GUIDELINES FOR THE
REGULATION OF PROMOTION AND
ADVERTISEMENT
OF DRUGS
(SECOND EDITION)

Drug Administration and Control Authority
(DACA) of Ethiopia

ADDISABABA
September, 2008
Table of content

1. SHORT TITLE ................................................................................................. 2
2. DEFINITIONS ................................................................................................. 2
3. SCOPE OF THE GUIDELINE ......................................................................... 3
4. EXECUTIVE BODY ......................................................................................... 4
5. PROCEDURE TO ISSUE CERTIFICATE OF COMPETENCY ......................... 4
6. PROFESSIONAL REQUIREMENTS AND CONDITIONS FOR
   PROMOTION OF DRUGS ............................................................................... 4
7. ORGANIZATIONAL REQUIREMENT ................................................................ 6
8. APPLICATION FOR EVALUATION OF PROMOTIONAL MATERIAL .............. 6
9. GENERAL PROVISIONS ............................................................................... 6
10. MODE OF ADVERTISING ............................................................................. 7
11. APPLICATION FOR ADVERTISING DRUGS IN MASS MEDIA ON
    SPECIAL CONDITION .................................................................................. 10
12. CLAIMS AND COMPARISONS ................................................................... 10
13. ADVERTISING TO HEALTH PROFESSIONALS ...................................... 11
14. ADVERTISEMENT INTENDED FOR THE GENERAL PUBLIC .................... 13
15. DUTIES AND RESPONSIBILITIES OF MEDICAL REPRESENTATIVE ....... 14
16. FREE MEDICAL SAMPLE ............................................................................ 15
17. ACTS OF INDUCEMENTS ........................................................................... 15
18. ADVERTISING PHARMACEUTICAL COMPANIES AND PLANTS ............. 16
19. RENEWAL OF PROMOTIONAL CERTIFICATE OF COMPETENCY ....... 17
20. REPLACEMENT OF CERTIFICATE OF COMPETENCY .......................... 17
21. REASONS FOR REVOKING CERTIFICATE OF COMPETENCY ............. 17
22. CANCELLATION OF CERTIFICATE OF COMPETENCY .......................... 18
23. SERVICE FEE ............................................................................................... 18
24. ENTRY INTO FORCE ...................................................................................... 19

ANNEX-1 APPLICATION FORM TO ISSUE PROMOTIONAL
   CERTIFICATE OF COMPETENCY .................................................................. 20

ANNEX 2 -APPLICATION FOR EVALUATION OF PROMOTIONAL
   MATERIAL ........................................................................................................ 22

ANNEX-3 APPLICATION TO ADVERTISE DRUGS IN MEDIA ..................... 26

ANNEX4. APPLICATION FORM TO ADVERTISE
   COSMETICS, INSECTICIDES, PESTICIDES, COSMETICS, MEDICAL
   EQUIPMENTS, AND MEDICAL SUPPLIES .................................................. 29

LIST OF PARTICIPANTS ..................................................................................... 30
ACKNOWLEDGEMENT

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GUIDELINE FOR THE REGULATION OF PROMOTION AND ADVERTISEMENT OF DRUGS

Any person involved in drug promotion should follow the following guideline in accordance with Article 22 of the proclamation to provide for Drug Administration and Control No. 176/1999.

PART ONE

1. SHORT TITLE

This Guideline may be cited as 'Guideline for the Regulation of Promotion and Advertisement of Drugs'

2. DEFINITIONS

In this guideline, unless the context provides otherwise

2.1. 'Drug' means any substance or mixture of substances or medical equipment or supplies, used for human and animal health care (i.e. diagnosis, treatment, mitigation or prevention of diseases or symptoms) including poisons, narcotics and psychotropic substances, chemicals, blood and blood products, vaccines, sera, radioactive pharmaceuticals, medicated cosmetics and sanitary products, household and industrial pesticides, medicated food stuffs, and Animal feed additives.

2.2) 'Person' means any physical or juridical person.

