Code of Conduct regarding the promotion of veterinary products

Considering:

- The fact Dutch producers and importers of veterinary products, including 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 products (of which, among other parties, veterinarians), in order to bring those under control of the repressive supervision of the Inspection Board and 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. Promotion means advertising that promotes the supply, sale, prescription, distribution or use of veterinary products.

1.2 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 to, for example, 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 1.2 and which does meet the criteria defined in the *Alternative Code of Conduct for providing information on prescription-only medicines, not being promotion* (Appendix).

1.3 ‘Veterinary products’ is defined as:
- veterinary medicinal products within the meaning of the EU Regulation on veterinary medicinial products (2019/6, hereinafter: Regulation on veterinary medicinal products);
- disinfectants and pest control products within the meaning of the EU Regulation concerning the making available on the market and use of biocidal products (528/2012, hereinafter: Biocidal Products Regulation); as well as

- animal feed with a particular nutritional purpose and complementary feed within the meaning of EC Regulation on the marketing and use of feed (767/2009, hereinafter: Feed Regulation); and
- other veterinary care products, not being veterinary medicines, disinfectants, pest control agents or animal feeds.

2. Supervision

2.1 The supervision on this Code of Conduct's compliance has been assigned to the Inspection Board and the Committee on the Code of Conduct on Promotion of Veterinary Medicines (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 Regulation on veterinary medicinal products, the Biocidal Products Regulation, 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 does not include information in any form which could be misleading as to the efficacy, characteristics, composition, price, content or origin of the veterinary 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 shall encourage the responsible use of the veterinary product, by presenting it objectively without the exaggeration of its properties. The use of vague terms or superlatives should be avoided.

3.5 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.

3.6 With regard to promotion addressed to animal keepers, it is inadmissible to incite excessive use of veterinary products by unnecessarily evoking feelings of fear of a disease or by other recruitment methods.

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

4.1 Promotion of a veterinary medicinal product in only permitted insofar as it is authorized or registered in the Netherlands. If the authorization has been suspended in the Netherlands, it is prohibited to promote the veterinary medicinal product during the period of that suspension.

4.2 The promotion shall comply with marketing authorisation of the veterinary medicinal product that is promoted or the Summary of Product Characteristics (SmPC) adopted by the competent authorities and must be presented objectively and must be stated in a responsible manner at all times.

4.3 Citations from and references to scientific works must be representative and verifiably correct and must be produced with full acknowledgement of the source, and must be submitted upon request.

4.4 The use of terms, descriptions or images that are apparently aimed at suggesting the existence of non-existent qualities of products, whether or not in a quasi-scientific way, should be avoided.

4.5 With every written promotion, insofar it is not a promotion as referred to in Article 4.6, the following will -as relevant- in any case be stated:
- the product name and registration number
- the active ingredients (in the case of vaccines, the correct generic description)
- at least one indication and target animal
- the main side effect(s) and contraindication(s)
- the dosage and, if applicable, the withdrawal periods
- the most important warnings (precautions for use)
- the classification of the veterinary medicinal product (prescription or not) with regard to delivery
- the name and address of the marketing authorisation holder
- that further information in available upon request from the relevant company

If the package leaflet is included with the promotion (either on paper or in electronic form) and reference is made to it in the promotion, this information may be omitted from the recommendation itself.

4.6 In the event that a promotion has the purpose of reminding the veterinary medicinal product and otherwise does not contain more information, -insofar as relevant- the following will in any case be stated:
- the product name and registration number
- the active ingredients (in the case of vaccines, the correct generic description)
- the classification of the veterinary medicinal product (prescription or not) with regard to delivery
- the name and address of the marketing authorisation holder
- that further information in available upon request from the relevant company

A promotion solely aimed at name or brand awareness does not need to contain any other information besides the name of the veterinary medicinal product concerned.

4.7 A promotion in which comparative advertising is made is permissible if the comparison:
- is not misleading;
- concerns comparable products;
- relates to properties relevant to effectiveness and safety
- is not unnecessarily derogatory

4.8 The promotion must not detract from the reputation of and/or confidence in the veterinary pharmaceutical industry or its products or the reputation and/or confidence in veterinarians and/or animal husbandry.

4.9 The promotion must not be formulated in such a way as to create the impression that the veterinary medicinal product could be a feed or a biocide.

4.10 If a veterinary medicinal product is advertised online, the supplier must ensure it complies with distance retailing regulations, including displaying the European logo for online veterinary medicinal product sales, along with a hyperlink to the website of the Medicines Evaluation Board (MEB).

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

5.1 Promotion of veterinary medicinal products subject to prescription is only permitted if it is aimed at veterinarians or other persons authorized to supply veterinary medicinal products.

5.2 The prohibition or Article 5.1 does not apply to promotion of immunological veterinary medicinal products in professional journals, direct mailings or the internet, addressed to or during trade fairs and meetings for professional keepers of animal. The promotion includes an explicit call to professional keepers of animal to consult the veterinarian about the immunological veterinary medicinal product.

5.3 Representatives must have sufficient (scientific) knowledge to provide accurate and complete information about the prescription veterinary medicinal products for which they make promotion.

6. Additional provisions regarding the promotion of biocidal products

6.1 Every promotion of biocidal products must comply with the labelling requirements of Regulation (EC) 1272/2008 and shall be accompanied by the following text: “Use biocides safely. Before use, read the label and product information.” This text must stand out clearly and be legible within the promotion.

6.2 In the promotion, the words “biocidal products”in the prescribed sentences of Article 6.1 may be replaced by a clear indication of the promoted product type.

6.3 The promotion of the biocidal product shall not refer to the product in a manner that is misleading as to the hazards of the product to human and animal health or the environment, or its effectiveness. Under no circumstances may the biocidal product promotion contain statemens such as “low-risk biocidal product”, “non-toxic”, “harmless”, “natural”, “environmentally friendly”, “animal friendly”or the like.

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 enjoying by members of the animal health professions to which this Code of Conduct applies of hospitality in association with gatherings is permitted, if this hospitality is appropriate and strictly limited to the main objective of the gathering. The hospitality requirements apply not only to gatherings organized directly or indirectly by a company to which this Code applies, but also to gatherings sponsored directly or indirectly by that 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, pecuniary advantage or benefit in kind is permitted, provided they are inexpesive and relevant to the professional practice. This provision is without prejudice to existing measures or trade practice relating to prices, margins and discounts.

7.3 Veterinary medicinal products are not distributed for promotional purposes except for small quantities of samples, specifically labelled for that purpose. Antimicrobial

veterinary medicinal products shall not distributed for promotional purposes as samples or in any other presentation.

7.4 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.

7.5 Other types of sponsoring than of the gatherings defined in Article 7.1 by companies to which this Code of Conduct applies which are directly of 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 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.

7.6 In the interest of the independent practice of veterinary medicine, veterinarians and companies to which this Code applies, provide transparency about the agreements referred to in Article 7.3 and 7.4 in accordance with the rules of conduct for disclosure of financial relationships CAVP.

Further conditions for permitted public information for veterinary medicinal products subject to prescription

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;
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 de 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.