

VETERINARY MEDICINES DIRECTORATE

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GUIDELINES FOR ADVERTISEMENT OF VETERINARY MEDICINAL PRODUCTS

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Approval

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Approved by			

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Abbreviations ID Identification card

SPC Summary of Product Characteristics

VMD Veterinary Medicines Directorate

VMP Veterinary Medicinal Products

GENERAL INTRODUCTION

This Guideline is intended to complement the provisions of the Veterinary Medicines Directorate (VMD) regulations.

Advertisements give notice and public information with the intent to draw attention and inform. As such they attract consumers to buy products or services and have a direct impact on business. Thus advertisers should be guided by the principles not to take undue advantage whilst laws and regulations are in place to ensure that advertisements contain a high standard of information and the contents are proper and reliable.

Veterinary Medicinal Products (VMP) have potential for beneficial as well as harmful effects and may cause serious problems if not used correctly. All advertising and promotion of VMP must therefore be responsible, ethical and done in a professional manner, as well as be of the highest standard, to ensure their safe and proper use.

Advertising is understood to encompass written or spoken words, and any pictorial representation or design, used or appearing to be used to promote the sale of VMP, generally by highlighting product claims.

The Veterinary Medicines Directorate may add to, delete from or amend the Guideline from time to time.

Advertisements that fall under this Guideline also must comply with any other laws and regulations or guidelines of this country.

DEFINITION

Advertisements include any notice, circular, report, commentary, pamphlet, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound which includes but not limited to print and electronic media.

Advertisements should contain information that is reliable, accurate, truthful, informative, fair, objective, unambiguous, balanced, up-to-date, be capable of substantiation and in good taste. They should not contain any misleading or unverifiable information either directly or by implication that is likely to induce unjustifiable medical use or to give rise to undue risks. It is important that advertisements do not abuse the trust or exploit lack of knowledge among the general public. Advertisements should not lead to self-diagnosis or inappropriate treatment of potentially serious diseases.

Standards of Promotion

An advertisement must present information which is factually correct and not exaggerated. Advertisements should take into account peoples' legitimate desire for information and must encourage the correct and proper use of a VMP and should not be misleading. An advertisement shall be taken to be false or misleading if it falsely describes the VMP, or it is likely to mislead as to the nature or quality of the product of that description or as to their uses or effects, or any reference to a false or misleading representation. Claims made should not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity. Promotional material should be accurate, objective, high ethical standards and be in good taste.

Products Allowed to Be Advertised The VMD regulations stipulates;

- 57. (1) A person who intends to advertise a veterinary medicine, shall make an application to the Council for authority to advertise.
- (2) The Council may, on payment of the requisite fee and subject to such conditions as the Council or these Regulations may impose, grant the authorization applied for under paragraph (1). Advertising standards for veterinary medicines.
- (3) An advertisement for a veterinary medicine shall not be misleading or contain any medicinal claim that is not in the summary of the product characteristics registered with the Council.
- 57 (4) A veterinary medicine listed under Category I and II shall not be advertised unless—(a) in the case of a veterinary medicine listed under Category I, the advertisement is aimed at veterinary surgeons; and (b) in the case of a veterinary medicine listed under Category II, the advertisement is aimed at veterinary surgeons or suitably qualified persons as recognized by the Council.
- (5) A veterinary medicine listed in Category III and IV may be advertised to general members of the public.

Denigration and Disparagement

The products, advertisers or advertisements of other companies should not be disparaged either directly or by implication. Advertisements should not:

- a) contain any statement(s) which either explicitly or by implication ridicules the veterinary profession; or the value of professional attention and treatment; or another product;
- b) discredit or unfairly attack other products, advertisers or advertisements directly or by implication.
- (c) However, comparisons of products from the same registration holder is allowed if substantiated

Misleading Statements

Advertisements should not contain any statement or visual presentation which, whether directly or by implication, is likely to mislead the consumer about any product.

Substantiation

Advertisements should not exploit the ignorance and naivety of the public by including scientific data that the general public cannot comprehend, verify, or validate. All claims, descriptions, and comparisons which relate to matters of objectively ascertainable facts should be capable of substantiation

SOCIAL-RESPONSIBILITY

Celebrity Endorsement

Advertisements may include a recommendation or endorsement by a person who, because of their status as a celebrity, encourage the general public to use a VMP but they must be responsible and accountable to the advertisement. Such advertisements should not, whether directly or by implication, mislead the consumer about the product advertised. The definition of a celebrity taken in this Guideline is an actual person who is very well-known in public life and who, because of their celebrity status, could encourage the consumption of a VMP.