2.3) ‘Promotion’ includes any representation such as sound, word, sign, image, electronics or other means whatever, for the purpose of promoting directly or indirectly the prescription, sale or dispense of any drug.

2.4). 'Medical representative' means a representative of a manufacturing firm directly or through the distributor, licensed by the Authority to
conduct promotional activities through provision of information on the
drugs manufactured by the firm.

2.5). 'Health professional' means medical practitioners and
veterinaries, Health officers, Pharmacists and druggists.

2.6). 'Authority' means the Drug Administration and Control Authority.

2.7) 'Proclamation' means Drug Administration and Control No.
176/1999

2.8) Words and phrases other than those defined in this guideline shall
have the same meaning as in the proclamation.

3. SCOPE OF THE GUIDELINE

3.1 The provisions set out below concern promotional materials issued
for commercial purposes, the purpose of which is to induce the
prescribing, supply or administration of drugs.

3.2. The provisions cover all means of communication, particularly:

- Print and electronic media
- Printed promotional materials such as brochures, newsletters,
  posters, stickers, algorithm, anatomical charts, calendar,
  Medical supplies, Dosage Cards, Writing Pad etc
- Professional and scientific journals,
- Medical samples,
- Technical exhibitions, lectures, symposia and congresses,
- Audio-visual media.
Guideline for the regulation of Promotion & Advertisement of drugs

- Promotional incentives/gifts/reminders such as T-shirts, Cap, Key Holders, Wall clock, Office Supplies, Stationeries, Pens, Bags etc

PART-TWO

4. EXECUTIVE BODY

4.1. The authority is mandated to issue certificate of competency for drug promotion and it has designated the plan, drug information establishment and distribution department for its execution.

5. PROCEDURE TO ISSUE CERTIFICATE OF COMPETENCY

5.1) A person requesting to issue certificate of competency for promotion should first submit an application to the plan, drug information establishment and distribution department filling out the application form prepared by the Authority (Annex-1).

5.2) The promotion control division shall then evaluate the application with all the necessary documents and proposes recommendation to the department for possible action.

5.3. The applicant fulfilling the entire requirement shall be given promotional certificate of competency and special identification card in not later than two days.

6. PROFESSIONAL REQUIREMENTS AND CONDITIONS FOR PROMOTION OF DRUGS

6.1. Only a medical representative who has been granted a certificate of competency from the authority is entitled to promote drugs the health professional.
6.2. A medical representative must fulfill the following requirement to be engaged in promotional activities

- A Degree graduate from a recognized university in bachelor of pharmacy or above

- A registered pharmacist with at least five years experience

- Ethiopian by Nationality.

- One who can present a contractual agreement from the employing company (manufacturer or distributor)

- One who is not denied by law not to serve in his profession anywhere for violating the law.

- One who can present a medical evidence proving that he/she is free from psychiatric problem, hearing & sight problem, speech impairment, addiction of alcohol; narcotic and psychotropic drugs so that he/she is capable of discharging his/her professional responsibilities.

- One who can present a release paper from the organization he/she was working previously.

- A medical representative who can present an evidence from the relevant law enforcing body confirming that he/she had returned the previous certificate of competency with which he/she was working in the sector.

6.3. Medical Equipments shall be promoted by medical equipment maintenance man, by one specialized in Biomedical Engineering or by one who took a short term courses in Equipment maintenance.
7. ORGANIZATIONAL REQUIREMENT

7.1. A medical representative should have a secured place to keep safely the free medical samples that he/she distributes.

7.2. Any medical representative should have a place to keep promotional materials and other documents used for his/her work.

8. APPLICATION FOR EVALUATION OF PROMOTIONAL MATERIAL

8.1. Prior to any promotion, any licensed medical representative should submit an application to the planning, drug information department attaching the sample promotional material with the application form (annex -2), prepared by the Authority.

8.2. The department shall then evaluate the content of the submitted sample promotional material and notify the result to the applicant within five working days.

PART THREE

9. GENERAL PROVISIONS

9.1) Only those drugs registered by the Authority shall be promoted.

