# Explanation of the Code for the Promotion of Veterinary Products

## *Introduction*

The veterinary pharmaceutical industry considers it of great importance that professionals -in particular the veterinarian, as well as the animal keeper- are adequately informed about the existence and properties of veterinary products, including veterinary medicines. The special nature of veterinary products and the importance of their responsible use also entail obligations with regards to the correct and appropriate character of the promotion of these products.

In this light, FIDIN, with the support and cooperation of the KNMvD (professional body for veterinarians), decided to draw up a Code containing rules of conduct for the promotion of veterinary products, which are subject to the repressive supervision by an independent Commission. FIDIN members endorse the Code by virtue of their membership of FIDIN. Furthermore, the Code can also be endorsed by non-members by submitting a written statement, describing their commitment, to the Promotion of Veterinary Products Committee (Commissie Aanprijzing Veterinary Producten, CAVP). In order for the Code to cover a broader scope with regards to companies that are neither a member of FIDIN nor wish to subscribe to the Code, the Promotion of Veterinary Products Committee has the possibility of giving a verdict based on a complaint. Failure to comply with this verdict, the Committee may, on the basis of the Dutch Advertising Code (Nederlandse Reclame Code) submit a complaint against the advertisement to the Advertising Code Committee (Reclame Code Commissie) or submit the complaint to the Dutch Food Safety Authority (NVWA).

The Code contains two fundamental rules of conduct, as well as an explanation of the legal restrictions on the advertising of veterinary products. The rules of conduct can be summarized as follows:

a) A ban on misleading or inciting misuse by promoting veterinary products;

b) An obligation to ensure that the promotion stimulates the responsible use of the veterinary product and is in accordance with the truth and the applicable standards of good taste and decency.

The rules of conduct are in line with the rules on advertising as mentioned in the EU Regulation on Veterinary Medicinal Products No. 2019/6 (hereinafter: Veterinary Medicines Regulation), the EU Regulation on the making available on the market and use of biocidal products No. 528/2012 (hereinafter: Biocidal Products Regulation), the EC Regulation on the marketing and use of animal feeds No. 767/2009 (hereinafter: Animal Feed Regulation) and the Civil Code.

The rules of conduct, respectively included in the general provisions of the Code, are further elaborated in special provisions for veterinary medicinal products and biocides. In addition, special provisions have been included with regard to the promotion of prescription-only veterinary medicinal products, for which advertising to the public is prohibited by law.

Moreover, the special provisions are not an exhaustive elaboration of the two fundamental rules of conduct.

In addition, provisions are included on the encouragement of sales of veterinary medicinal products, such as offering of hospitality, granting of premiums and benefits in cash or in kind and other benefits to veterinarians and other persons authorized to supply veterinary medicinal products.

In this explanation, the content of the provisions of the Code will be discussed in further detail. This explanation is intended as a guideline for the interpretation of relevant provisions and does not contain any mandatory rules.

***Article-by-article explanation:***

***Scope***

*Article 1.1*
The meaning of promotion: any public promotion of goods, services or ideas aimed at promoting the supply, sales, prescription, distribution or use of veterinary products. Announcements that do not contain any promotional element are not included in the definition. The total expression in particular plays a roll in this (text, size, layout, use of colour, use of images, etc.). After all, the mere mention of the advertisers name or brand name can already be promotion. Promotions must be assessed in their entirety, including any referenced material.

*Article 1.2*
Article 1.2 indicates which forms of information are in any case not a recommendation and therefore fall out of the scope of the Code. These are forms of information that the European Commission has explicitly excluded in the Directive for human medicinal products (Article 86, par. 2 of Directive 2001/83/EC) and in a proposal to amend Directive (COM(2008) 663 final 10 December 2008) from the definition for advertising. Furthermore, this information about veterinary medicinal products must not conflict with the information in the summary of product characteristics (SmPC) and the package leaflet (see Article 4.2).

