

**The South African**

**Code of**

**Marketing Ethics**

**For**

**Veterinary  
Pharmaceuticals**

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## **A. Introduction.**

### **1. Aims and Objectives**

This code aims at promoting and applying marketing practices, that are accurate, unambiguous factual and fair.

Furthermore, the objective of this Code of Practice for the Marketing of Veterinary Pharmaceuticals in South Africa is to ensure that the marketing of veterinary pharmaceuticals to veterinary and allied professionals and the general public is carried out in a responsible, ethical and professional manner, based on practical and scientifically validated information. It also aims to ensure that marketing activities encourage the rational use of veterinary medicines by veterinary and allied professionals and the general public.

### **2. Promoting Health**

The National Department of Health, The Department of Agriculture, the Animal Health industry and other stakeholders are committed to the provision of quality health care for all South Africans and the Animal population. High quality, effective and accessible medicines are a cornerstone of healthcare. Accurate information about veterinary pharmaceuticals and ethical business practices is integral to providing affordable quality animal health services.

The veterinary pharmaceutical industry provides a wide range of effective, quality veterinary pharmaceuticals that ultimately, bring health and economic benefits both to agriculture and the nation.

### **3. Scope**

All companies or individuals who supply Veterinary Pharmaceuticals in South Africa which are subject to registration by the Medicines or Stock Act are bound by this code, Measures will be applied against a company or individual ruled in breach of the Code.

Advertising and promotional material that are subject to the Code include:

1. Advertorials
2. Aerial promotions such as hot air balloons
3. Booklets
4. Cinema commercials
5. Consumer leaflets
6. Direct mail materials
7. Internet materials, including press releases intended for internet publication
8. On-pack statements
9. Outdoor advertising
10. Point of sale materials
11. Posters
12. Print advertisements
13. Promotional aids
14. Sales promotions
15. Telephone help lines
16. Television and radio commercials
17. Sports, art and other sponsorships

Advertising does not include factual, accurate, informative announcements and reference material concerning registered medicines and relating, for example, to adverse reaction warnings, trade catalogues and price lists provided they include no product claims, measures or trade practices relating to prices, margins or discounts.

Legal labeling requirements and package inserts are subject to the Medicines and Stock Acts requirements .

#### 4. Ensuring high standards

High standards of marketing practice are essential and in the best interests of veterinary professionals, patients and consumers.

All companies involved in the marketing of veterinary pharmaceuticals are obliged to ensure that all relevant personnel be appropriately trained on the requirements of the Code and to have effective internal procedures under which promotional material and activities are reviewed. This is to ensure compliance with the letter and spirit of the Code and the appropriate legal requirements.

The provisions of the Code apply in their entirety to the promotion of veterinary pharmaceuticals to appropriate administrative staff except where the text indicates otherwise.

### B. Definitions

“**Advertisement**”, in relation to any veterinary pharmaceutical, means any written, pictorial, visual or other descriptive matter or verbal statement or reference:

- (a) Appearing in any newspaper, magazine, pamphlet or other publication; or
- (b) Distributed to members of the public; or
- (c) Brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that veterinary remedy; and “advertise” has a corresponding meaning;

“**Company**” may refer to a company, closed corporation, organisation or individual who may sell or promote veterinary pharmaceuticals.

‘**Veterinary profession**’ includes members of the Veterinary and para-veterinary professions and any other persons who in the course of their professional activities may prescribe, supply or administer a prescription remedy.

“**Veterinary professional**” is a person who provides a veterinary service and is registered with a statutory Council as such.

“**Medicines Act**“ means Act 101 (1965) as amended, and includes the Regulations.

“**Prescription**” means a written instruction from a veterinarian to an authorised supplier, for the supply of a veterinary pharmaceutical to a third person, who under normal circumstances would not be permitted to be in possession of such veterinary pharmaceutical.

“**Prescription Veterinary Pharmaceutical**” means a prescription veterinary medicine or a stock remedy that carries the restriction “For use by or under the control of a veterinarian or a person registered in terms of the Veterinary and Para-Veterinary Professions Act”.

**"Representative"** means a company representative or an agent of the company calling on members of the veterinary professions and administrative staff, co-operatives, farmers and consumers in relation to the promotion of veterinary pharmaceuticals.

**"Promotion"** means any activity undertaken by or on behalf of any company or person, which promotes the prescribing, supply, sale or use of its veterinary pharmaceuticals. It includes:

1. Media advertising
2. Direct mail advertising
3. The activities of representatives including detail aids and other printed material used by representatives.
4. The provision of information to the general public either directly or indirectly and all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, radio, television, the Internet, cell phone (SMS), electronic media, interactive data systems and the like
5. The provision of inducements to prescribe, supply, administer, recommend or buy veterinary medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind, is not permitted under the Medicines Act.
6. The supply of samples of veterinary medicines to veterinary professionals is not permitted under the Medicines Act.

It does not include:

1. Replies made in response to individual enquiries from members of veterinary professions or appropriate administrative staff or in response to specific communications whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature.
2. Factual, accurate, informative announcements and reference material concerning registered veterinary pharmaceutical and relating, for example, to pack changes, adverse reaction warnings, trade catalogues and price lists, provided they include no product claims, measures or trade practices relating to prices, margins or discounts.
3. Package inserts, the contents of which are determined by regulations made under the Medicines and Stock Acts and summaries of product characteristics, the labelling on veterinary pharmaceutical and accompanying package leaflets insofar as they are not promotional for the veterinary remedies concerned; the contents of labels and package inserts are covered by regulations statements relating to veterinary health or diseases provided there is no reference either direct or indirect, to specific veterinary pharmaceutical.
4. Un-sponsored and unsolicited editorial in any media.