9.2) No one shall carryout promotional activity unless approved by the Authority.

9.3) Samples of informational and promotional materials must be submitted to the authority for approval prior to any promotional activity.
9.4) All informational or promotional material must be consistent with the information provided in the product monograph approved by the Authority.

9.5) New information, other than those submitted at the time of registration, must be submitted to the Authority for approval before being disseminated to health professionals.

9.6) Any drug, drug products, active ingredient or substance shall not be advertised for purposes that cause danger to life or health of the public.

9.7) Promotional materials should be prepared in English and/or Amharic and if possible in other national languages as well.

10. MODE OF ADVERTISING

10.1) Advertisements in promotional materials approved as per article 8, and those advertised in health-related journals, health symposia and congresses shall be allowed subject to the provisions of this directive.

10.2) The following drugs can be promoted on mass media, newspapers, and billboards.

- Oral contraceptives
- ORS
- Condoms
- Vitamins,
- Food additives
- Analgesics, Antihistamines,
- Medical equipments
- Medical supplies including self-test for pregnancy and Hypertension but not self-test for HIV
- Medicated & Non-medicated Cosmetics
- Sanitary and Beutifying agents eg. Tooth paste, diapers, Modes,
- Industrial & Household Insecticides, pesticides
- Disinfectants

b) By Billboards

- Condoms
- Oral contraceptives (one month)
- Sanitary and beautifying agents eg. Tooth paste, diapers, Modes,
- Vitamins
- Cosmetics
- Sanitary and Beutifying agents eg. Tooth paste, diapers, Modes,

10.3. The information content of the drugs to be promoted as in 10.2 shall be strictly evaluated by the Authority and

10.4. The information content of promotion in media for Analgesics, Anthilemantics shall include the right source of availability and shall state that the advice of health professional is required.

10.5 The information content of promotion in media for Cosmetics shall include the necessary precaution to be taken during application.

10.6. The information content of promotion in media for Industrial & household insecticide and pesticides shall state that

- Foods and liquids be covered before spraying.
- The person should cover his mouth and nose during spray
- They are not to be sprayed on fire
- They are to be kept away from the reach of children
- The place should be closed for 30-40 minutes after spray
- Skin contact with the insecticide and pesticide should be avoided.

10.7. All Drugs except as indicated under 10.2 shall not be advertised by:

- radio, television, press, or in films;
- means of aircraft, ship, boats, cars, vans and all other transport vehicles.
- means of posters and billboards in places accessible to the public except as otherwise indicated under section 14 (2) of this regulation.
- illuminated signs.
- telephone, SMS
- organizing competitions or sponsorship
- the provision of leaflets of detachable inserts in non health or pharmaceutical publications.
- the display in theatre or role play
- door to door advertising.
11. Application for **ADVERTISING DRUGS IN MASS MEDIA ON SPECIAL CONDITION**

11.1. A medical representative shall apply to the planning, drug information department for drug promotion in mass media attaching the information to be promoted with the application form (annex - 2) prepared by the authority.

11.2. The department, in reply to the application, shall give proper decision within five working days.

11.3. If the application is accepted, the authority shall write an approval letter to the concerned media on which the drug is to be promoted.

12. **CLAIMS AND COMPARISONS**

12.1. Advertising claims shall be consistent with the body of scientific and medical evidence pertaining to that product.

12.2. Advertising claims shall not be presented exaggerating the advantage of a drug nor imply that the drug has no disadvantage unless this can be substantiated.

12.3. Advertising material must not misuse research results or quotations from the scientific literature to support such claims.

12.4. Comparisons of products must be factual, fair and capable of substantiation.

12.5. The products or services of other companies should not be disparaged either directly or by implication.
13. ADVERTISING TO HEALTH PROFESSIONALS

13.1. The information disseminated should at least contain the following particulars which is the same as that accepted at the time of registration.