Impressions of Professional Advice or Endorsement Advertisements should not:-

- (a) Have any visual and/or audio presentation of veterinary professionals., which give the impression of professional or scientific advice, recommendation or endorsement; or
- (b) Contain statements giving the impression of professional by scientific advice, endorsement or recommendation made by associations or persons who appear in the advertisements and who are presented either directly or by implication, as being qualified to give such advice, endorsement or recommendation, any expression that provides undue authority that the product is recommended by a veterinary professional. Endorsement by professional bodies may be allowed with the consent from the respective professional bodies. Authorization from said bodies should be given in writing and produced upon demand.

User Testimonials

Advertisement may include testimonials but the individual who give the testimony must genuinely exist and responsible as well as accountable to the advertisement and its testimonials must refer to indications approved. Use of minors is discouraged.

Advertisement containing testimonials by general public must be supported by a consent letter of testimony. The consent letter must include the following:

- 1) Name
- 2) ID/ Passport No
- 3) Signature
- 4) Contact No

Claims and Evidence

Claims must be based on an up to date evaluation (e.g. the most recent available data) of all evidence and must reflect this evidence accurately and clearly including the reference of this substantiating scientific evidence. All claims should be capable of substantiation either by reference to approved labelling or by scientific evidence from properly conducted investigations. Such evidence should be readily available and reproduced upon demand.

Comparative Advertising Comparative claims should:

- a) be made on a factual and fair basis and is capable of substantiation. The intent and connotation of the advertisement should be to inform and not to discredit, disparage, degrade, or attack competitors, competing products or services directly or by implication;
- b) be unambiguous, clearly understandable and should not mislead by distortion, undue emphasis or omissions;
- c) be used for honest comparison purposes and not simply to upgrade by association;
- d) be made clear what comparison(s) is being made;
- e) not make unjustifiable use of the name or initials of any firm, company or institution nor take advantage of the goodwill attached to the trade name or symbol of another firm or its product(s) or the goodwill acquired by its advertising campaign;
- f) not explicitly identify the competitive product, whether by name, brand, name, company, or any form of identification that clearly exposes the identity of the competition;
- g) not state that a product does not contain an active ingredient or ingredients used in competitor products;
- h) not involve the selection of a subject matter of a comparison as to confer an artificial advantage upon the advertiser or so as to suggest that a better bargain is offered that is actually the case;
- i) where appropriate, be supported by documentary evidence that is easily understood
- j) when referring to a competitive test, such tests should have been conducted by an independent and objective body. The test must be supportive of all claims made in the advertisements that are based on the test;
- k) should never use or draw on partial results or stress insignificant results to mislead the consumer to draw an improper conclusion;
- l) should not involve the use of 'baseless' hanging comparatives which merely claim that a product is e.g. "longer-acting", "quicker" or "stronger".

MANDATORY STATEMENT AND WARNING OR CAUTIONARY STATEMENTS

Each advertisement must include approved registration number by the VMD anywhere on the advertisement in a clear manner and a statement: "This is a medicine /pest control product/ supplement / traditional product advertisement" (Select where appropriate).

For an audio advertisement, it is sufficient to mention: "This is a veterinary medicine advertisement approved by the Veterinary Medicines Directorate"

The Chief Executive Officer,

Veterinary Medicines Directorate,

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Applicant's details:				
Applicant's name		• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •
Wholesale Dealer's. No				
Location				
Email address				• • • • • • • • • • • • • • • • • • • •
Cell Phone No				•••••
Superintending Vet				••••••
Product Details:				
Product Name				
Marketing Authorization No.				
Country of Manufacture				
Category				
Formulation				
Uses				
Target Audience				
Form of Advertisement				
Evaluation by the VMD				
The application is	Approved		Not Approved	

ii not approved state reason(s) below.	

Notes:

An application fee of KSh 50,000 per Veterinary Medicine.

If not approved state massam(s) halovy

A sample of the envisaged advertisement should be submitted together with the application

Advertising is any activity that is aimed or designed to promote the sale, supply or use of a veterinary medicine, including electronic advertising but not including price lists.

These activities are considered advertising whether they are for profit or not.

The following Veterinary medicines shall not be advertised:

- > Medicines available on prescription to the general public,
- > Medicines that are not authorised for use in Kenya, including products that do not have an import permit,
- Medicines in a way that they have not been authorised for, for example not in line with the Summary of Product Characteristics (SPC), or in a way that is misleading.

In addition, a veterinary medicine listed under Category I and II shall not be advertised unless—

- (a) In the case of a veterinary medicine listed under Category I, the advertisement is aimed at veterinary surgeons; and
- (b) in the case of a veterinary medicine listed under Category II, the advertisement is aimed at veterinary surgeons or suitably qualified persons as recognized by the Council.

A veterinary medicine listed in Category III and IV may be advertised to general members of the public.

Advertisement of antibiotics should not encourage unnecessary use of these medicines and all advertising material should contain a caption indicating that the prescription and use of the medicine should be in accordance with the responsible use of antibiotics.

Frequently asked questions

How soon can my advertisement be on air? Once evaluation of the advertisement is completed and advertisement approval granted

What constitutes advertisement? Any electronic or print media messaging