*Article 1.3*
The Code applies to promotion of veterinary medicines within the meaning of the Veterinary Medicines Regulation, as well as to disinfectants and pest control agents within the meaning of the Biocidal Products Regulation. Pesticides that are applied to (the coat of) the animal and have a medical effect fall under the Veterinary Medicines Regulation. Pesticides that are used to make the environment of the animal parasite-free are regulated under the Biocidal Products Regulation. Both categories of pest control agents fall under the scope of the Code.

Furthermore, the Code applies to feeds with a specific nutritional purpose and supplementary feeds within the meaning of EC Regulation 767/2009, as well as other veterinary care products, not being veterinary medicines.

Feeds with a specific nutritional purpose were previously referred to as dietary feeds and therefore must meet a specific nutritional need of an animal whose digestive or absorptive mechanism or metabolism is in danger of being disrupted or has temporarily or irreparably been disrupted.

Complementary feeds are characterized by the fact that they contain a higher concentration of certain substances and, due to their composition, can only form a complete diet combined with other feeds.

Ordinary animal feeds and additives, with the exception of coccidiostats and histomonostats, do not fall under the scope of this Code. As long as they are authorized as additives, coccidiostats and histomonostats fall under the scope of this Code because of their medicinal properties.

***Supervision***

*Article 2*
The Promotion of Veterinary Products Committee repressively monitors compliance with the Code on the basis of received complaints.

***General provisions***

*Article 3.1*
Under this provision, companies are obliged to do their promotions in line with this Code and the law, including veterinary medicinal products legislation, biocides legislation, animal feed legislation and other rules that apply to the promotion of veterinary products, as well as other applicable codes (such as the Dutch Advertising Code Committee and AnimalHealthEurope and FVE codes).

*Article 3.2*
This provision contains the general rule of conduct that the promotion may not contain any form of information that could be misleading or lead to incorrect use of the veterinary product (Article 119 paragraph 5 of the Veterinary Medicines Regulation). This applies in particular to veterinary products with regard to information about the effect, properties, composition, price, content or origin of the product.

*Article 3.3*
The promotion must clearly show the person to who the promotion is directed, that it concerns a promotion of a veterinary product and not something else (Article 119 paragraph 2 of the Veterinary Medicines Regulation). In particular, it must be clear should it concern an editorial article or a promotional text.

*Article 3.4*
The properties of the veterinary medicinal product may not be exaggerated (Article 119 paragraph 6 of the Veterinary Medicines Regulation). Therefore, the use of superlatives, and concepts such as ‘absolute’, ‘all’, ‘completely’ and the like must be critically examined. Vague terms, for example giving unclear guarantees, should be omitted. If a warranty is given, the scope, content and duration of that warranty should be clear. The recommendation may not state or suggest that effectiveness of the veterinary medicinal product is guaranteed.

*Article 3.5*
This clause contains the obligation to ensure that the promotion of the product in in accordance with the truth and applicable standards of good taste and decency.

*Article 3.6*
The promotions aimed at animal keepers must not contain false, deterrent or deceptive

depictions of changes within the animal as a result of illness or injury, leading to excessive or inappropriate use.

***Special provisions for the promotion of veterinary medicinal products***

*Article 4.1*
Pursuant to Article 4.1, it is not permitted to promote non-registered use of a veterinary medicinal product (Article 119 paragraph 1 of the Veterinary Medicines Regulation). This prohibition also applies to the use of veterinary medicinal products on the basis of the so-called cascade or, for example autovaccines (Art. 120 paragraph 3 of the Veterinary Medicines Regulation). In the event of suspension of a veterinary medicinal product, promotion is not permitted during the suspension (Article 119, paragraph 7, of the Veterinary Medicines Regulation).