- The name(s) of the active ingredient(s) using either international non proprietary names (INN) or the approved generic name of the medicament.
- The brand name, (if any)
- Content of active ingredient(s) per dosage form or regimen,
- Approved therapeutic uses.
- Dosage form or regimen.
- Side-effects and major adverse drug reactions.
- Precautions, contra-indications and warnings.
- Major interactions
- Name and address of manufacturer or distributor.
- Reference to scientific literature as appropriate
- Storage Condition

13.2. Full Information as in 13.1 is needed when the promotion is presented in the form of
13.3. The following promotional material shall have minimum information mentioned under each

a) Writing pad
   - Brand name/or Name of Manufacture
   - Generic name
   - Major indication

b) Dose Cards
   - Brand name/Manufacturer
   - Generic name
   - Indication
   - Dose

C) Medical supplies
   - Brand name/Manufacturer
   - Generic name

d) Calender
   - Brand name/Manufacturer
   - Generic name

e) Anatomical Chart
   - Normal Anatomy of specific organ system
   - Indication

f) Posters
   - Some promotional phrases
   - Brand name/Manufacturer
   - Generic name
g) Algorithm
   o Schematic representation of treatment for the disease using the drug to be promoted
   o Brand name/Manufacturer
   o Generic name

h) Promotional Incentives /gifts
   o Brand name/Manufacturer
   o Generic name

14. ADVERTISEMENT INTENDED FOR THE GENERAL PUBLIC

14.1. Advertising prescription only drugs to the public is prohibited

14.2 Advertising of non-prescription drugs intended for the public shall be limited to poster and stickers displays in pharmacies, licensed private and public health institution, and limited to lists as indicated in 10.2.

14.3. Advertising for the public using promotional material as in 14.2 shall conform to the package insert approved at the time of registration.

14.4. Advertising using promotional material as in 14.2 intended for the public shall not,

- Include testimonials of persons, who have been cured.
- Include reproduced pictures or graphic representation of the state of the patient before and after treatment.
- Be in a manner that encourages self-medication.
- Be in a manner that induces abortion in women.
- Be in a manner that induces fear or distress.
14.5. Advertisement to the general public should contain the following particulars:

- The name(s) of the active ingredient(s) using either international non proprietary names (INN) or the approved generic name of the drug;
- The brand name;
- Major indication(s) for use;
- Major Precautions, contra-indications and warnings;
- Name and address of manufacturer or distributor

14.6. Advertisement to the public should be presented in a simple language that they understand. When lay language is used, the information should be consistent with the approved scientific data sheet.

14.7. Posters and stickers promoting prescription only drugs shall be limited only in Wards and Physicians room.

15. DUTIES AND RESPONSIBILITIES OF MEDICAL REPRESENTATIVE

15.1. Medical representatives shall be responsible for pharmaceutical information, advertising and promotion for only those drugs manufactured by the employer.

15.2. Medical representatives must safely keep and record of all promotional materials including samples to ensure their security.

15.3. When distributing medical samples, the medical representative shall keep a record of the following, which shall be presented to the Authority upon request

- Name, quantity and content of the sample supplied
16. FREE MEDICAL SAMPLE

16.1. Free medical samples can be used for promotional purpose only after the drug is registered and market authorized by the authority.

16.2. Samples may be provided to health personnel.

16.3. The labels of medical samples intended for, promotional purposes must state in Amharic and/or English that they are free samples not intended for sales.

16.4. It is prohibited to sell free medical samples.

16.5. The information on the label of free medical samples should be consistent with the information approved by the Authority.

16.6. Distribution of samples (both for prescription only and OTC) at medical, pharmaceutical congresses, symposia and exhibitions is prohibited.

16.7. Postal sampling is prohibited.

17. ACTS OF INDUCEMENTS

17.1. The value of Promotional items, which are provided to health professionals free of charge during promotion, should not exceed ETB 100.
17.2. The quantity of promotional item ready to be distributed for health care professional shall be in a reasonable quantity which doesn’t affect the business of any organization selling the same items.

