promotion is prohibited at emergency rooms or at outpatient clinics during patient-seeing hours
- Claims of superiority over other brands will not be permitted.
- No poster or similar promotional material, which may be perceived as promoting a medicine, may be exhibited, placed, posted and/or affixed at state-owned healthcare institutions. However, this excludes posters and similar promotional materials used for purposes of campaigns run by the Ministry to promote health, including vaccination campaigns, outbreak alerts and anti-smoking or anti-obesity campaigns.
- Advertising to the general public should not suggest that one medicine is better than (or equivalent to) another identifiable treatment or medicine, or that the effects of taking it are guaranteed. Material which refers in improper, alarming, or misleading terms to claims of recovery must not be included.
- Advertising should not give the impression that a medical consultation or surgical operation is unnecessary, for example by offering a diagnosis or suggesting treatment by post, electronic communication, or telephone. Nor should it suggest that health can be enhanced by taking a medicine or that health could be affected by not taking the medicinal medicine.
- Publish advertisements reflecting false or erroneous claims indicating or suggesting that the use of a medicine is promoted, supported or endorsed by EFDA.

- Words or images that contain exaggerated defamatory content such as "unique", "first", "unprecedented", "everyone's choice", "one-size-fits-all", "unique", "first", "acclaimed" or otherwise
- It is not possible to prepare advertisements or use promotional materials in a manner that encourages abortion and self-treatment.
- It is prohibited the sale or supply of samples of medicinal medicines to any member of the public for promotional purposes by:
    a) holders of a marketing authorization and persons acting on their behalf (such as importers and distributors), and
    b) commercial undertakings including registered pharmacies, general retailers and third parties acting on behalf of, or with the consent of, these persons.
- Web based advertisement of medicines is prohibited but the Authority may be allowed in below circumstances
    a) Advertisements for POMs are acceptable only on websites whose nature and content are directed at health professionals.
    b) Sections of a website aimed at health professionals and containing promotional material should ideally be access restricted.
    c) If no restriction is applied and websites provide both information for consumers and information aimed at health professionals that includes advertising, the sections for each target audience should be clearly separated and clearly marked for the respective target audience. For persons or institutions/companies wishing to give information through the website, there shall be two windows; one for the health professionals and another for the general public
    d) The value of Promotional items, which are provided to health professionals free of charge during promotion, should not exceed ETB 200.

5.7. Targeted audience in promotion and advertisement

5.7.1. Promotion and advertising to the Healthcare professionals

A written promotion material and advertisement for medicines should contain the following elements:

a) Trade/ Brand name or proprietary name,
b) A quantitative listing of all active ingradient(s) using either approved generic name or international Non-proprietary Name (INN) of medicine
c) An accurate statement of the dosage and strength
d) Daily dose, frequency of administration
e) Route or method of administration
f) Major indication(s) for use;
g) Adequate warnings (caution side effects, interactions)
h) Major precautions, contra-indications and warnings;

Name and address of manufacturer or packaging company. If an imported drug, the name and address of the local packing company or distributor must appear on the label in such a manner as to identify the relationship between the packing company or distributor with such drug.

5.7.2. Promotion and advertisement to the general public

Promotion and advertisement targeted to the general public must contain the following:

a) The generic name of a drug, brand name/trade name of the drug
b) name(s) of the active ingredient(s) using international non-proprietary names (INN)
c) approved major indication(s) for use
d) major precautions, contra-indications and warnings
e) name and address of manufacturer
f) dosage regimen
g) phrase “If symptoms persist seek medical advice” or a similar meaning phrase

Promotion, advertisement and marketing to the general public shall take into consideration the following:

a) Help people to make an informed decision on the choice and use of drugs determined to be legally available without a prescription.
b) Take account of people’s legitimate desire for information regarding their health.
c) Not take undue advantage of people’s concern for their health

6. Role and responsibility

SN	Stakeholders name	Responsibilities
1.	The pharmaceutical manufacturers or Marketing Authorization Holder (MAH	• Shall be responsible for any advertisement and promotion that it transmits; • shall be jointly responsible for the promotional activities carried out by medical representatives. • Should have a medical representative directly or through MAH or importers or wholesalers to promote its medicinal medicines. • should promote their medicines in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare. • Its interactions with stakeholders must at all times be ethical, appropriate, and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence. • All promotional content produced/disseminated (in printed/electronic form and communicated orally) must be accurate, scientifically sound, objective, reflect the current state of knowledge and must be consistent with the prescribing information as approved by Authority; • All clinical trials and scientific research sponsored or supported will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients

