

Code of Conduct regarding the promotion of veterinary products

Considering:

- The fact Dutch producers and importers of veterinary medicines who are member of the FIDIN organization, with support and cooperation of the KNMvD, decided to adopt self-disciplining measures regarding the promotion of veterinary products as well as on offering hospitality, gifts and other advantages;
- The fact that the aim of these measures, framed in this Code of Conduct, is to elaborate the legal provisions in the field of advertising of veterinary medicines, to protect professionals and keepers of animals against misleading promotion, as well as to ensure promotion meets the standards of good taste and fashion;
- The fact this Code of Conduct has to be applicable also to other producers, importers and suppliers of veterinary medicines (of which, among other parties, veterinarians), in order to bring those under control of the repressive supervision of the Committee on the Code of Conduct on Promotion of veterinary Medicines (CAVP);

The following provisions have been defined:

1. Scope

- 1.1 This Code of Conduct applies to public promotion of veterinary products in the broadest sense of the word, that is: orally, in writing, by means of audiovisual means, through the internet, at exhibitions, conferences and symposia or in any other way. This Code of Conduct does not cover:
- labelling, instruction leaflet and packing of veterinary medicines;
 - correspondence, possibly accompanied by material of non-promotional nature, needed to answer a specific question about a particular veterinary product;
 - factual, informative announcements and reference material relating, for example, to pack changes, adverse reaction warnings as part of general drugs precautions, trade catalogues and price lists, provided they include no promotional data concerning the veterinary product;
 - information relating to animal health and animal diseases, provided that there is no reference, even indirect, to a veterinary product;
 - information on prescription-only medicines meant for the public which is not covered by the exceptions set out in Rule 1.1 and which does meet the criteria defined in the *Alternative Code of Conduct for providing information on prescription-only medicines, not being promotion* (Appendix).
- 1.2 ‘Veterinary products’ is defined as: veterinary medicines covered by the Dutch Animals Act (Wet Dieren), disinfectants and parasiticides covered by the Dutch Plant Protection Product and Biocide Act (Wet Gewasbeschermingsmiddelen en Biociden), as well as animal feed with particular nutritional purposes and additional animal feed covered by EC Regulation 767/2009 and other, remaining veterinary products not being veterinary medicines.

2. Supervision

2.1 The supervision on this Code of Conduct's compliance has been assigned to the CAVP pursuant to the provisions defined in the CAVP Regulation.

3. General provisions

3.1 Notwithstanding applicable provisions in or under Dutch law, such as the Animals Act (Wet dieren) and the Civil Code (Burgerlijk Wetboek) and notwithstanding other applicable Codes of Conduct, promotion of veterinary products in The Netherlands must be carried out pursuant to this Code of Conduct.

3.2 The promotion of veterinary products must be carried out in such way that the entity to which it is addressed will not be misled in any way regarding the efficacy, characteristics, composition, price, content or origin of the product.

3.3 The promotion must be recognizable as being promotion to the entity it is addressed to through appearance, presentation, content or any other way.

3.4 The promotion of veterinary products must be in accordance with the truth and the current standards of good taste and fashion, to which with respect to both the entity to which the promotion is addressed and the fellow industry members must be adhered.

4. Extraordinary provisions regarding the promotion of prescription-only veterinary medicines

4.1 It is prohibited to promote a veterinary medicine to the public in case this veterinary medicine is available on prescription only or contains psychotropic or narcotic substances falling under the United Nations treaties of 1961 and 1971.

4.2 The prohibition mentioned under Rule 4.1 does not apply to promotion in professional journals, direct mailings or on the internet, or during trade fairs and meetings for the benefit of persons entitled to prescribe or deliver veterinary medicines, or persons keeping animals professionally.

4.3 Moreover, with respect to advertising of a veterinary medicine as defined under Rule 4.1, if the advertising is aimed at persons keeping animals professionally, it applies that:

- It must not encourage excessive consumption due to the promotional nature of the advertising;
- from the advertising it must be apparent whether the veterinary medicine can be delivered, after prescription, by a licensed merchant, or may only be provided by a veterinarian or pharmacist, or where appropriate may solely be administered by a veterinarian;
- It is prohibited if the veterinary medicine belongs to a class of veterinary medicines included in Appendix 1.