*Article 4.2*
This Article stipulates that any claim with regard to the effect and/or properties of the veterinary medicinal product must be presented objectively. The summary of product characteristics (SmPC) established by the competent authorities is binding, which means that every claim that is made must be covered by the SmPC of the concerned veterinary medicinal product (Article 119, paragraph 4 of the Veterinary Medicines Regulation). Furthermore, the claim may not conflict with the information in the package leaflet or on the packaging. This prohibition also applies in the case other insights have been published in scientific literature. The information must be accurate, current and truthful and in its entirety be correct and verifiable.

*Article 4.3*
In the case information from scientific articles is used, all quotations must be reproduced correctly and with reference to the source. It must be checked whether the cited publications reflect the current state of science and technology. The cited works must be publicly available or available through the promotor. In the latter case, the promotor must send the cited works within a reasonable period of time to the applicant when receiving such a request.

*Article 4.4*
Especially when the promotion is aimed at animal keepers, medical-veterinary and scientific terminology should be avoided in order to avoid confusion or ambiguity. Nor should any direct or indirect reference be made to recommendations done by scientist or veterinarians.

*Article 4.5*
Any written promotion (not being a promotion as referred to in Article 4.6) must contain the information that is essential for proper use for the person to whom the promotion is addressed. Promotions aimed at veterinarians will therefore contain more information than promotions aimed at animal keepers. It is important that at least stated are the following: name and components, main indication area(s), target animal(s) and contra-indication(s), as well as the instructions for use (dosage, withdrawal periods and precautionary measures). After all, for the decision to prescribe or purchase a veterinary medicinal product, it is necessary to know what it can be used for. In addition to the above, the name and address of the marketing authorisation holder in the Netherlands should be stated should it be necessary to obtain further information.

In the case the package leaflet has been made available together with the promotion in paper or in electronic form and reference is made to the information in the promotion, the information in Article 4.5 may be omitted from the promotion itself. This is in line with Article 14 par. 3 of the Veterinary Medicines Regulation (implemented in Article 4.2 of the National Rules on veterinary medicines), in which the option has been created to make the package leaflet available electronically, for example by using a QR-code. This means that the information mentioned in Article 4.5 can also be made available using a QR-code in the promotion, resulting in the package leaflet being made available electronically.

*Article 4.6*
In the instance that the promotion is in the nature of a reminder of a veterinary medicinal product, not all information needs to be provided. However, as soon as possible applications or other product properties are indicated, the promotion does not fall under reminder advertisement anymore. The reminder advertising as mentioned in this Article, must be distinguished from an advertisement that is solely aimed at name and brand awareness. The latter form of advertising need not mention more than the brand name.

*Article 4.7*
With regard to comparative advertising, relevant rules from our Civil Code (Article 6:194a) are adhered to.

Almost every promotion has a comparative element in it. After all, emphasizing positive product properties can already imply that comparable products do not have those properties or to a lesser extent. To suggest that a veterinary medicinal product works as good or better than another, when in fact it does not, is misleading. A comparison with another substance or sample is therefore in principle only permitted if it serves to correctly explain the effect of the veterinary medicinal product. The requirement that the comparison is not unnecessarily derogatory concerns a further elaboration of the applicable standard of decency (Article 3.5).

*Article 4.8*
This Article describes the standards of good taste and decency, as described in Article 3.5, in more detail.

*Article 4.9*
This provision corresponds with Article 119 paragraph 3 of the Veterinary Medicines Regulation.

***Special provisions for the promotion of veterinary medicinal products that are subject to prescription***

*Article 5.1*
Pursuant to the Veterinary Medicines Regulation (Article 120, paragraph 1), it is prohibited to promote prescription only veterinary medicines to the public. This means that prescription-only veterinary medicinal products may only be advertised to veterinarians and other persons authorized to supply veterinary medicinal products. This ban also extends to advertising made by veterinarians in the waiting room or via their website of prescription veterinary medicinal products.

