

GUIDELINES FOR THE ADVERTISEMENT OF DRUGS, COSMETICS, HOUSEHOLD CHEMICALS & MEDICAL DEVICES

In pursuance of Sections 114 and 115 of the Public Health Act 2012, Act 851, these guidelines are hereby made to provide guidance to applicants on the procedure for writing and registering an advertisement script in Ghana. Applicants are encouraged to familiarize themselves with this document and the above law before initiating the registration process.

INTERPRETATION

In these guidelines, unless the context otherwise states: -

a) **'Product'** means drugs (including orthodox, herbal and homoeopathic), cosmetics, medical devices and household chemical substances.

b) **'Related Products'** means products that are complementary products or products with different strengths, pack-sizes or are variants of the same products (different flavours).

c) **'Drug product'** means a substance or mixture of substances manufactured, sold, or presented for in-vivo use in the diagnosis, treatment, mitigation or prevention of a disease disorder, abnormal physical state, or the symptoms thereof; or in restoring, correcting or modifying organic function(s) in man, but excluding mechanical devices and cosmetics.

d) **'Rational Drug Therapy'** means appropriate therapy, recommended or prescribed which legally may be expected to remedy or ameliorate a disordered state of physical or mental health? Drugs may be logically employed for diagnostic and prophylactic purposes to prevent or lower the incidence of illness.

e) **'Full Disclosure'** as used in this context means adequate information for the prescriber concerning the accepted indications and appropriate use of the product, including warning precautions, contraindications, adverse reactions, dosage forms and dosage regimens.

f) **'Therapeutic classification of a pharmaceutical product'** means either the accepted pharmacological classification (anxiolytic, diuretic, analgesic, antibiotic) or the identity of the purpose or purposes for which the pharmaceutical product (as defined) is intended (migraine, hypertension) or both.

g) '**Advertising**' means the publicity of goods and description of all products; this includes any form of notices in circulars, handouts, label wrappers, catalogue and price lists, newspaper, magazines and many other documents made orally or otherwise or by means of projected light, sound recording, Radio, presenter mentions, television, bill boards, mobile vans and writings.

h) '**Over-the-counter drugs (OTC)**' means drugs that are generally regarded as safe for the consumer for use by following the required label directions and warnings. They may be purchased without a prescription.

i) '**Prescription Drugs**' means a drug which can only be made available to consumer through a written order signed by a duly qualified and registered medical practitioner, dentist or veterinary surgeon and disposed by a fully registered and licensed pharmacist. Such drugs shall not be made available or sold directly to the general public without the said written order.

They are identifiable under the Scientific or Chemical names of their active ingredients as well as by the generic or established names of the active ingredients.

j) '**Label**' means a display of written printed or graphic matter upon the immediate drug container.

k) '**Package Labelling**' includes the label on the immediate containers plus all other printed matter, such as outer wrapper, carton or leaflet associated with the package.

l) '**Appropriate authority**' means the Chief Executive of the Authority.

m) '**Claims**' means any representation which states, suggests or implies that a drug has particular qualities relating to its origin, properties, nature, processing, composition or any other quality.

n) '**Justification**' in respect of any claim shall be in the light of current scientific knowledge.

APPLICATION

1. An application for the advertisement of a product shall be accompanied by:
 - (a) A duly signed covering letter
 - (b) Two (2) samples of the product in the final package and ready for the market
 - (c) Proposed script or story sketch intended for the advertisement
 - (d) **Non-refundable application** fee as specified in the Authority's Fee Schedule.

2. The proposed script shall be approved before the final print, audio Cassette, video cassette, compact disc is made to be broadcast or telecast.

3. The final version of the advertisement in whatever form shall be submitted for vetting **before publication.**

4. Advertisements considered unacceptable by the Authority will be communicated to the advertiser with the unacceptable information or illustration clearly clarification on the ruling will be given in writing.

5. The duration of an approval for an advertisement will be one (1) year from the date of approval.

6. Any alterations in the format of the approved script, film or story sketch without express written permission of the Food and Drugs Authority shall render the approval null and void and shall attract a penalty.

7. Notwithstanding the above, the Authority reserves the right to revoke approval as a result of new evidence concerning product or public safety or product efficacy or quality.

8. If approval of an advertisement is withdrawn during the one year period of approval, an appeal may be made to the Minister in writing and accompanied by supporting information. Such an appeal shall be lodged with the Minister within twenty one (21) days of notification and supporting materials provided within sixty days of notification.

9. In the event of any publication of an advertisement not approved by the Authority, the sponsor, advertising agent and the advertising media organization shall be jointly and severally liable.

GENERAL REQUIREMENTS

10. No person shall advertise any product unless the product is registered with the Authority.

11. No person shall advertise any product unless such advertisement has been approved by the Authority.

12. No advertisement shall contain more than one product per script per media per language, unless the products are related. Any additional product or language on a script shall attract an additional approval fee.

13. No person or media house shall carry any advertisement of a product in the print or electronic media or by any means unless there is evidence of prior approval of the advertisement granted by the Authority.

14. An advertisement should not directly or indirectly refer to the fact that, a product is licensed by or has the approval of the Authority.

15. An advertisement shall not contain material, which refers to recommendations by scientists or health professionals or which refers to recommendations by celebrities or well-known organizations, who because of their status could encourage consumption of products.

16. No advertisement shall be targeted at pregnant or lactating women and persons with disease conditions specified in Fifth Schedule of the Public Health Act.

17. An advertisement shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health practitioners. Statements or illustrations must not mislead directly or by implication.