18. ADVERTISING PHARMACEUTICAL COMPANIES AND PLANTS.

18.1. A pharmaceutical company or plant can advertise its facility or address

- by radio, television, press, or in films;
- by means of aircraft, ship, boats, cars, vans and all other transport vehicles.
- by means of posters and billboards
- by illuminated signs.
- by oral recommendations in public,
- by organizing competitions or sponsorship
- by the provision of leaflets of detachable inserts in health or pharmaceutical publications.
- by the display in theatre or role play

18.2. When advertising the facility, the company shall not directly or indirectly promote its medical products.

18.3. The content of the information to be disseminated during the advertisement of the facility in media or as in 1 shall first be approved by the authority.
19. RENEWAL OF PROMOTIONAL CERTIFICATE OF COMPETENCY

19.1. Certificate of competency for promotion must be renewed upon duly payment every year after the first issuance.
19.2. If the certificate is not renewed with the time frame given in 19.1, a 50% additional fee per month shall be charged to renew it in the next two consecutive months.
19.3. If again the certificate is not yet renewed as in 19.2, it will be considered as cancelled.
19.4. Renewal of certificates is made only after ensuring that the requirements set are fulfilled.

20. REPLACEMENT OF CERTIFICATE OF COMPETENCY

20.1. Medical representatives can request the authority for replacement of promotional certificate of competency if the original is lost or defected.
20.2. Upon request as in 20.1, the authority shall give replacement after the defected certificate is returned.
20.3. The request for replacement of lost certificate must be supported with adequate evidence from relevant law enforcing body confirming that it is lost.
20.4. Service fee shall be charged for replacement of the certificate.

21. REASONS FOR REVOKING CERTIFICATE OF COMPETENCY

Certificate of competency may be revoked for one of the following reason

21.1. A medical representative who fail to carry out his/her activity and found to cause danger to the public as result of psychiatric problem,
Guideline for the regulation of Promotion & Advertisement of drugs

physical disability, old age, mental problem due to intake of alcohol, narcotics and psychotropic, and other compounds.

21.2. When the requirements for promotional certificate of competency are not met.

21.3. When a medical representative hinders the duties of the regulatory inspectors.

21.4. When it is confirmed that the employing company of the medical representative has been rejected by relevant body not to be engaged in business activity.

21.4. When the employing company is found to have been engaged in activities contrary with the objective of the certificates of competency.

22. CANCELLATION OF CERTIFICATE OF COMPETENCY

Promotional certificate of competency may be cancelled for any of the following reason

22.1. When the certificate was found to have been transferred to another person.

22.2. When it is found that the medical representative had obtained the certificate by fraud.

22.3. When the medical representative is found promoting a drug, which is unregistered, rejected for market, or a drug with misleading label.

22.4. When the medical representative resigns from his job.

23. SERVICE FEE

The authority shall charge the following service fee.

23.1. ETB 400 shall be charged to issue a new promotional certificate of competency.

23.2. ETB 200 shall be charged to issue a yearly renewal or replacement of certificate of competency.

23.3. ETB 200 shall be charged to issue a replacement for lost identification cards.
24. ENTRY INTO FORCE
The provisions of the Directive shall come into operation on September, 2008
ANNEX-1 APPLICATION FORM TO ISSUE PROMOTIONAL CERTIFICATE OF COMPETENCY

This form is to be filled by the applicant and it has to be submitted to ADR Monitoring and Promotion Control Division attaching all the required documents.

1. Full Name of the Applicant________________________

2. Address of applicant
   Region_________ Zone_________ Wereda_________
   City_________ Kebele_________ House No.________
   Telephone___________

4. Level of Education _______________________
   ________________________ (attach copy of degree/diploma/certificate awarded)

5. University/college attended ______________________

6. Professional Level______________________ (attach Registration Certificate). Registration no. given from Ministry of Health________________________

7. Years of Experience____________________________________
   (attach release paper)

8. Name of the Manufacturing firm which the applicant intends to represent __________________________
   Address____________________________________________

9. Name of the importing agency____________________

10. Intended position of the applicant in the firm.( attach contractual agreement entered)
Medical representative □
Technical Manager □
Owner □
Other □ , mention____________________