		• should adhere to both the spirit and the letter of applicable industry codes. • Information in promotional materials must support proper assessment of the risks and benefits of the medicine and its appropriate rational use. • The healthcare and well-being of patients are the first priority for pharmaceutical companies. • Should respect the privacy and personal information of patients and of the healthcare professionals they serve • Should conform to high standards of quality, safety and efficacy as determined by regulatory authorities and work to develop them further. • shall notify the EFDA within five working days after a medicine promotion representative stop working for them for any reason or when he/she starts to work. • shall internally establish a scientific service, responsible for managing information pertinent to their marketed medicines, led by a qualified person who will be in charge of the operation. • Congresses, symposia, seminars and similar meetings which a registration/permit holder intends to organize or partially sponsor will be submitted to the EFDA and at least fifteen working days before each meeting, the content, a list of potential participants, projected expense items and the events shall be notified to the EFDA. A response will be given to the applicant within ten working days after a submission is officially received, or the

		request will be deemed approved if no response is given. • Must not make a false or exaggerated advertisement in relation to their name, method of manufacturing or indications or effects, apply to advertisements of non-prescription medicines to the general public • Ensuring submission of an annual report with in the first two months of fiscal year on promotional activities to authority, including promotional materials distributed, sponsorship and participation in promotional scientific meetings and events.
2.	Medical representatives	• Shall hold a promotional license issued by EFDA. • Shall comply with principles of good promotion practices and promotional codes. • Shall be equipped with full, adequate, and relevant scientific data and knowledge on the medicines promoted. • Shall have adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and complete as possible about the medicines they are promoting. • Shall forward any adverse events/reactions, reported to them during medicine promotion, to the relevant scientific service in their companies. • Shall not give medicine promotional materials to anyone other than a physician, dentist, or pharmacist • Possess sufficient medical and pharmaceutical knowledge and professional integrity to enable them present information on medicines and carry out other promotional activities

		accurately and responsibly. • must also report all information relating to the safety of a medicine which they receive from healthcare professionals directly to scientific services set up by the license holder • Shall inform medicine safety directorate without delay of any adverse event information or new data on medicines which they receive. • Should not give expensive gifts or presents to health professionals whose value does not exceed 200 Birr at a time, other than the promotion materials used for promotion, • When a free sample provided for health professionals the medical representatives should record below information: o The name of the free medicine sample, the number of samples given; o The date the free medicine sample was given, the address of the health professional or health facility where it was given; • If he/she leaves the company, he is obliged to return his/her promotional license by informing the authority;
3.	Healthcare professionals	Should not be influenced to prescribe, recommend, purchase, supply or administer a medicine because of any benefits offered (financial or otherwise).

7. Promotion control

1. The advertising of medicinal shall be subject to effective and adequate market monitoring by EFDA market surveillance and control regulatory function implementers namely

medicine inspection and licensing directorate and Surveillance and Relevance Confirmation Directorate.

2. Promotion of prescription-only medicinal medicines can only be made to physicians, dentists and pharmacists.
3. The promotion of medicine not registered or permitted, or the promotion of an indication not approved by the EFDA shall not be conducted except for the following two exceptions
    i. Promotional conducted in international congresses held in Ethiopia are not included into the scope of this article.
    ii. The information personally provided by a scientific service officer of the registration/permit holder, upon the written request of a healthcare professional physician, dentist or pharmacist is not included into the scope of this article.
4. The promotion of medicine shall be consistent with the information, data and details provided in the updated Summary of Medicine Characteristics (SmPCs) approved by the EFDA.
5. The abbreviated summary of medicine characteristics shall consist of the following: constitute a whole with the promotional materials.
    a. Commercial name of the medicinal medicine;
    b. INN (International Nonproprietary Names) or approved generic names of the active substance(s);
    c. Quantity of active substances in its composition in a single unit dose (quantitative composition)
    d. Content in the package of the commercial form;
    e. At least one registered indication in compliance with the updated SmPC;
    f. Dosage and method of use;
    g. Major side effects and precautions to be adopted;
    h. Major interactions, incompatibilities;
    i. Contra-indications, warnings and conditions to be observed during the administration of the medicine (pregnancy,
    j. lactation, driving);

k. Other information to be requested by the Ministry or other authorized bodies or regulatory authorities (overdose,
l. storage conditions, shelf life, reimbursement conditions of the Social Security Institute) and other warnings to be included in promotions;