**"SAAHA"** means the South African Animal Health Association.

**"Stock Act"** means Act 36 of 1947 as amended, and includes the Regulations

**"Stock Remedy"** means a stock remedy as defined in Act 36 (1947).

**"Trade Dress"** means overall appearance or image of a product as discerned by the eye, including but not limited to trade marks, slogans, colours, graphs logos, tables, and other information, and label or package lay out.

**"Veterinary Medicine"** means a veterinary medicine as defined in Act 101 (1965).

“**Veterinary Pharmaceutical**” is a general term which includes a veterinary medicine and a stock remedy.

## **C. General Code of Conduct**

### **1. Registration**

- 1.1 Veterinary Pharmaceuticals must not be promoted prior to the product obtaining registration from either the Medicine or Stock Act, which permits its sale, supply and use in South Africa.
- 1.2 The promotion of a registered Veterinary Pharmaceutical must be in accordance with the terms of its registration and must be consistent with the particulars listed in the approved package insert (Act 101/1965) or label (Act 36/1947).
- 1.3 The legitimate exchange of medical and scientific information during the development of a veterinary pharmaceutical, including un-sponsored editorial in the public media is not prohibited provided that any such information or activity does not constitute promotion, which is prohibited under this or any other clause.

### **2 Advertising**

- 2.1 Advertising shall be balanced, true and shall not mislead or contain any exaggerated claims, either direct or implied. All advertising must be consistent with the requirements of the Medicines or Stock Act, where relevant
- 2.2 Advertising shall not cause animal owners unwarranted anxiety that their animals are suffering from any ailment.
- 2.3 Advertising shall not show children under ten years of age handling, veterinary pharmaceuticals without adult supervision.
- 2.5 Advertising shall not offer to diagnose, advise, prescribe or treat personally by correspondence.
- 2.6 Advertising shall not claim, or imply, that a product’s effects are guaranteed.
- 2.7 Advertising can refer to the prevention of signs and use of a product in chronic conditions, if in accordance with the registered indication. However, as with all advertising for non-prescription Veterinary Pharmaceuticals, care should be taken not to encourage either directly or indirectly, the indiscriminate, unnecessary or excessive use of any veterinary pharmaceutical.
- 2.8 Advertising shall use language, which can be understood by the animal owner, or veterinary professional, where applicable.
- 2.9 The use of medical terminology is acceptable. Care must be taken that this does not confuse or mislead the animal owner if applicable.
- 2.10 Advertising shall be clearly distinguished from editorial matter.

- 2.11 Advertising shall not suggest that a veterinary consultation or surgical operation is unnecessary nor shall it discourage animal owners from seeking veterinary or pharmaceutical advice.
- 2.12 Advertising shall not be misleading as to the nature of the product, its ingredients or indication.
- 2.13 Advertising shall not contain or imply improper, alarming or misleading claims of an animal's recovery.
- 2.14 Advertising shall not contain recommendation of a product by scientists or veterinary professionals unless substantiated.
- 2.15 Advertising shall not include a recommendation by a person who, by virtue of their celebrity, status may encourage consumers to use veterinary Pharmaceuticals.
- 2.16 Examples of misleading advertising would include the following:
- suggestion that the product is a foodstuff, cosmetic or other non-medicinal product.
  - Suggestion that a product is free of side-effects. It is however acceptable to highlight the absence of a specific side effect.
  - Advertising should not refer to a 'college' veterinary 'hospital' 'clinic', 'institute', 'laboratory' or similar establishment unless the establishment genuinely exists.
- 2.17 Advertising shall not state that a product does not contain an active ingredient or ingredients used in competitor products other than permitted by the relevant regulatory authority.
- 2.18 Advertising shall not use misleading or improper visuals to represent changes in the animal body.
- 2.19 It is acceptable to state that a product's active ingredients, formulations or preparations have been used or prescribed by a veterinary professional, provided that there is evidence that this is the case and that it does not contravene the product's conditions of registration.

### **3 Information in advertising**

- 3.1 All advertising must be consistent with the provisions of the Medicines or Stock Act as applicable and should contain at least the following information:
- The statement "Veterinary Medicine" ,, in the case of veterinary medicines, or "For animal use only" in the case of stock remedies.
  - the name of the veterinary pharmaceutical (which may be a proprietary name but should always include the approved name)
  - a quantitative list of the active ingredients, using approved names where such exist;
  - at least one registered indication for use consistent with the package insert
  - any warning issued by the Medicines Control Council or Act 36, which is required to be included in advertisements
  - The scheduling status and pharmacological classification of the product (as determined by MCC or Stock Act where applicable)
  - The registration number and the name and address of the registered licence holder or the name and address of the part of the business responsible for its sale or supply.
  - A statement as to where full information relating to the product in question can be found.



- 3.2 In addition, the approved name of the veterinary pharmaceutical and a list of the active ingredients using approved names where such exist must appear in legible type.
- 3.3 In the case of promotional material included on the Internet, there must be a clear, prominent statement as to where the required information can be found.
- 3.4 Legibility of required Information  
The required information must be provided in promotional material in a clear and legible manner that assists readability.
- 3.5 Electronic Journals  
The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the required information can be found.
- 3.6 Promotional items that feature only the brand name and no other promotional copy are acceptable provided that such advertising conforms with the spirit of the Code and that no claims are made for the product.