*Article 5.2*
Promotion of immunological veterinary medicinal products (such as vaccines) in professional

journals, direct mailings, and on the internet and during professional trade shows and meetings, for persons who keep animals professionally (such as livestock farmers) do not fall under the ban of advertising towards the public (Article 120 of the Veterinary Medicines Regulation). The public, to which these trade journals, direct mailings, websites, professional trade shows and meeting are aimed must be distinguished from the general public to which the ban on advertising to the public applies. The advertisement must contain an explicit invitation to consult the veterinarian (Article 120 paragraph 2 of the Veterinary Medicines Regulation).

Article 5.2 relates to professional journals that are specifically aimed at livestock farmers or other persons who keep animals professionally. This must concern magazines with a specific subscriber base with a specific target group. Professional journals can be added to the list on request in accordance with the procedure mentioned in Article 10.3 of the Rules of the CAVP.

Article 5.2 also refers to the promotion of immunological veterinary medicinal products via direct mailings and the internet, addressed to person who keep animals professionally. For direct mailings, it is important that the advertisement is sent in the name of the professional. Promotional texts on websites may only be accessible to the professional by, for example, logging in with a username and password or other techniques to which only the professional has access. The professional must also be located in the Netherlands.

Article 5.2 also distinguishes the promotion of immunological veterinary medicinal products during professional trade shows, specifically aimed at livestock farmers and other persons who keep animals professionally, from fairs open to the general public. A professional trade fair that is open to the public therefore does not automatically fall outside of the concept of trade fair within the meaning of Article 5.2. It is important that the trade fair is mainly visited by the target group to which it is aimed. Trade fairs can be added to the list when requested, in accordance with the procedure laid down in Article 10.3 of the Rules of the CAVP.

Suppliers of veterinary medicines, as well as veterinarians, organize meetings for customers in which information is given about immunological veterinary medicines and their use. Such meetings may have a promotional character. If this is the case, it should be borne in mind that such a meeting is only open to persons who keep animals professionally.

*Article 5.3*
It goes without saying that veterinary practice visitors who are employed by or work on behalf of a company that falls under the scope of the Code must also comply with the provisions of the Code. It is necessary that they have sufficient (scientific) knowledge.

***Special provisions for the promotion of biocidal products***

*Article 6*
This Article concerns the codification of Article 72 of the Biocidal Products Regulation.

***Special provision regarding hospitality, gift and other benefits***

*Article 7.1*
The Veterinary Medicines Regulation contains provisions regarding the promotion of the sale of veterinary medicines, including the granting of premiums or benefits in cash or in kind (Article 121 paragraph 1) or the provision of hospitality during meetings with an exclusively

professional and scientific character (Article 121 paragraph 3). Article 7.1 elaborates on the element of hospitality.

Providing hospitality is understood as reimbursing or taking into account travel, accommodation and registration costs for meetings. If companies to which the Code applies (co-)organise meetings for veterinarians and other persons authorized to supply veterinary medicinal products by providing a financial contribution, this provision applies, regardless of whether the financial support takes the form of an individual contribution to a participating veterinarian, or by making a sponsorship amount available to the organizer of the meeting. Companies to which the Code applies are: the manufacturers, importers, or traders of veterinary products. Veterinarians and other persons authorized to supply veterinary medicinal products include the following persons: the veterinarian, pharmacist, pharmacist's assistant, veterinary obstetrician, castrator, veterinary assistant, para-veterinary veterinary assistant and license holders insofar as it concerns the marketing of veterinary medicinal products with POM-V status.

To prevent veterinarians and other persons authorized to supply veterinary medicinal products from being improperly influenced in their prescribing or dispensing behaviour, Article 7.1 states that companies to which the Code applies must ensure that when providing hospitality in the context of conferences, symposia or other gatherings, this hospitality remains within reasonable limits and is subordinate to the purpose intended with the meeting. Vice versa, veterinarians and other persons authorized to supply veterinary medicinal products have their own responsibility not to accept hospitality contrary to this Code (reciprocity).