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

Name and signature of the Applicant. _______________
Date ______________

To be completed by ADR Monitoring and Promotion control Division

1. Any warnings given by the Authority /relevant law__________
_____________________________________________________

2. Comment and recommendation by ADR Monitoring and Promotion Control Division
_____________________________________________________
_____________________________________________________
Name and Signature _______________Date ___________________

Final Decision passed by the Planning, Drug Information Department Head
Certified □
Not Certified □
Date _________________ Signature ___________________

NA - not applicable
ANNEX 2 - APPLICATION FOR EVALUATION OF
PROMOTIONAL MATERIAL

This form is to be filled by the Medical Representative of the company in three copies and it has to be submitted to ADR Monitoring and Promotion Control Division with the promotional material attached to it.

PART I

1. Name of the manufacturing firm________________________________
   Address_________________________________________________

2. Name of the importing agency____________________________________
   Address_________________________________________________

3. Name and profession of the medical representative________________________
   License No.___________________

4. Name of the drug to be promoted_________________________(INN)
   ____________________(Brand)

5. Is the drug to be promoted registered? Yes☐ No☐
   If Yes, Registration No._______________________

6. Legal sales category of the drug
   OTC☐ Prescription only☐ Restricted ☐ Other ☐ _______

7. Type of promotional material
   __________________________________________

8. How long has the product been promoted in Ethiopia?
   __________________________
9. Reference used for preparation of the promotional material

10. Any previous warning issued by DACA

I hereby certify that all the information above are 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 __________

PART II

To be completed by ADR Monitoring and Promotion control Division
Content of the promotional material

1. Does the information on the promotional material state
   - Name of the drug (INN, Brand)  
   - Active ingredient  
   - Approved indication  
   - Dosage form and regimen  
   - Side effects and major ADR  
   - Precaution and warning  
   - Contraindications  
   - Major interaction  

2. Is the information in conformity with the package insert/product monograph?
   Yes  No  NA If No, specify  

3. Is the information written legibly and clearly? Yes  No  
   If No, specify  

4. Does the promotional material imply that the drug is free of side effects or adverse drug reactions? Yes  No  NA  

23
If yes, specify

___________________________________________

5. Are there any omissions of major side effects, contraindication and drug interaction?  Yes ☐   No ☐   NA ☐
If yes, specify

_____________________________________________

6. Does the promotional material have exaggerated or all embracing claims about the drug to be promoted?  Yes ☐   No ☐   NA ☐
If yes, specify

_____________________________________________

7. Is there any unverifiable or misleading statement in the content?  Yes ☐   No ☐
If yes, specify __________________________________

______________________________________________

8. Is the comparison made between the drug to be promoted and the other drugs factual and capable of substantiation?   Yes ☐
No ☐  No comparison ☐
If No, specify

_______________________________________________

_____________________________________________________

9. Does the promotional material have disparaging content against the product or services of other company either directly or by implication? Yes ☐   No ☐   If yes, specify

_______________________________________________

Comment and recommendation by ADR Monitoring and Promotion Control Div.

_______________________________________________

Name and Signature ________________Date ________________
PART III.
Final Decision by the Planning, Drug Information Department Head

Approved ☐
Not approved ☐

_____________________________________________________
_____________________________________________________

Date ____________________Signature _________________
ANNEX-3 APPLICATION TO ADVERTISE DRUGS IN MEDIA

This form is to be filled by the Medical Representative of the company and it has to be submitted to ADR Monitoring and Promotion Control Division with the information content to be promoted in the media.

PART 1

1. Name of the manufacturing firm ____________________________
   Address ________________________________________________

2. Name of the importing agency _____________________________
   Address ________________________________________________

3. Name and profession of the medical representative _____________
   ________________________________________________________
   License No. ____________________________

4. Name of the drug to be promoted in the media ________________ (INN)
   ________________ (Brand)

5. Type of media in which the drug is to be promoted ________________

6. Is the drug to be promoted registered? Yes ☐ No ☐
   If Yes, Registration No. ____________________________

7. Any previous warning issued by DACA _________________________
   Name and signature of the Med. Rep. _________________ Date ________
PART II

To be completed by ADR Monitoring and Promotion control Division

Information Content of the promotion.