#### **4 Information, Claims and Comparisons**

- 4.1 Upon reasonable request, companies must promptly provide members of the veterinary and allied professions and appropriate administrative staff as well as farmers and members of the public, with accurate and relevant information about the veterinary pharmaceuticals that the company markets.
- 4.2 Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication.
- 4.3 A comparison involving generic active ingredient names is only permitted in advertising or promotional material if:
- it is not misleading.
  - Veterinary Pharmaceuticals or services for the same needs or intended for the same purpose are compared;
  - one or more material, relevant, substantiable and representative features are compared;
  - no confusion is created between the veterinary pharmaceutical advertised and that of a competitor.
  - the trademarks, proprietary names, other distinguishing marks, veterinary pharmaceutical, services, activities or circumstances of a competitor are not displayed.
  - Veterinary pharmaceuticals or services are not presented as imitations or replicas of goods or services bearing a competitor's trademark or trade name.
  - in cases where comparisons are made in accordance with the above, reference(s) to the publication(s) from which the comparisons were derived must be given. Such publications must be peer reviewed by independent experts.
  - companies may refer to the "standard" or "reference" product if such comparisons are made;
  - comparisons such as "best", "biggest", will under no circumstances be allowed.
- 4.4 Any information, claim or comparison must be capable of technical substantiation.
- 4.5 Substantiation for any information, claim or comparison must be provided without delay at the request of the SAAHA. It need not be provided, however, in relation to the validity of indications approved in the product registration

- 4.6 When promotional material refers to published studies, clear and complete references must be given.
- 4.7 All artwork including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made
- 4.8 Information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side effects, or toxic hazards. The word 'safe' must not be used without qualification.
- 4.9 Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a veterinary pharmaceutical. Claims should not imply that a veterinary pharmaceutical or an active ingredient has some special merit, quality or property unless this can be substantiated.
- 4.10 The word 'new' or the abbreviation NF (new formulation) must not be used to describe any product or presentation, which has been generally available, or any therapeutic indication, which has been available for more than twelve months in South Africa unless 'NF' is incorporated into the products name due to historical reasons.
- 4.11 The only acceptable meaning of the abbreviation LA is "Long Acting". Such abbreviation may only be applied if so authorised by the relevant regulatory authority.
- 4.12 Advertising shall not suggest, directly or indirectly, that a product contains an unknown active ingredient.
- 4.13 A product, or any of its attributes, shall not claim to be unique unless substantiated.
- 4.14 Advertising shall not mislead about the novelty of a preparation.
- 4.15 Advertising claims relating to speed of absorption, dissolution, distribution or other pharmacokinetic particulars are acceptable if supported by evidence and if in accordance with the product's registration approved dossier. However, such evidence may not be extrapolated to claims that a product offers improved efficacy or speed of efficacy, without supporting evidence to substantiate such claims.
- 4.16 Advertising shall not suggest that the safety or efficacy of a product is due to the fact that it is natural unless this has been proven to accepted industry standards.
- 4.17 Advertising shall not claim that a product is 'natural' unless all of its active components are naturally occurring. 'Natural' can be used to describe those elements which are naturally occurring eg 'natural ingredient'.
- 4.18 Advertising shall not suggest that a product is herbal, unless all the active ingredients are plants or extracts of plants.
- 4.19 Advertising shall not unfairly denigrate or discredit, either directly or by implication, a competitor product, ingredient or treatment.

- 4.20 Superiority claims shall not be used, unless supported by direct comparative tests or other demonstrations.
- 4.21 Advertisements shall not contain any statement or visual presentation which, directly or by implication, omission, ambiguity or exaggerated claim., is likely to mislead the buyer, in particular with regard to the safety of the product, its nature, composition or suitability for use, or official recognition or approval;
- 4.22 Advertising must not encourage uses other than those specified on the approved label or package insert.
- 4.23 Promotional material must not include use recommendations at variance with those of recognized research and advisory agencies; unless substantiated.
- 4.25 Misleading statements are not to be made concerning the effectiveness of the product;
- 4.26 Advertisements are not to contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, use near food, or use by or near children;
- 4.27 Advertising or promotional material must draw attention to the appropriate warning phrases and symbols as laid down in the labelling guidelines;
- 4.28 Technical literature must provide adequate information on correct practices, including the observance of recommended rates, frequency of applications, and safe withdrawal periods;
- 4.29 Advertisements must encourage users to read the label carefully, or have the label read to them if they cannot read.
- 4.30 No advertisements or promotion should encourage the use of empty containers of veterinary pharmaceuticals for containment of any other material or product.
- 4.31 No advertisement or promotion of a veterinary pharmaceutical should encourage the decanting of veterinary pharmaceuticals, except by a pharmacist or veterinarian.

## 5 Misleading Information, Claims and Comparisons

The following are areas where particular care should be taken by companies:

- **claims for superior potency in relation to weight** are generally meaningless and best avoided unless they can be linked with some practical advantage, for example, reduction in side-effects or cost of effective dosage;
- **economic evaluation of veterinary pharmaceuticals.** Care must be taken that any claim involving the economic evaluation of a veterinary pharmaceutical is borne out by the data available and does not exaggerate its significance. To be acceptable as the basis of promotional claims, the assumptions made in an economic evaluation must be clinically appropriate and consistent with the product registration.
- **Guarantees.** No guarantees or implied guarantees - e.g. "more profits with..." "guarantees high yields" - are to be made, unless definite evidence to substantiate such claims is available

- **emerging clinical or scientific opinion.** Where a clinical or scientific issue exists that has not been resolved in favour of one generally accepted viewpoint, particular care must be taken to ensure that the issue is treated in a balanced manner in promotional material. A systematic review of the debate must be available upon request;
- **hanging comparisons** whereby a veterinary pharmaceutical is described as being better or stronger or suchlike without stating with which the veterinary pharmaceutical is compared, must not be made; in addition to being substantiated as required in paragraph 4.4.
- **price comparisons.** Price comparisons, as with any comparison, must be accurate, fair and must not mislead. A valid comparison can only be made where a price comparison is made on the basis of the therapeutically equivalent dosage requirement for the same indications.
- **Statistical information.** Care must be taken to ensure that there is a sound statistical basis for all information, claims and comparisons in promotional material. Differences that do not reach statistical significance must not be presented in such a way as to mislead. Instances have occurred where claims have been based on published papers in which the arithmetic and/or statistical methodology was incorrect. Accordingly, before statistical information is included in promotional material it must have been subjected to statistical appraisal. Care should also be taken if there is statistical significance but no obvious clinical significance.

