



FOOD AND DRUGS AUTHORITY

CODE OF PRACTICE FOR SALES

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1.0 Introduction

In pursuance of Section 148 of the Public Health Act, 2012, Act 851, this Code of Practice for Sales is hereby promulgated for information, guidance and strict compliance by all concerned on the procedure and requirements for the sale, marketing and promotion of medical products including drugs, herbal medicines, medical devices, cosmetics, and household chemical substances in Ghana.

The Code must be read and used in conjunction with the enabling legislation, the Public Health Act, 2012, Act 851, Part 7, the FDA Guidelines on Advertisement, and any other relevant FDA Guidelines and Legislative Instruments (LIs).

The FDA would not ordinarily seek to regulate ethical practices with respect to sales, marketing, advertisement, promotion of regulated products and associated areas. However, when these practices adversely affect the health and safety of the general public, the FDA in prosecuting its mandate, shall wield its regulatory powers to curb same..

Examples of negative effects on health and safety of the public include:

- Irrational prescribing by health care practitioners
- Abuse and/or misuse of regulated products including OTCs
- Promoting self-medication for serious health conditions where appropriate diagnosis is required

Scope

The Code of Ethics shall regulate ethical practices with respect to sales, marketing and advertisement in connection with medical products including drugs, herbal medicines and any other products or devices regulated by the FDA. Code of Practice shall be read and applied in conjunction with the public Health Act, 2012, Act 851, Part 7, the FDA Guidelines on Advertisement and any other relevant FDA Guidelines and Legislative Instruments (LIs).

Objectives

The Code has been promulgated in furtherance of FDA's mandate to ensure and guarantee the health and safety of consumers of regulated medical products including drugs, herbal medicines, medical devices, cosmetics, and household chemical substances in Ghana, by regulating the safety, quality, efficacy and performance of these products.

In this regard, the FDA would work closely and collaborate effectively with industry players to enforce the tenets of this Code. The FDA would thus urge the industry to institute appropriate voluntary self-regulatory regimes to complement the efforts of the FDA. The industry should also, in collaborating with the FDA, endeavour to hand over its members whose acts run counter to the Code.

2.0 Glossary and Acronyms

2.1 Glossary

Advertisement: includes a representation by any means for the purpose of promoting, directly or indirectly, the sale, distribution and/or use of a product regulated under this part; as well as any acts or methods to have the product information seen or known by the public

Advertising: means the publicity of goods and description of 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, social media and writings.

Marketing: involves finding out what people want and why they want it; and consequently provide products or services to meet these wants and needs at a profit.

Medical device: means an instrument or apparatus including components, parts and accessories of it manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptom of it in man or animal.

Promotion: to make a product, service or business known to a target audience by the use of different channels, including communicating with them and influencing their decision to patronize the product, service or business.

Sales: include sale by wholesale or retail, import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale, or prepare or possess for sale and barter or exchange, supply or dispose of to a person whether for a consideration or otherwise

2.2 Acronyms

OTC: Over-the-Counter Medicines

POM: Prescription only Medicines

FDA: Food and Drugs Authority

HCP: Health Care Practitioner

3.0 Sales and Marketing

3.1 Sales

3.1.1 Section 149 of Act 851 interprets sale to include sale by wholesale or retail, import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale, or prepare or possess for sale and barter or exchange, supply or dispose of to a person whether for a consideration or otherwise.

3.1.2 The section also interprets selling to include offering for sale, exposing for sale and having in possession for sale or distribution.

3.1.3 Sales involve persuading people (clients, consumers, healthcare professionals, etc.) that the products and/or services on offer provide the benefits they are looking for and hence meet their needs and wants.

Sale includes sale by wholesale or retail, import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale, or prepare or possess for sale and barter or exchange, supply or dispose of to a person whether for a consideration or otherwise.

3.2 Marketing

3.2.1 Marketing involves finding out what people want and why they want it; and consequently provide products or services to meet these wants and needs at a profit.