Name and address of the manufacturer, importer or distributor;

m. Registration date and number;
n. The statement reading, "Please contact our company for detailed information;
o. Legal classification (prescription or non-prescription, narcotics, controlled medicines);
p. Tracking code/number of the material and the printing date (or intended usage date) of the materials;
q. The date of preparation and/or latest date of update of the SmPC taken as basis in the information of the materials.

6. Promotion shall assist healthcare professionals in establishing their own views regarding the therapeutic value of the medicine, be informative, evidence-based, accurate, consistent with scientific facts, reliable, fair and objective and contain sufficiently complete, clear and balanced medical information about the characteristics of the medicine.
7. The referred promotion shall not only conform to legal requirements, but also to high ethical standards and be in good taste.
8. The promotion of medicines shall be conducted in an objective and unexaggerated manner and encourage the rational use of medicines.
9. Promotion shall not be made through use of misleading, exaggerated or unproven information which can encourage unnecessary use of a human medicinal medicine or lead to unexpected risks.
10. Information and claims which are misleading, exaggerated or whose accuracy is not sufficiently proven shall not be used in promotion. Healthcare professionals shall not be misled by distortion, exaggeration, undue emphasis of information or by any other method. Claims presented shall not be stronger than the current scientific evidence.
11. Healthcare professionals cannot take part in the promotion of medicines unless permit is obtained from the EFDA. Likewise, also legal entities such as associations or foundations cannot take part in the promotion of these medicines, unless permitted by the EFDA.

12. All medicine launch materials or press release of the medicine shall be as approved by the EFDA for the medicine advertising materials.
13. Promotional materials shall not imitate the logos, forms, slogans or general designs used by other companies or in a manner that may give rise to confusion.
14. The regulatory inspection function is responsible for:
    a) Checking advertising for compliance with the law prior to publication (Vetting) in clearly defined circumstances,
    b) Monitoring of published advertising material for medicines,
    c) Monitoring the promotional practice
    d) Handling of complaints about advertising, and
    e) Enforcement in relation to materials not compliant with the requirements

8. Mode of promotion and advertisement

8.1. Still

This includes any promotional adverts in print media such as magazines, newspapers, journals, diaries, flyers, brochures, billboards, posters, branding on vehicles, buildings, benches and other print publications. A promotional aid (note pads, calendars and other such items) shall be limited to bear names of products currently registered in Ethiopia.

8.2. Light and sound

Includes any promotional adverts with light and sound effects, such as broadcast over radio, radio cassettes or any audio, television, cinema advertisements and videos.

8.3. Web based

Includes any promotional adverts on websites. Promotion of prescription medicines are acceptable only on websites whose nature and content are directed to healthcare professionals. Sections of a website aimed at airing such adverts should ideally be access restricted. Where an information is presented as a linked page on an internet website, the link should be clearly visible.

8.4. Sales promotion

This is any activity with the purpose of introducing, publicizing or promoting the sale of a product

8.5. Symposia and other meetings

All meetings including workshops, conferences, seminars symposia and exhibitions that are organized or sponsored by any company or under its control targeting the healthcare professionals, or any other person for the purpose of promoting of medicines or its launching should first obtain approval from Authority.

8.6. Promotion in public health program /campaigns

a) Public health programmes such as government-controlled programmes (vaccination &malaria campaigns etc) that have been approved by the responsible ministry are required to obtain an approval letter from the Regulatory Authority.
b) Campaigns relating to medicines that are directed to the general public with a view of providing information, promoting awareness or education about a particular condition or disease are encouraged. But care must be taken to ensure that the information provided that is correct as per this guideline.
c) public health programme such as government programme (vaccination and malaria campaigns etc) that have been approved by the responsible ministry are required to obtain an approval letter from the authority.