## 6. **Artwork, Illustrations, Graphs and Tables**

- Care must be taken to ensure that artwork does not mislead as to the nature of a veterinary pharmaceutical or any claim or comparison and that it does not detract from any warnings or contra-indications.
- Particular care should be taken with graphs and tables to ensure that they do not mislead, for example by their incompleteness or by the use of suppressed zeros or unusual scales.
- Differences that do not reach statistical significance must not be presented in such a way as to mislead.
- Graphs and tables must be adequately labelled so that the information presented can be readily understood. If a graph, table or suchlike is taken from a published paper but has not been reproduced in its entirety, the graph must clearly be labelled as having been adapted from the paper in question Any such adaptation must not distort or mislead as to the significance of that graph, table etc. It should also be noted that if a table, graph etc in a paper is unacceptable in terms of the requirements of the Code, because, for example, it gives a visually misleading impression as to the data shown, then it must not be used or reproduced in promotional material.

## 7. **Use of the word 'safe' and similar terminology**

- 7.1 The restrictions on the word 'safe' apply equally to grammatical derivatives of the word such as 'safety'. For example, 'demonstrated safety' or 'proven safety' are prohibited under this Clause, unless so approved by the regulatory authority.
- 7.2 Claims as to safety, including statements such as "safe", "non poisonous", "harmless", "non-toxic", are not to be made regarding pesticides;
- 7.3 The word "safe" and its derivatives must not be used without qualification. Information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience.
- 7.4 It must not be stated that a product has no side effects.

## **8 Superlatives**

Superlatives are those grammatical expressions that denote the highest quality or degree, such as best, strongest, widest etc. A claim that a product was ‘the best’ treatment for a particular condition, for example, could not be substantiated as there are too many variables to enable such a sweeping claim to be proven. The use of a superlative which could be substantiated is a simple statement of fact that can be very clearly demonstrated may be used, such as that a particular veterinary pharmaceutical is the most widely used in South Africa for a certain condition, if this is not presented in a way that misleads as to its significance.

## **9 Use of the Words ‘The’ and ‘Unique’**

In certain circumstances the use of the word ‘the’ can imply a special merit, quality or property for a veterinary pharmaceutical that is unacceptable under this clause if it cannot be substantiated by scientific and refereed publications. For example, a claim that a product is ‘The anthelmintic’ implies that it is in effect the best, and might not be acceptable under this clause.

Similarly, great care needs to be taken with the use of the word ‘unique’. Although in some circumstances the word unique may be used to describe some clearly defined special feature of a veterinary pharmaceutical, in many instances it may simply imply a general superiority. In such instances it is not possible to substantiate the claim, as the claim itself is so ill defined.

## **10 Disparaging References**

- 10.1 The veterinary pharmaceuticals, products and activities of other veterinary pharmaceutical companies must not be disparaged.
- 10.2 The veterinary professions and the clinical and scientific opinions of their members must not be disparaged.
- 10.3 Much veterinary advertising contains comparisons with other products and, by the nature of advertising; such comparisons are usually made to show an advantage of the advertised product over its competitor. Provided that such critical references to another company’s products are accurate, balanced, fair etc, and can be substantiated, they are acceptable under the Code.
- 10.4 Such references must not mislead either directly or by implication or omission.
- 10.5 Unjustified knocking copy in which the products or activities of a competitor are unfairly denigrated is prohibited under this clause.
- 10.6 Attention is drawn to the requirements for comparisons set out in Clause 4.3.

## **11 Suitability and Taste**

- 11.1 The name or photograph of a member of a veterinary or allied profession must not be used in any way that is contrary to the conventions of that profession.
- 11.2 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.
- 11.3 Promotional material must not include any reference to the regulatory authority unless this is specifically required by the regulatory authority, or approved by the regulatory authority.

- 11.4 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

## **12. Prescription Veterinary Pharmaceuticals**

The special nature of prescription Veterinary Pharmaceuticals and the professional audience to which the material is directed require that the standards set for the promotion of prescription Veterinary Pharmaceuticals are higher than those that might be acceptable for general commodity advertising.

It follows therefore that certain types, styles and methods of promotion even where they might be acceptable for the promotion of products other than these Veterinary Pharmaceuticals are unacceptable.

These include:

- The use or display of sexual imagery for the explicit purpose of attracting attention to the material;
- The provision of private prescription forms pre-printed with the name of a veterinary pharmaceutical.

## **13 Disguised Promotion**

- 13.1 Promotional material and activities must not be disguised.
- 13.2 Market research activities, post-marketing surveillance studies, clinical assessments and the like must not be disguised promotion, nor contain or lead to disparaging comments about competitors or their products.
- 13.3 Advertisements in published media must not resemble editorial matter, unless such advertisements are clearly labelled as being “Advertorial”. Care must also be taken with company-sponsored reports on meetings and the like to ensure that they are not disguised promotion.