3.3 Sales and Marketing of Regulated Products

3.3.1 Since FDA's regulated products are basically intended for prevention, diagnosis, treatment and management of diseases, any sales or marketing techniques or procedures or processes adopted must not result in creating demand, purchase or use that falls outside the above. FDA's mandate is to ensure the health and safety of consumers. Consequently, no selling or marketing of any of FDA's regulated products should, directly or indirectly, hinder the achievement of this objective.

3.3.2 Competition among manufacturers and their agents shall not be to the disadvantage of the consumer, patient, or client. Consequently, practices including unfair tactics and hoarding shall not be used, whilst price competitions and brand wars should not be over-used in marketing regulated products.

- 3.3.3 Marketing activities shall be conducted to:
- i. support fair competition
 - ii. compete on the basis of accurately representing the company's products and services
 - iii. fulfill obligations in good faith
 - iv. offer only safe products that are suitable for their intended use
 - v. respect the privacy of customers and safeguard their data
- 3.3.4 The FDA shall expect practitioners to exhibit professional responsibility towards all including healthcare practitioners, clients, consumers, patients and institutions. These should include:
- i. respectful interactions
 - ii. consideration for cultural diversity
 - iii. nondiscriminatory behavior toward people
 - iv. observe the applicable laws and regulations at all times

4.0 Advertisement and Promotion

4.1 Advertising is an essential tool in the dissemination of information. However, there is a thin line between it been useful and harmful to its intended target audience. It is thus necessary for the FDA to regulate and monitor to ensure compliance with all applicable legal requirements.

The Code is to ensure that untruthful and misleading advertisement and promotion, from both legal and clinical perspectives, are not encouraged. It shall also assist health care practitioners to identify and report suspected untrue or misleading advertisement and promotion to the Authority for immediate redress.

4.2 It is noted that though the FDA would not regulate the use of the elements within the science of influence employed in promotion and advertisement of regulated products, the use of these in a manner that deviates from the ultimate aim of the

FDA to assure consumer health and safety, shall attract the intervention of the Regulator. Consequently, the use of the following, among others, to create an unhealthy demand, purchasing, stocking, prescribing and use of regulated products would attract the FDA's requisite sanctions:

4.2.1 Scarcity

People are attracted to what is limited in supply, and may pay more and exert greater effort to obtain them. This makes limited-time offers relatively exciting.

4.2.2 Authority

People are more likely to take advice from those who are experts on a subject matter and who are also more likely to accurately assess and respond to situations in their area of expertise. It generally serves us well to follow them.

4.2.3 Liking

People more often comply with requests made by those they like. Regardless of the reasons for liking someone, people have a greater ability to influence our decisions and behavior than do people for whom we have lower positive regard.

4.2.4 Commitment and consistency

People would like to be consistent with what they have done or said, including previous endorsements and support, and hence more likely to agree to greater investments of time and money that are consistent with initial testimonies.

4.2.5 Social proof

People look for evidence of what others like them are doing and do same; they follow the lead of similar others. If people like them are behaving in a particular way, it might be the appropriate way to behave.

4.2.6 Reciprocity

People are likely to give back to those who give to them and hence willing to help one another. Helping behavior is said to keep society strong. People are more likely to purchase or patronize a product or service after accepting a sample, a small gift or a favour in return.

The use of samples must thus be in conformity with the requirements of S. 121 of Act 851; and where applicable, and to avoid undue pressure on recipients of such samples in the interest of public health and safety, the Authority would issue guidance on the maximum pecuniary value of such samples.

4.3 Major areas prone to misleading and untruthfulness in advertisement and promotion include, but are not limited to:

4.3.1 Over-stating effectiveness

- i. Exaggerate effectiveness of the product
- ii. Present claims not supported by substantial evidence
- iii. Misrepresent data from clinical trials

4.3.2 Misleading comparisons

- i. Product safer than others
- ii. Product more effective than other similar products
- iii. Absence of substantial evidence (two adequate and well-controlled trials) and or substantial clinical evidence (similar study designs, appropriate doses and dosage regimen, similar study populations).

4.3.3 Omission of risk

- i. Claims of efficacy and effectiveness must be also include risks
- ii. Cautions, precautions, contraindications, etc. must accompany statements of efficacy and effectiveness

4.3.4 Minimization of risk

- i. Information on risk must be presented with the same readability and prominence as the effectiveness and efficacy claim.
- ii. Style, font, size, colour, positioning and appropriate heading of the risk must be similar to those of the effectiveness and efficacy claim.