In accordance with the regulations for human medicines, the Veterinary Medicines Regulation distinguishes between meetings of an exclusively professional and scientific character (Article 121 paragraph 3) and other meetings in which benefits in kind are offered (the rules for human medicines refer to manifestations). Depending on the type of meeting, different maximums apply for the height of the costs of the hospitality that may be offered by a license holder to an individual professional. For scientific meetings, the standards for hospitality are broader (a maximum of € 500 per event and €1,500 per year is calculated, unless the professional practitioner pays 50% himself) than for events (where a maximum of €75 per event and € 375 per year is used). These policy rules (in the case of human medicines) do not apply as such in the context of this Code, but are a starting point for the assessment whether the hospitality provided or received in a specific case is of very little value (pursuant to Article 121 paragraph 1 of the Veterinary Medicines Regulation), or has remained limited with regards to the main purpose of the meeting (pursuant to Article 121 paragraph 3 of the Veterinary Medicines Regulation). This applies mutatis mutandis to the schemes for inducement in human medicine as referred to in this explanation (policy rules and Code of Conduct for Medicines Advertising).

The hospitality rules apply not only to gatherings organized (directly or indirectly) by a company to which a Code applies, but also to gatherings sponsored (directly or indirectly) by the company. The fact that the hospitality is of very little value or must be limited to the main purpose of the meeting means, among other things, that it may not extend to others than the participants in the meeting, so that no partner program may be offered. In the case of subordination, the balance in time allocation between the scientific program and the other components plays a crucial role.

*Article 7.2*
The Veterinary Medicines Regulation also contains a provision regarding the giving and receiving of premiums and benefits in cash or in kind (Article 121 paragraphs 1 and 2). Article 7.2 provides that these premiums or benefits must be of small value. The term 'minor value' denotes something that is modest in size. The value should also be seen in relation to the frequency. It is not the intention that premiums or benefits of little value will be provided so frequently, or to such an extent, that their total value becomes substantial.

In the case of human medicines, the concept of 'low value' has been linked to the regulation regarding the acceptance of gifts by civil servants (circular of the Minister of Home Affairs and Royal Affairs of 14 July 1999/nr AD 1999/U75958 (Government Gazette 154, 13 August 1999)). Roughly speaking, this is based on a maximum of €50 per premium or benefit, with a maximum of €150 per year, which maximum is applied per company.

Moreover, the provision relating to the granting of premiums or benefits does not apply to commercial practices regarding prices, discounts and bonuses with regard to the purchase and sales of veterinary medicinal products by veterinarians and other persons authorized to supply veterinary medicinal products (Article 121 par. 4 of the Veterinary Medicines Regulation).

*Article 7.3*
The Veterinary Medicines Regulation has specific regulations for the provision of samples (Article 119 paragraphs 8, 9 and 10). Samples concern the smallest packaging form of a veterinary medicinal product that, with specific mentioning, are provided free of charge to a veterinarian in order to become acquainted with the veterinary medicinal product in question. This is permitted provided it concerns small quantities and does not relate to antimicrobial veterinary medicinal products (Article 119, paragraph 9 of the Veterinary Medicines Regulation). In human medicine small quantities are considered as: 2 samples per year within a maximum period of 2 years. For the explanation of this Code, reference is made to the practice in human medicine.

*Article 7.4*
Veterinarians and other persons authorized to supply veterinary medicines provide services for companies to which the Code applies (in particular veterinary pharmaceutical companies). There is also no objection to this, unless the relationship between the service to be provided and the fee may give rise to doubts about the independence of the service provider. In the case of a service agreement, there is right to a reasonable remuneration and reimbursement of the costs actually incurred. Which remuneration is reasonable will usually be tested against the time spent and the market conformity of the hourly rate.

The written requirement of the agreements has been taken over from the Code of Conduct for Medicines Advertising and contributes to the necessary transparency.

*Article 7.5*
Sponsorship usually involves payments for which there is no direct compensation. This must involve sponsoring extra things that benefit innovation, quality or science or support of a good cause. The written requirement of the agreements has also been taken over from the Code of Conduct for Medicines Advertising with regard to sponsorship agreements.