## **14 Provision of Reprints and the Use of Quotations**

- 14.1 Advertising and promotional material should be clearly distinguished from editorial matter.
- 14.2 Quotations from veterinary and scientific literature must accurately reflect the meaning of the author(s). If unpublished, “personal communications” shall not be used unless the company is able to supply a written substantiation upon request.
- 14.3 Any quotation chosen by a company for use in promotional material must comply with the requirements of the Code itself. For example, to quote from a paper that stated that a certain veterinary pharmaceutical was ‘safe and effective’ would not be acceptable even if it were an accurate reflection of the meaning of the author of the paper, as it is prohibited under Clause 7 of the Code to state without qualification in promotional material that a veterinary pharmaceutical is safe.
- 14.4 Care should be taken in quoting from any study or the like to ensure that it does not mislead as to its overall significance. (See Clause 5) which prohibits misleading information, claims etc in promotional material).

- 14.5 Quotations relating to veterinary pharmaceuticals taken from public broadcasts, for example radio, television or Internet, and from private occasions, such as veterinary conferences or symposia, must not be used without the written permission of the speaker.
- 14.6 Testimonials should be less than 3 years old and be the genuine views of the user.
- 14.7 Promotional material should not include a recommendation by a person who, because of their celebrity status, may encourage consumers to use a veterinary remedy. A veterinary professional or celebrity should not be identified as the writer of a testimonial.
- 14.8 The utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned. If there is any doubt as to the current view of an author, companies should check with the author prior to its use in promotional material.
- 14.9 When promotional material refers to published studies, clear references must be given to where such studies can be found.

## **15 Certification of Promotional Material**

- 15.1 Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by two persons on behalf of the company, to the effect that such material complies with this code. Each company should have a Standard Operating Procedure for this process, which must be available for audit by regulatory authorities.  
One of the two persons must be a registered veterinarian or a responsible pharmacist. The other must be an appropriate senior official of the company.
- 15.2 All promotional material must be certified in this way including promotional aids, audio-visual material, promotional material on databases, Internet websites and veterinary representatives' technical briefing materials.
- 15.3 Other material issued by companies that relates to veterinary pharmaceuticals but which is not intended as promotional material for those veterinary pharmaceuticals per se, for example corporate advertising, press releases, market research material, financial information to inform shareholders, the stock exchange and the like, and educational material for animal owners etc, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.
- 15.4 Account should be taken of the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the Code.
- 15.5 In certifying audio, audio-visual material and material used on interactive data systems or Internet, all companies must ensure that a written transcript of the material is certified including reproductions of any graphs, tables and the like that appear in the recording. In the event of a complaint, a copy of the written transcript of the material will be requested.

## **16 Distribution of Promotional Material**

- 16.1 Promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed. Promotional material should be tailored to the audience to whom it is directed
- 16.2 Mailing lists must be kept up-to-date. Requests from veterinary professionals to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at their request or with their permission.

## **17. Product Development**

The legitimate exchange of medical and scientific information during the development of a veterinary pharmaceutical is not prohibited provided that any such information or activity does not constitute promotion, which is prohibited under this or any other clause.

## **18. Promotion at International Conferences**

The promotion of veterinary pharmaceuticals at international meetings held in South Africa may on occasion pose certain problems with regard to veterinary pharmaceuticals or indications for veterinary pharmaceuticals, which do not have a registration in South Africa although they are so authorised elsewhere. The display and provision of promotional material for such unregistered veterinary pharmaceuticals is not permitted in South Africa, whether the meeting is national or international in nature unless specific permission has been granted by the relevant Registrar.

## **19. Unauthorised Indications**

The promotion of “off-label” indications, unregistered in South Africa, is prohibited. This does not preclude discussing the merits of such unregistered, “off-label” indications in proper scientific discussions.

## **20 Information Claims and Comparisons**

- 20.1 When promotional material refers to (unpublished) data on file, the relevant part of this data must be provided without delay at the request of members of the veterinary professions or appropriate administrative staff.

## **21. Market Research**

- 21.1 Market research is the collection and analysis of information and must be unbiased and non-promotional. The use to which the statistics or information is put may be promotional. The two phases must be kept distinct. Approval by an Ethics Committee and, where required, approval by MCC or Act 36, must be obtained for post-marketing trials.
- 21.2 Market research material should be examined before publication or use to ensure that it does not contravene the Code, as required in paragraph 15.

## **22 Samples**

- 22.1 The Medicines Act does not permit sampling of veterinary medicines.
- 22.2 The supply of samples of veterinary medicines for promotional purposes is not permitted under the Medicines Act. The supply of veterinary medicines for exhibition purposes may be permitted under Act 101 (1965). Provision of samples to MCC or drug inspectors is,



however, permitted in the normal function of their duties. Samples are also permitted for compassionate use programmes or for clinical trial purposes.

- 22.3 Donations of Veterinary Medicines to Registered Welfare organisations are permitted.

## **23 Gifts and Inducements**

- 23.1 No gift, benefit in kind, , discount, kickback or any other pecuniary advantage shall be offered or given to members of the veterinary professions, administrative staff, government officials, or the general public as an inducement to inappropriately prescribe, supply, stock, dispense, administer or buy any veterinary medicine, subject to the provisions of Clause 23.2.
- 23.2 Clause 23.1 does not prevent the provision of medical and educational goods and services, which will enhance animal care or benefit the South African Animal Health System.

## **24 Educational Goods and Services**

The following guidance is intended to assist companies in relation to veterinary and educational goods and services.

The role of veterinary representatives in relation to the provision of goods and services supplied needs to be in accordance with the principles set out below. In this context companies should consider using staff other than veterinary representatives.