9. Medicine advertisement claims

1. Function such as “most effective “, “least toxic “, “best tolerated “, or special status such as “the medicine of choice “, or any such statements, for a medicine shall not be used unless it can be adequately substantiated and shall not imply superior efficacy to other medicines in same category.
2. Where an advertisement portrays a medicine as “fast”, “immediate” “instant” or “rapid” in action, or any similar descriptions, such claims must be substantiated using studies based on the rate of absorption of the medicine.
3. “Duration of action” claims in medicine advertisements shall be allowed provided such claims can be supported by the pharmacokinetic attributes of such medicines, particularly plasma half-life.
4. Where claims on efficacy are made in the advertisement of a medicine, such claims shall be substantiated using efficacy studies carried out in actual patients. Absorption data alone are not enough to substantiate efficacy claims.

5. Superiority claims may be used only when a medicine proves to be superior to an identified comparator or to all medicines in same category.
6. Top parity claims and 'Natural' claims may be permitted provided they are adequately substantiated.

10. Reporting and recording records

1) A license holder or manufacturer has a duty to keep samples of advertising materials available, to respond to requests for information on advertising materials.
2) Companies shall preserve all certificates of approval and relevant materials for at least two years after the final use of approved materials.
3) The EFDA may require copies of any published advertisement from any person appearing to be involved in its publication.
4) All advertisers must therefore have arrangements to ensure that copies of all advertising material are retained, by themselves or on their behalf.
5) The minimum time that materials should be kept for by license holders and/or other parties is a period of three years after either the last use of the piece or the conclusion of any regulatory or self-regulatory action, whichever is later. Where pieces are likely to be in use by recipients for a period of time, the three years should start from the end of the expected normal period of use.

11. Administrative measures

1. The EFDA may withdraw the approval for an advertisement or promotion if:
    a) the grounds on which the approval was granted was later found to be false or incomplete; or
    b) any of the conditions under which the approval was granted has been contravened; or
    c) in the light of new scientific evidence against claims contained in the advertisement.
2. The EFDA may request return of promotional certificate if:
    a. the promoter stops his/her job or died
    b. the promotional certificate is revoked and suspend

c. the promotional certificate is not renewed

3. The medical representative shall return the promotion certificate to the Authority within three days

12. Compliant and appeal

1. Any person aggrieved by a decision of the Authority in relation to any application for advertisement or promotion of medicines
2. The Authority is particularly keen to receive complaints where promotional adverts may have an adverse impact to public health.
3. A submitted complaint should have detailed of when and where the promotion advert was seen and if possible, a copy of the advertisement, together with detailed of the concerns about the advertisement should be attached.
4. The Authority will investigate complaints received from anyone who has seen promotion advert for a medicine that in his/her view is misleading or otherwise fails to comply with the legal requirements.
5. The Authority will complete the investigation within 30 days. This time may be extended when statutory action is taken. Should the investigation take longer, the complainant will be updated on progress.
6. When closing the case, the Authority will provide the complainant with details of the outcome

13. Annexes

Annex I: Application form for medicine promotion representative license

EFDA የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን ETHIOPIAN FOOD & DRUG AUTHORITY	**Ethiopian Food and Medicine Authority**	FORM-EFDA-000
Title	Application form for medicine promotion representative certificate	Revision No.001

** This form is to be filled by the medical representative and shall be submitted to the Authority**

1) Name of the importing agency/applicant/…….....
   ክልል_____ዞን/ክ/ከተማ_____ወረዳ_____ከተማ_____
   Region Sub city/Zone Woreda City
   ቀበሌ_____ የቤ/ቁጥር_____ስ/ቁጥር_____ፋክስ_____
   Kebele House no Telephone Fax

2) Applicants certificate of competency Reg. No……...
3) Name of medicine company/manufacturer ……
   ክልል_____ዞን/ክ/ከተማ_____ወረዳ_____ከተማ_____
   Region Sub city/Zone Woreda City
   ቀበሌ_____ የቤ/ቁጥር_____ስ/ቁጥር_____ፋክስ_____
   Kebele House no Telephone Fax

4) Name and profession of the medical representative……
   Professional license No._____ (attach all credentials and working experience)
5) Name of Medicines to be promoted
   Generic name…… (if more than one medicine attaches)
   Brand name…… (if more than one medicine attaches)
6) Legal sales category of the Medicine

OTC ☐ Prescription only ☐ Restricted ☐ Other ☐

I hereby certify that all the information above is correct to the best of my knowledge.