18. No advertisement shall bring the respective industry into disrepute, undermine confidence in advertising or prejudice public confidence in the product.

19. No advertisement shall unfairly disparage any product of a competitor, either directly or by implication.

20. No advertisement shall imitate the general layout, text slogans or visual presentation or devices of other advertisements from other companies in a way likely to mislead, deceive or confuse the consumer.

21. No advertisement shall be framed in such a manner as to exploit the superstitious belief and/or induce fear in the consumer to purchase the product. No advertisement shall contain words such as magic, miracle or mystical; exotic descriptions, such as 'super potency' or such other words as to induce the daily and continuous use of the product.

22. No OTC drug advertisement shall:

a. Imply that the consumer is suffering, or without treatment may suffer or suffer more severely from any illness, ailment or disease.

b. Over-dramatise any symptoms or signs.

c. Denigrate or attack unfairly any competitive products, goods and services.

23. Advertisements for a product shall present information that is reasonably balanced between side effects and contra-indications and efficacy and safety.

Specific Requirements for Drugs

24. Drug advertising shall reflect an overall attitude of caution in relation to drug usage, with emphasis on rational use of medicines. It shall provide sufficient and balanced information to permit assessment of risk against the benefits.

25. No advertisement for drugs shall contain any price, competition or similar scheme.

26. No drug advertisement shall contain offers of gifts or refund of money to dissatisfied consumers.

27. No drug advertisement shall state or imply in absolute terms or by quotations taken out of context, that any pharmaceutical product is 'safe', 'non-toxic' or 'has guaranteed efficacy'.

28. An advertisement which contravenes the ethical standards of the health and other professions is prohibited.

29. No drug advertisement shall make statements claiming or implying superlative functions such as being the "drug of choice", 'the most frequently prescribed', 'the only drug for the purpose or that the drug has no side effects, unless such claims can be adequately and scientifically substantiated.

30. Advertisements of all drugs that may be used by pregnant women and lactating mothers shall state any known effects of the drug on the pregnant woman, foetus and infant.

31. The indications for use of any therapeutic agent must conform to the approved product monograph and label.

Prescription and Pharmacy Drugs:

32. No person shall advertise any prescription drug in the lay press or non-medical press.

33. Prescription drugs shall be advertised only for indications for which the drug has been registered by the Authority.

34. No person shall advertise any prescription drug in a health professional journal unless the drug is properly labelled, and the advertisement contains the following information;

- (1) Names of drug product - International non-proprietary and brand name
- (2) A quantitative listing of all the ingredients
- (3) An accurate statement of the dosage and strength
- (4) Daily dose
- (5) Frequency of administration
- (6) Preparation before use (shaking, dilution, refrigeration)
- (7) Quantity of contents in metric units where applicable
- (8) Route or method of administration
- (9) Adequate warning (cautions,, side effects, interactions, treatment of overdose, effects on pregnancy and lactation, when necessary for the protection of the user as provided in drug labelling regulations.
- (10) 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.

35. All Prescribing information must be legibly presented.

36. All data illustrations presented in advertisements including charts, graphs and tables extracted from the literature or other sources or reproduced by artwork, must be accurate, complete and clear with the source specifically identified. Data illustrations which are misleading or ambiguous or which distort the original intended meaning or interpretation either directly or by implication will be considered a violation of these regulations.

37. Claims and quotations from the scientific literature concerning efficacy, safety, adverse reactions, use in children below the age of eighteen, use in pregnancy and lactation within the constraints of the product monograph, shall mention the scientific source(s) of information. Copies of all references cited should be provided to the Authority for verification.

38. Claims based on, or quotations that have been selected from a scientific article or series of articles and emphasize only positive features while ignoring negative findings, will not be accepted. Claims and quotations must be readily verifiable by the Authority.

39. Selected quotations should not refer to another brand of the same pharmaceutical entity or to a different formulation of the same active ingredients unless data of accepted methodology are available to warrant cross reference between products

Over the Counter Medicines (OTC's),

40. OTC medicines including allopathic, food supplements, herbal and homeopathic, shall not be advertised for diseases specified in the Fifth Schedule of the Public Health Act 2012, Act 851.

41. An advertisement shall advise the consumer on any age restrictions and special precautions and the need to seek medical attention should the symptoms persist after 48 hours.

PUBLIC HEALTH ACT, 2012 ACT 851, FIFTH SCHEDULE (Section 114)

Diseases for which advertisement for treatment, prevention or cure are prohibited.

Sexually Transmitted Diseases, other forms of Genito-Urinary diseases. Acquired Immune Deficiency Syndrome (AIDS) or diseases connected with the human reproductive functions.

Any of the following:-

Alcoholism	Appendicitis
Amenorrhoea	Arterio-Sclerosis (Strokes)
Asthma	Blindness
Bladder Stones	Cancer
Convulsion	Deafness
Diabetes	Diphtheria
Epilepsy or fits	Diseases of the reproductive organ
Erysipelas	Fibroid
Gallstones	Goitre
Heart Disease	Hernia or Rupture
Hypertension	Infertility
Kidney Stones	Kidney Failure
Leprosy	Leukemia
Systemic Lupus Erythematosus	Locomotortazy
Mental Disorders	Nephritis or Bright's disease
Obesity	Paralysis
Pleurisy	Pneumonia
Poliomyelitis	Prostate Diseases
Scarlet Fever	Septicaemia
Smallpox	Sexual Impotence
Tetanus or Lock-jaw	Trachoma
Tuberculosis	