- 24.1 Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.
- a.) Service providers must operate to detailed written instructions provided by the company. It is recommended that these should be similar to the briefing material for veterinary representatives as referred to in Clause 33.5 of the Code. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed etc should be included. The written instructions must not advocate, either directly or indirectly, any course of action that would be likely to lead to a breach of the Code.
  - b.) Service providers must abide by the principle set out in Clause 33 of the Code that in an interview, or when seeking an appointment, reasonable steps must be taken to ensure that they do not mislead as to their identity or that of the company they represent.
  - c.) Any printed material designed for use in relation to the provision of veterinary and educational goods and services must be non-promotional. It is not acceptable for such materials to promote the prescription, supply, sale or administration of the sponsoring company's veterinary medicines. Nor is it acceptable for materials to criticise competitor products as this might be seen as promotional. All printed materials must identify the sponsoring veterinary company.
  - d.) Materials relating to the provision of veterinary and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and printed material etc, must be examined by the Code signatories within companies to ensure that the requirements of the Code are met as

recommended in Clause 15 of the Code. A copy of the materials must be made available to the Authority on request.

- e). Companies are recommended to inform relevant parties such as veterinary authorities, and animal welfare organisations of their activities where appropriate. This is particularly recommended where companies are proposing to provide veterinary and educational goods and services, which would have budgetary implications for the parties involved. For example the provision of a screening service for a limited period might mean that funds would have to be found in the future when company sponsorship stopped.
- 24.2 Gifts in the form of promotional aids and prizes, whether related to a particular veterinary medicine or of general utility, may be distributed to members of the veterinary professions and to appropriate administrative staff, provided that the gift or prize is inexpensive and relevant to the practice of their profession or employment. For the purposes of this clause, “inexpensive” means that the value of the gift, promotional aid or prize, shall not be more than twenty percent (20%) of the value of product purchased or promoted.
- 24.3 The required information for a veterinary pharmaceutical as required under clause 3 does not have to be included on a promotional aid if the promotional aid includes no more than the following about the veterinary pharmaceutical:
- The name of the veterinary pharmaceutical
  - An indication that the name of the veterinary pharmaceutical is a trade mark
  - The name of the company responsible for marketing the product.

## **25 Terms of Trade**

Schemes, which enable veterinary professionals to obtain personal benefits, for example gift vouchers in relation to the purchase of veterinary medicines are acceptable, provided that the value of the gift, voucher, shall not be more than twenty percent (20%) of the value of product purchased. .

## **26 Package Deals**

Clause 25 does not prevent the offer of package deals whereby the purchaser of particular veterinary medicines receives with them other associated benefits, such as apparatus for administration, provided that the transaction as a whole is fair and reasonable and the associated benefits are relevant to the veterinary medicines involved, and the value is appropriate to the cost of the package.

## **27 Donations to Charities**

Donations to charities made by companies in return for veterinary professionals’ attendance at company stands at meetings or offered as rewards for completing and returning quiz cards in mailings and such like are not necessarily unacceptable under this clause, provided that the level of donation for each individual is modest, the money is for a reputable charity and any action required of the veterinary professional is not inappropriate. Any donation to a charity must not constitute a payment that would otherwise be unacceptable under the Code. For example, it would not be acceptable for a representative to pay into a practice equipment fund set up as a charity as this would be a financial inducement prohibited under Clause **23.1**.

Donations to charities in return for veterinary representatives gaining interviews are also prohibited under Clause 23 of the Code. Any offer by a company of a donation to a charity, which is conditional upon some action by a veterinary professional must not place undue

pressure on the veterinary professional to fulfil that condition. At all times the integrity of the industry must be kept in mind.

## **28 Competitions and Quizzes**

The use of competitions, quizzes and suchlike for the purposes of sales promotion of a veterinary medicine is not necessarily an unacceptable form of promotion. Any competition must, however, be in good taste and must not involve any subject matter that is inappropriate for the promotion of a veterinary remedy. A competition is more likely to be considered acceptable if its subject matter is clearly related to the animal health.

Any competition used for promotional purposes must be a bona fide test of skill and must recognise the professional standing of the recipients.

The provisions of Clause 23.3 apply to the provision of competition prizes. Prizes of a higher value than would ordinarily be acceptable for a promotional aid are acceptable where the competition is a serious one and the prizes are few in number, relevant to the potential recipient's work and not out of proportion to the skill required in the competition.

## **29 Gifts to or for use by animal owners or animals**

Some items distributed as promotional aids are intended for use by animal owners or animals and these are acceptable provided that they meet the requirements of Clause 23.3.

Other items that may be made available to animal owners, for example by completing a request card enclosed with a veterinary pharmaceutical, should meet the relevant principles set out in Clause 23, that is they should be inexpensive and related to either the condition under treatment or general health. Care must be taken that any such activity meets all the requirements of the Code.

## **30. Scientific Information Service**

All companies must compile and collate all information about the veterinary pharmaceuticals that they market, and must be able to provide such information to authorities, members of veterinary professions or the general public, where appropriate. This must include information about adverse drug reactions.

## **31. Joint Ventures and Co-Promotion**

31.1 In a joint venture in which a third party provides a service on behalf of a number of veterinary companies, the responsibility for any activity carried out by that third party on their behalf remains that of the veterinary companies.

31.2 It follows therefore that the veterinary companies involved should be aware of all aspects of the service carried out on their behalf and take this into account when certifying the material or activity involved.

31.3 Under co-promotion arrangements whereby companies jointly promote the same veterinary pharmaceutical and the promotional material bears both company names, each company should certify the involved promotional material, as they will be held jointly responsible for it under the Code.

### **32. Retention of Documentation**

Companies should note that the relevant local regulatory authority is entitled to request particulars of an advertisement, including particulars as to the content and form of the advertisement, the method of dissemination and the date of first dissemination, and such a request is not subject to any time limit. This does not apply to the certificates themselves in respect of which the three-year limit is applicable.

### **33. Veterinary Representatives**

33.1 Veterinary representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide accurate information about the veterinary pharmaceuticals that they promote.