Name and signature of the Med. Rep. _____Date _____

Annex II: Application form for advertising and promotional materials approval

EFDA የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን ETHIOPIAN FOOD & DRUG AUTHORITY	Medicine Registration and Market Authorization	FORM- EFDA-00.000 SOP/00.00.00

APPLICATION FOR PROMOTION AND ADVERTISEMENT FOR MEDICINE

1. PARTICULARS OF APPLICANT

(1) Name of applicant ……..……..……..

(2) Physical address/location……...

(3) Plot No……Street…….....City/town……..…..……Country ……...

(4) Box No……..… ……..……Telephone No ……....

(5) Email: ..... Mobile. Tel. No.: .....

(6) Signature…….....

(7) Full name and title of signatory …….…….....

(8) Registration Certificate No of Med Rep: (attach copy of medical representative License)

2. DESCRIPTION OF PUBLICATION OR ADVERTISEMENT

(1) Type of activity for which application is made (*for example launch, advertisement, talk-show, exhibition*) ……..…..…… …….…….....

2) Type of material to be used (for example, posters, literature, bags, calendars) *(applicant to attach 2 samples of materials)* …….....

For multiple products, submit completed form and specimen of advertising/promotional materials to one application of choice, and attach separate sheet of each for easy processing.

(3) Generic name of the medicine…….…….

(4) Brand Name of the Medicine

(4) Language of the publication or advert ……..……...….

(5) Date of submission of application.…….……

(6) Intended target group ……

3. DECLARATION OF THE APPLICANT

I, ...(full name of the authorized Medical Representative) , the undersigned, hereby declare that all the information and documents submitted with this application are true and same as the promotional material which are going to be published and /or advertised to healthcare promotional based on Authority Authorization or Modification following comments of the EFDA.

…….. **……**

Signature of the Applicant **Date**

4. FOR OFFICIAL USE ONLY

(1) Fees payable……...

(2) Receipt No……..…Date…….. ……..

(3) Application received and assessed by (name)……...

Signature…….Date…….....

Annex III: Pharmaceutical advertising and promotional material evaluation checklist

EFDA የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን ETHIOPIAN FOOD & DRUG AUTHORITY	**Ethiopian Food and Medicine Authority**	FORM-EFDA-000
Title	Pharmaceutical advertising and promotional material evaluation checklist	Revision No.001

** This form is to be used by the Authority, for the evaluation of the promotional material. **

1. Name of the Applicant: .....
2. Address of applicant ክልል_____ዞን/ክ/ከተማ_____ወረዳ_____ከተማ____
   Region Sub city/Zone Woreda City
   ቀበሌ_____ የቤ/ቁጥር_____ስ/ቁጥር_____ፋክስ_____
   Kebele House no Telephone Fax
3. Name of Manufacturer/agency (to be represented) ……
   ክልል_____ዞን/ክ/ከተማ_____ወረዳ_____ከተማ_____
   Region Sub city/Zone Woreda City
   ቀበሌ_____ የቤ/ቁጥር_____ስ/ቁጥር_____ፋክስ_____
   Kebele House no Telephone Fax
4. Name: Importing agency……
   ክልል_____ዞን/ክ/ከተማ_____ወረዳ_____ከተማ_____
   Region Sub city/Zone Woreda City
   ቀበሌ_____ የቤ/ቁጥር_____ስ/ቁጥር_____ፋክስ_____
   Kebele House no Telephone Fax
5. Does the information on the promotion state?
   - Name of the pharmaceutical (INN, Brand) ☐
   - Active ingredient ☐
   - Approved indication ☐
   - Dosage form and regimen ☐
   - Side effects and major ADR ☐
   - Precaution and warning ☐
   - Contraindications ☐
   - Major interaction ☐
6. Type of Promotional Material……
7. Is the information in conformity with the package insert/medicine monograph during registration? Yes …. No….. NA……
   If No, specify…….....
8. Does the promotion imply that the medicine is free of any problem?
   Yes…. No…….NA If yes, specify…….....