5. Extraordinary provisions regarding the content of promotion of veterinary medicines

- 5.1 Every claim regarding de efficacy and/or characteristics of the veterinary medicine must be pursuant to the marketing authorisation or the summary of product characteristics (SPC) defined by the authorised authorities, must be presented objectively, and a sound explanation must be available at any time. The use of vague terms or superlatives or any other form of exaggeration related to the characteristics of the veterinary medicine must be avoided.
- 5.2 Quotations from and references to scientific data must be representative and verifiably correct and presented accompanied by full acknowledgement, as well as producible whenever requested.
- 5.3 The use of terms, descriptions and images which appear to be meant to suggest, whether or not in a quasi-scientific way, the existence of non-existing characteristics of products, has to be refrained from.
- 5.4 Every print advertising, not being advertising as referred to in Rule 5.5, reports, where relevant, in every case:
- Product name and marketing authorisation number;
 - Active ingredients (in case of vaccines, the correct generic description);
 - At least one indication and target animal species;
 - The most important side effects and contra-indication;
 - The dose and, if this applies to the product, the withdrawal period;
 - The most important warnings (precautions concerning the use);
 - The categorisation of the medicine (whether or not prescription-only) with respect to the delivery;
 - Name and address of the company responsible for marketing it;
 - Notice of availability of more information on request at the company concerned.

In case the instruction leaflet has been added to the advertising and the advertising refers to this instruction leaflet, information mentioned in the leaflet does not have to be repeated in the promotion.

- 5.5 When advertising intended to remind a veterinary medicine and contains no further data, at least, where relevant, the following has to be included:
- Product name and marketing authorisation number;
 - Active ingredients (in case of vaccines, the correct generic description);
 - The categorisation of the medicine (whether or not prescription-only) with respect to the delivery;
 - Name and address of the company responsible for marketing it;
 - Notice of availability of more information on request at the company concerned.

Advertising intended solely as a reminder of a trade or brand name, does not have to contain other information than the name of the veterinary medicine.

5.6 Advertising which includes comparable advertisement is permitted if the comparison:

- is not misleading;
- refers to comparable products;
- concerns characteristics relevant for the efficacy and safety;
- is not unnecessarily disparaging.

5.7 The advertising must not bring discredit upon the reputation of and/or trust in the animal health industry or its products or the reputation of and/or trust in professionals and/or life stock industry.

5.8 Regarding advertising directed at animal keepers it is inadmissible to encourage excessive use of veterinary medicines by needlessly provoking feelings of fear for a disease or by any other promotion method.

6. Additional provisions regarding orally communicated promotion

6.1 Representatives have sufficient (scientific) knowledge of the veterinary medicines they advertise to provide detailed and complete information.

6.2 All representatives from companies to which this Code of Conduct applies comply with the rules of conduct defined in this Code of Conduct in case of oral advertisement.

7. Extraordinary provisions regarding hospitality, gifts and other advantages

7.1 The direct and indirect offering by companies to which this Code of Conduct applies and accepting by members of the animal health professions to which this Code of Conduct applies of hospitality in association with meetings must be appropriate and must be secondary to the purpose of the meeting. The demands on hospitality do not solely apply to meetings directly or indirectly organized by a company to which this Code of Conduct applies, but also to meetings directly or indirectly sponsored by such a company.

7.2 The direct and indirect offering by companies to which this Code of Conduct applies and accepting by members of the animal health professions to which this Code of Conduct applies of gifts is permitted, if these gifts are of negligible value and are significant to the professional's provision of services.

7.3 Compensation of members of the animal health professions to which this Code of Conduct applies for consultancies or other services to companies to which this Code of Conduct applies – whether this is in money or kind – must be reasonable and reflect the fair market value of the services provided. The arrangements which cover these genuine consultancy or other services (including the services which are to be provided and the quid que pro) must be agreed upon in a written contract.