33.2 Veterinary representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code.

33.3 Donations to Charities

Donations to charities in return for veterinary representatives gaining interviews are prohibited.

Veterinary Representatives must always endeavour to treat veterinary professionals' time with respect and give them no cause to believe that their time might have been wasted. If for any unavoidable reasons, an appointment cannot be kept, the longest possible notice must be given.

33.4 All company representatives must transmit forthwith to the scientific service referred to in Clause 30 any information that they receive in relation to the use of the veterinary Pharmaceuticals that they promote, particularly reports of side effects and adverse drug reactions.

33.5 Companies must prepare detailed briefing material for veterinary representatives on the technical aspects of each veterinary remedy that they will promote. A copy of such material must be made available to the relevant regulatory authority upon request. Briefing material must comply with the relevant requirements of the Code, and is subject to the certification requirements of Clause 15. Briefing material must not advocate, either directly or indirectly, any course of action that would be likely to lead to a breach of the Code.

33.6 Companies are responsible for the activities of their veterinary representatives if these are within the scope of their employment even if they are acting contrary to the instructions that they have been given.

33.7 All provisions in the Code relating to the need for accuracy, balance, fairness, good taste etc apply equally to oral representations as well as to printed material. Veterinary representatives must not make claims or comparisons that are in any way inaccurate, misleading, disparaging, in poor taste etc, or which are outside the terms of the product registration, unless substantiated and only to veterinary professionals, for the veterinary pharmaceutical.

### **34 Contract Representatives and Agents**

Companies employing or using contract representatives or agents are responsible for their conduct and must ensure that they comply with the provisions of this and all other relevant clauses in the Code, and in particular the training requirements under Clause 35

## **35 Training**

- 35.1 All personnel including members of staff concerned in any way with the preparation or approval of promotional material or of information to be provided to members of South African veterinary professions and to appropriate administrative staff or of information to be provided to the public must be fully conversant with the requirements of the Code.
- 35.2 Extensive in house training on the Code should be given by companies and SAAHA.
- 35.3 Veterinary Representatives must pass appropriate examinations, in line with SAQA requirements, within 2 years of commencing employment as a veterinary representative. Upon completion of such training, veterinary representatives will receive a certificate and their names will be entered into a Register. Additionally, representatives in the employ of SAAHA member companies, will be issued with a card confirming that such training has been completed. The validity of such card will be subject to regular review.

In the event of extenuating circumstances, such as prolonged illness, the company may agree to the continued employment of a person as a representative past the end of the two-year period, subject to the representative passing the examination within a reasonable time.

Companies are reminded about the Labour Relations Act. It is suggested that the requirement of passing the veterinary representative exam within a specified time period, should be mentioned in their contracts.

- 35.4 The following exemptions apply in relation to Clause 35.3:
- Persons with not less than 15 years demonstrable continuous employment as veterinary representatives on 31 December 1993.
  - Persons with an acceptable professional qualification, for example in pharmacy or veterinary science, are exempt from the need to take the Veterinary Representatives Examination

## **36. Relations with the General Public and the Media**

- 36.1 Veterinary Pharmaceuticals must not be advertised to the general public if they are prescription Veterinary Pharmaceuticals or are Veterinary Pharmaceuticals, which, though not prescription only, may not legally be advertised to the general public.
- 36.2 Information about veterinary pharmaceuticals that is made available to the general public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.  
Statements must not be made for the purpose of encouraging members of the public to ask their veterinarians to prescribe a specific medicine.
- 36.3 Companies are responsible for information about their products issued by their public relations agencies.
- 36.4 The advertising of prescription veterinary pharmaceuticals to the general public is prohibited by regulations under the Medicines Act 1965 and the Stock Act.

### **37. Information to the General Public**

- 37.1 This clause allows for the provision of non-promotional information about prescription Veterinary Pharmaceuticals to the general public either in response to a direct inquiry from an individual, including inquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like. It also includes information provided by means of posters distributed for display in surgery waiting rooms etc.
- 37.2 Any information so provided must observe the principles set out in this clause, that is, it should be factual, balanced and must not be made for the purpose of encouraging members of the public to ask their veterinarians to prescribe a specific prescription remedy. It must not constitute the advertising of veterinary pharmaceuticals to the general public prohibited under Clause 2.
- 37.3 Particular care must be taken in responding to approaches from the media to ensure that the provisions of this clause are upheld.
- 37.4 In the event of a complaint which relates to the provisions of this clause, companies will be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information will be assessed to determine whether it fulfils the requirements of this clause. Assessment reports and package inserts may be provided to members of the public on request.
- 37.5 Companies may provide members of the veterinary professions with inserts concerning a prescription veterinary pharmaceutical with a view to their provision to owners of animals to whom the prescription veterinary pharmaceutical has already been prescribed, provided that such an insert is factual and non-promotional in nature. Companies may conduct disease awareness and animal health campaigns provided that the purpose of these is to encourage members of the public to seek treatment for the signs which their animals may show

### **38. Financial Information**

Information made available in order to inform shareholders, the Johannesburg Stock Exchange and the like by way of annual reports and announcements etc. may relate to both existing prescription Pharmaceuticals and those not yet marketed. Such information must be factual and presented in a balanced way.

### **39 Replies Intended for Use in Response to Individual Enquiries**

Replies intended for use in response to enquiries that are received on a regular basis may be drafted in advance provided that they are used only when they directly and solely relate to the particular enquiry. Documents must not have the appearance of promotional material.

### **40 The Internet**

- 40.1 Information about prescription Pharmaceuticals which is provided on the Internet and which can be accessed by members of the public must comply with Clause 1.2 of the Code.
- 40.2 Access to promotional material directed to an South African audience provided on the Internet in relation to prescription only veterinary pharmaceuticals, or veterinary pharmaceuticals which, though not prescription only, may not legally be advertised to the general public, must be limited through a password protection scheme, and be accessible to veterinary professionals and appropriate administrative staff only.