4.3.5 Promoting uses not addressed and/or included in approved labeling

- i. Off-label uses/permission
- ii. There must be adequate information to enable healthcare professionals to use the product safely and effectively. This information must be included in the labelling approved by the FDA.

4.4 All advertisement and promotion activities shall:

- i. promote products and services on their own merits and highlight those features that members of a target market might find valuable
- ii. promote honesty and accuracy
- iii. be truthful, not deceptive and not unfair
- iv. be devoid of the subtle use of undue influence

4.5 The following must be noted:

- i. Deceitful statements are likely to mislead consumers who act reasonably under normal circumstances and are also likely to affect consumers' purchase decisions in an unhealthy manner.
- ii. Deceptive advertising
 - uses humor as a masking device in order to mislead potential customers; humor provides an escape or relief from some kind of human constraint; some advertisers take advantage by deceptively advertising a product that can potentially alleviate that constraint through humor.
 - appeals to "base" human emotions such as fear, greed or lust. Fear for the audience's health if they do not purchase the product, or rely on

inexplicit and explicit sexual images to generate interest rather than the virtues of the product itself.

- strives to blur the distinction between the product and other similar products by its overall tone and imagery; subsequently capitalizing on the resulting confusion to sell products to customers who may not be able to distinguish between it and an alternate product (that may offer better features)

iii. The use and/or misuse of less-than-ethical yet legal tools including, but not limited to, subliminal advertising, emotional appeals, and taking undue advantage of less educated individuals

iv. Unfair advertisements include those that are likely to cause substantial, unavoidable injury when using a product, unless the injury is outweighed by the provable benefits

5.0 Qualification and Training

5.1 Qualification

In view of the scientific and technical nature of the regulated products under this Code, the FDA requires that all personnel engaged to perform marketing, advertising and promotion activities should have the requisite qualification which would be complimented by periodic training in relevant areas.

Such personnel shall have qualification in any of the applied sciences including, but not limited to, the following, as well as any qualification approved by the Traditional Medicine Practice Council (TMPC), and any other qualifications approved by the Board of the FDA from time to time:

- i. pharmacy
- ii. medicine
- iii. biomedical engineering

- iv. biochemistry
- v. chemistry
- vi. biological sciences
- vii. human biology

5.2 Training

Practitioners shall be periodically trained in the following areas, among others as determined by the FDA

- i. Safety monitoring/Device vigilance
- ii. FDA’s Code of Sales Practice
- iii. Regulatory science

6.0 Grievance Procedures

6.1 Any person, , including healthcare professionals (HCPs), shall report or submit a complaint, in writing, to the Chief Executive Officer (CEO) of the Food and Drugs Authority (FDA), on any suspected infringement or violation of any provision of the Code.

6.2 The CEO, upon receipt of such written complaint, shall cause same to be investigated using the established grievance procedures of the FDA.

6.3 Any aggrieved person dissatisfied with the decision of the Food and Drugs Authority may appeal against same, in writing, to the body appointed by the Chief Executive Officer for such purpose.

7.0 Administrative

A person who contravenes these Guidelines or sections thereof is liable to regulatory sanctions per Sections 119 and 132, Part 7, Act 851, the Public Health Act, 2012 which shall be imposed by the Authority. These sanctions may include, but not limited to, any of the following:

- 5.1 Suspension of the processing of a pending application for advert approval.
- 5.2 Payment of administrative charges as per the Fees and Charges (Amendment) Instrument, 2013, L.I. 2206.

8.0 Penalties

In line with the provisions of Section 129, Part 7, Act 851, the Public Health Act, 2012, a person who contravenes these Codes commits an offence and is liable on summary conviction

- 8.1 to a fine of not less than seven thousand five hundred (7,500) penalty units and not more than Fifteen thousand penalty units (15,000), or
- 8.2 to a term of imprisonment of not less than fifteen years and not more than twenty-five years, or
- 8.3 to both.

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