7.4 Other types of sponsoring than of the meetings defined in Rule 7.1 by companies to which this Code of Conduct applies which are directly or indirectly beneficial to members of the animal health professions to which this Code of Conduct applies, are only permitted if it is made plausible that the sponsoring involves innovative and/or quality

**CAVP Code of Conduct regarding the promotion of veterinary products
from January 1, 2013**

improvement and/or scientific encouraging activities for animal health care, and/or a charity. The arrangements which cover the sponsoring (including the sponsor's obligations and quid quo pro) must be agreed upon in a written contract.

APPENDIX - Alternative Code of Conduct for providing information on prescription-only medicines, not being promotion

1. The hereafter mentioned types of information about prescription-only medicines which have a Dutch marketing authorisation are permitted to the public:
 - a. Information which does not go beyond the elements of the summary of product characteristics, labelling, and the package leaflet of the veterinary medicine and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;
 - b. medicinal product-related information about non-interventional scientific studies or accompanying measures to prevention and medical treatment.
2. To the exclusion of unsolicited material actively distributed to the general public or members thereof, the information referred to under 1 above is only to be made available through one or more of the following channels:
 - a. The veterinarian who prescribes the veterinary medicine concerned or the retailer delivering the veterinary medicine concerned;
 - b. magazines or other publications and websites, which are (partially) aimed at the target animal species for which the veterinary medicine concerned has been assessed;
 - c. magazines or other publications and websites on all or groups of authorised veterinary medicines.
3. The content and presentation of the information as referred to under 1 above shall fulfil the following conditions:
 - a. It must be objective and unbiased; in this regard, if the information refers to the benefits of a veterinary medicine, its risks shall also be stated;
 - b. it must take into account the general needs and expectations of the public involved;
 - c. it must be based on evidence and be verifiable;
 - d. it must be up-to-date and include the date of publication or last revision;
 - e. it must be reliable, factually correct and not misleading;
 - f. it must be understandable for the general public or members thereof;
 - g. it must clearly state the source of the information indicating its author and giving references to any documentation that the information is based on;
 - h. it must not contradict the summary of product characteristics, labelling and package leaflet of the veterinary medicine, as approved by the competent authorities.
4. The information as referred to under 1 above shall include:
 - a. A statement that the veterinary medicine concerned is available on prescription only and that instructions for use appear on the package leaflet or on the outer packaging, as the case may be;
 - b. a statement indicating that the information is intended to support, not to replace, the relationship between animal keeper and veterinarian and that a veterinarian should be contacted if the animal keeper requires clarification on the information provided;

CAVP Code of Conduct regarding the promotion of veterinary products
from January 1, 2013

- c. a statement indicating that the information is disseminated by a marketing authorisation holder;
 - d. a mail address or e-mail address allowing members of the general public to send comments to the marketing authorisation holder.
5. The information as referred to under 1 above shall not include:
- a. Comparisons between veterinary medicines;
 - b. the impression that a medical consultation or surgical operation is unnecessary, in particular by suggesting treatment with a veterinary medicine causes this, unless the veterinary medicine concerned is primary so indicated for such purpose;
 - c. the suggestion that the effects of taking the veterinary medicine are unaccompanied by adverse reactions or are better than, or equivalent to those of another treatment;
 - d. the suggestion that the health of an animal can be enhanced by taking the veterinary medicine;
 - e. the suggestion that the health of an animal could be affected by not taking the veterinary medicine. This prohibition shall not apply to information on veterinary medicines that have a preventive indication, such as vaccines and parasiticides;
 - f. a reference to recommendation by scientists, veterinarians or anyone from the veterinary field who are neither of the foregoing but who, because to their celebrity, could encourage the consumption of veterinary medicines;
 - g. the suggestion that the veterinary medicine is animal feed or other veterinary product;
 - h. the suggestion that the safety or the efficacy of the veterinary medicine is due to the fact that it is natural;
 - i. improper, alarming or misleading terms, evoking fear for a disease or which in any other way encourages irresponsible use of veterinary medicines.

Appendix 1 of the Code of Conduct

Classes of veterinary medicines as referred to under Rule 4.3 of which the advertising aimed at persons keeping animals professionally is prohibited:

- All antimicrobial products.