9. Does the promotion have exaggerated or all-embracing claims about the medicine to be promoted? No…….NA If yes, specify…….
10. Is there any unverifiable or misleading statement in the content? Yes…. No…. NA…. If yes, specify…….....
11. Is the comparison (if any) made with other pharmaceuticals factual and capable of substantiation? Yes…. No…. NA…. If yes, specify…….....
12. Does the promotion content have disparaging content against the medicine or services of other company either directly or by implication? Yes…. No…. NA…. If yes, specify…….
13. Reference used for preparation of the promotional material …….
14. Any previous warning issued by FMHACA/? Yes…. No….NA…. If yes, specify…..….

I hereby certify that all the information above is correct to the best of my knowledge and the information on the promotional material are in conformity with the registration dossier.

Name and signature of the Med. Rep. _____Date _____

Annex IV: pharmaceutical representative certificate

EFDA የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን ETHIOPIAN FOOD & DRUG AUTHORITY	**Ethiopian Food and Medicine Authority**	FORM-EFDA-000
Title	Format for certificate for medical representative	Revision No.001

Photo

በማስዋወቅያ ስራ ለሚሰማሩ ባለሙያዎች

የሚሰጥ የማስታወቂያ ምስክር ወረቀት

Promotional Certificate for Professionals Working as Medical Representatives

አስመጭው ድርጅት ስም _____

Name of Importer _____

አድራሻ፣ ክልል _____ክ/ከተማ _____የቤት ቁ. _____

Address: Region _____Subcity _____House No. _____

ስልክ_____ፋክስ _____ኢሜል_____

Telephone_____Fax _____e-mail - _____

የባለሙያው ሙሉ ስም _____የወንድ አያት _____

Professional's Full Name _____Grand Father's _____

ሙያ _____የምዝገባ ቁጥር _____

Qualification _____Reg. No. _____

የአምራችና ቀጣሪ ድርጅት ስም ፡_____

Name of Manufacturer and Employer _____

የአምራች ድርጅቱ ሙሉ አድራሻ፡ _____

Manufacturer's Full Address _____

የማስተዋወቅ ፍቃድ ቁጥር _____የወኪሉ መታወቂያ ቁጥር _____

በምግብ መድኃኒት ጤናክብካቤ አስተዳደርና ቁጥጥር አዋጅ 661/2002 መሠረት የመድኃኒት ወይም የህክምና መሳሪያን ማስተዋወቅ ተግባርን ለመቆጣጠር በወጣው መመሪያ ላይ የሰፈሩትን ተፈላጊ ሙያዊና ሌሎች መሥፈርቶች ማሟላቱ ተረጋግጦ ይህ የማስታወቂያ ምስክር ወረቀት ተሰጥቷል።

This Certificate is issued to the Professional hereby in accordance with Food, Medicine health care Administration and Control Authority of Ethiopia Proclamation 661/2009 after assuring the fulfillment of the required criteria as per the existing Directive for the Regulation of Promotion and Advertisement of pharmaceuticals.

_____

የባለሥልጣን ፊርማ

Signature of an Authorized Officer

ድጋል Renewed	ድጋል Renewed	ድጋል Renewed
200_5_____E.C. 20 12/13_____G.C	2006 _____E.C. 2013/14 _____G.C	2007_____E.C. 2014/15_____G.C
የደረሰኝ ቁጥር / R/No _____	የደረሰኝ ቁጥር / R/No _____	የደረሰኝ ቁጥር /R/No _____
ፊርማ /Signature _____	ፊርማ /Signature _____	ፊርማ/Signature _____

Annex V: - Authorization Template for promotional material and advertisement of medicine

EFDA የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን ETHIOPIAN FOOD & DRUG AUTHORITY	Medicine Evaluation and Market Authorization	FORM- MRMA-00.000 SOP/00.00.00

AUTHORISATION TO MAKE A PROMOTION AND ADVERTISEMENT OF MEDICINE

This is to certify that ……., is authorized to make promotion or an advertisement for the following drugs:

1. (Name of the promotional material) branded (with name of the branded)
2. …….
3. ……..

This authorization is issued with the following conditions –

1. Only the Authorized person is responsible for promotion or advert of the material for the target group .

2. Authorization to make a publication or an advertisement for a drug, shall not deviate from the above conditions or change the authorized publication after approval.

This authorization is valid from dd/ mm/yy to dd/ mm /yy

For: ETHIOPIAN FOOD AND DRUG AUTHORITY.

……

Medicine registration and Market Authorization LEO

Date of issuance: dd/mm/yy