1. Is the drug one among those permitted by DACA to be promoted in media?  Yes □  No □

2. Does the information on the promotion state
   - Name of the drug (INN, Brand) □
   - Active ingredient □
   - Approved indication □
   - Dosage form and regimen □
   - Side effects and major ADR □
   - Precaution and warning □
   - Contraindications □
   - Major interaction □

3. Is the information in conformity with the package insert/product monograph? Yes □  No □  NA □  If No, specify

   ______________________________________________________

4. Does the promotion imply that the drug is free of any problem? Yes □  No □  NA □
   If yes, specify___________________________________________

5. Does the promotion have exaggerated or all embracing claims about the drug to be promoted? Yes □  No □  NA □
   If yes, specify  ______________________________________________

6. Is there any unverifiable or misleading statement in the content? Yes □  No □  If yes, specify ________________________
7. Is the comparison made between the drug to be promoted and the other drugs factual and capable of substantiation?
Yes [ ] No [ ] No comparison [ ] If No, specify ________________________________

8. Does the promotion content have disparaging content against the product or services of other company either directly or by implication? Yes [ ] No [ ] If yes, specify ________________________________

Comment and recommendation by ADR Monitoring and Promotion Control Division

______________________________
Name and Signature Date __________________________

PART III.
Final Decision passed by the Planning, Drug Information Department Head
Permitted [ ] Not permitted [ ]
Date __________________ Signature ________________________

N.B. NA - not applicable
Annex 4. Application form to advertise cosmetics, insecticides, pesticides, cosmetics, medical equipments, and medical supplies

<table>
<thead>
<tr>
<th>Ser. No.</th>
<th>Name and kind of product</th>
<th>Is the product Medicated?</th>
<th>Information content Acceptable for media</th>
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</tbody>
</table>

Comment and recommendation by ADR Monitoring and Promotion Control Division

______________________________  __________________________
Name and Signature           Date

PART III.
Final Decision passed by the Planning, Drug Information Department

Head
Permitted ☐
Not permitted ☐

Date ________________ Signature __________________________

N.B. NA - not applicable
List of participants

List of Institute and professional Associations participated in the consultative workshop

15. Pelican Pharmacy, Addis Ababa
16. Anbessa Pharmacy, Addis Ababa
17. Harar Pharmacy, Addis Ababa
18. Dalga Anbessa Pharmacy, Addis Ababa
19. Alem Tena Pharmacy, Addis Ababa
20. Mekalle hospital, Mekelle
21. Dubti Hospital, Dubti
22. Bishoftu Hospital, bishoftu
23. Felege Hiwot Hospital, Bahirdar
24. Jijiga Hospital, Jijiga
25. Assossa Hospital, Assossa
26. Dilla Hospital, Wenago
27. Black Lion Hospital, Addis Ababa
28. Amanuel Specialized Psychiatry Hospital, Addis Ababa
29. Zewditu Memorial Hospital, Addis Ababa
30. Polis Hospital, Addis Ababa
31. DiChora Hospital, Diredawa
32. Gambella Hospital, Gambella
33. Hiwot Fana Hospityal, Harari
34. Misrak Arbegochn Hospital, Harar
35. Gondar University Medical Faculty, Gondar
36. Addis Ababa University Medical Faculty, Addis Ababa
37. Jimma University Medical faculty, Jimma
38. Mekalle University Medical Faculty, Mekelle
39. Gondar University School of Pharmacy, Gondar
40. Addis Ababa University School of Pharmacy, Addis Ababa
41. Jimma University School of Pharmacy, Jimma
42. Ethiopian Medical Association Addis Ababa
43. Ethiopian Pharmacy Association, Addis Ababa
44. Ethiopoian Public Health Assocition, Addis Ababa
45. Ministry of Health, Addis Ababa