- 40.3 Assessment reports and package inserts for prescription Veterinary Pharmaceuticals covered by Clause 1.3 above may be included on the Internet and be accessible by members of the public provided that they are not presented in such a way as to be promotional in nature.
- 40.4 Internet sites linked via company sites are not necessarily covered by the Code.
- 40.5 Advertisements in Electronic Journals  
It should be noted that the MCC's guidance notes on advertising and promotion state that each page of an advertisement for a prescription only veterinary medicine should be clearly labelled as intended for veterinary professionals.

## D. Enforcement

1. When an undertaking has been given in relation to a ruling under the Code, the company, organisation or individual concerned, must ensure that it complies with that undertaking.

### Enforcement Procedure

#### 1. Complaint receipt and processing.

- 1.1 All complaints regarding alleged contravention of this Code must be forwarded in writing, to the President of SAAHA.
- 1.2 Should a Regulatory Authority receive a complaint, such authority shall forward such complaint to the President of SAAHA.
- 1.3 All complaints must state reasons, and where possible, provide evidence, for alleged contravention of the Code.

#### 2. Formation of an investigation committee

- 2.1 Upon receipt of a complaint, the President of SAAHA, will form an investigation committee (IC) comprising of:
  - A veterinarian employed in the Animal Health Industry
  - A pharmacist employed in the Animal Health Industry
  - A person employed in the Animal Health Industry who is involved in the marketing of products similar to the product(s) being promoted to which the complaint relates.
  - A secretary in the employ of SAAHA.
- 2.2 None of the persons involved in the investigation committee may be involved directly or indirectly with affairs of the complainant or defendant, and all except the secretary described in 2.1, shall be conversant with the requirements of the code.
- 2.3 Additionally, the President of SAAHA will allocate a unique reference number to the complaint, which must appear on all future documents relating to the investigation.

#### 3. Procedure to be followed by the investigation committee.

- The investigation committee (IC) will:
- 3.1 Inform the complainant that the complaint is under investigation, and request further information if deemed necessary.
  - 3.2 Inform the defendant that a complaint has been received, together with the nature of the complaint.
  - 3.3 Request the complainant and defendant, if either or both are not members of SAAHA, to confirm whether or not they agree to submit to the jurisdiction of SAAHA.

#### 4. Jurisdiction of SAAHA

- 4.1 Should both complainant and defendant be members of SAAHA, or in cases where either or both of the complainant and defendant are not members of SAAHA, but agree in writing to submit to the jurisdiction of SAAHA, then the investigation will proceed as detailed in point 5

4.2 When the complainant or defendant, is not a member of SAAHA, and such complainant or defendant refuses to submit to the jurisdiction of SAAHA, then the President of SAAHA will forward the complaint to

4.2.1 the advertising committee of the MCC when products registered under Act 101 are involved,

or

4.2.2 to the Registrar of Act 36 when stock remedies are involved, for investigation and possible prosecution.

## **5. Procedure to be followed when both parties agree to submit to the jurisdiction of SAAHA**

5.1 The IC will request the defendant to provide evidence or reasons to support the contention that the complaint is not valid, should the defendant wish to contest the matter.

5.2 Should the defendant indicate that he/she/it does not wish to contest the matter, then the IC will evaluate the matter and make a ruling.

5.3 Should the defendant confirm that he/she/it wishes to contest the matter, then the IC will evaluate the evidence and reasons supplied by both the complainant and defendant.

5.4 The IC may call for oral representations from the complainant and/or the defendant, and may consider requests for oral representations from both the complainant and defendant.

## **6. Rulings**

6.1 If the IC is of the opinion that it is in possession of sufficient evidence and justifications to arrive at a fair and equitable ruling, then it shall do so, otherwise the IC may request further evidence, information and reasons from both the complainant and defendant, until it is in a position to make a ruling.

6.2 Once the IC has made a ruling, the IC will submit a report to the President of SAAHA, complainant and defendant stating.

- The original complaint with the reference number contemplated in 2.3.
- The ruling
- Justification for the ruling.

6.3 Should the ruling require any action by the complainant or defendant, such action must be carried out within 60 days of receipt of notification of the ruling, and proof of compliance with the ruling must be submitted to the President of SAAHA.

6.4 The ruling arrived at by the IC shall be considered as final, and no discussion will be entered into between the IC and the complainant or the defendant, once the ruling has been made.

## **7. Penalties that may be imposed by the IC.**

7.1 Any or all of the following penalties may be imposed, in terms of the code, on the defendant, in the event that the IC finds that the complaint is valid:

- A written letter of apology from the guilty party to the aggrieved party.
- A written retraction in all media in which the offending promotion appeared.
- A fine not exceeding 20 000 Rand, payable to SAAHA in the case of a first offence.
- A fine not exceeding 50 000 Rand payable to SAAHA in the case of a repeat offence.

## **8. Record keeping**

8.1 The President of SAAHA shall cause all documents relating to the investigation of any complaint, to be stored in files at the SAAHA offices, reserved for this purpose.

8.2 Detailed records of all discussions within the IC and between the IC and the President of SAAHA and the complainant and defendant are to be maintained and stored as described in 2.3.

## **E. Amendment of the Code**

This code may only be amended by agreement of the SAAHA Executive Committee and the Regulatory Authorities.



## **Acknowledgements**

This South African Code of Marketing Ethics for Veterinary Pharmaceuticals, has been based on Code of Practice for the Marketing of Medicines in South Africa

Additionally, AVCASA and IFAH Codes have been consulted as well as the Department of Agriculture's advertising requirements.