*Article 7.6*
Financial relationships between veterinary pharmaceutical companies and veterinarians with

regard to services and sponsorship must be reported to the Healthcare Transparency Register Foundation if the amount exceeds €500 in a year.

***Explanation of the further conditions for permitted public information for prescription-only veterinary medicinal products***

*Introduction*
Pursuant to the Veterinary Medicines Regulation, it is prohibited to publicly advertise veterinary medicines subject to prescription (Article 120 paragraph 1). This means that it is not permitted to advertise to private and/or professional animal keepers. Advertising towards persons who are entitled to prescribe or supply veterinary medicinal products is permitted under Article 5.1 of the Code.

In practice, there appears to be the need to inform animal keepers about veterinary medicinal products subject to prescription, without there being any advertising. However, the question of when it is a case of advertising, and when it is a case of providing information, is not always clear. In practice, the concept of advertising is broadly interpreted.

Also in the human pharmaceutical sector, there is a ban on advertising to the public of prescription-only medicines, and there appears to be a need for the possibility of informing patients about prescription-only medicines. In light of the fact that the scope for providing information differs per Member State, the European Commission has taken the initiative to propose an amendment to the Medicines Directive that explicitly allows certain forms of information about prescription-only medicines in addition to the advertising ban. Additionally, the Medicines Advertising Code Foundation (CGR) has included provisions in the Medicines Advertising Code of Conduct with regard to informing about prescription medicines.

In view of these developments, FIDIN and KNMvD have decided to provide more clarity in the Code for the Promotion of Veterinary Products (hereinafter: the Code) by laying down the conditions under which information towards the public for veterinary medicinal products subject to prescription is permitted (Article 1.2 under 5).

***Article-by-article explanation***

*Article 1*
Certain forms of expression fall outside the scope of the Code on the basis of Article 1.2 of the Code. This concerns, for example, information in the form of the summary of product characteristics, package leaflet, label and packaging text, public assessment report, as well as factual information such as price lists and changes in pack size. In line with the proposal of the European Commission of 10 December 2008, it is added that the information about the characteristics of the veterinary medicinal product for which it has been authorized may also be presented in a different format (sub a). This means that on the basis of the texts approved by the registration authority, public brochures, publications or vaccination cards can be made which can be distributed through a limited number of channels. The CAVP will assess on a case-by-case basis whether an expression in which the information in question is included falls under the exception referred to in article 1.2 fifth dash or whether it counts as a public recommendation. A promotional character can for example arise through a selective display of product features or through the prominent use of the brand name or logo or the way in

which the brochure is designed.
It is further clarified that it is permitted to provide information about non-interventional scientific studies with the veterinary medicinal product concerned, or accompanying measures regarding prevention or treatment (sub b). Non-interventional scientific studies should be understood as studies where the veterinary medicinal products are prescribed in the usual way, in accordance with the conditions laid down in the registration decision.

*Article 2*
In accordance with the proposal of the Commission, it should be prevented that private persons receive unsolicited information about prescription-only veterinary medicinal products. This will be further elaborated in the additional conditions. Veterinarians or suppliers of veterinary medicinal products subject to prescription must be able to provide animal keepers who receive prescription-only veterinary medicinal products, with information about that veterinary medicinal product (sub a). Furthermore, it should be possible to inform animal keepers about prescription-only veterinary medicinal products through channels in which information about the animal concerned (sub. b) or about veterinary medicines (sub. c) is provided. An example of the latter is the FIDIN Repertory.

*Article 3*
Just as there are relevant requirements for advertising, they also apply to information in order to prevent the information from leading to incorrect use of veterinary medicinal products or to irrational prescribing behaviour. Information must be objective, unbiased and balanced (sub a). In order to prevent the information from being disguised advertising, the information must take into account the general (information) needs and expectations of the public concerned (sub b). In accordance with Article 4.2 of the Code, it must be possible to corroborate the content of the information (sub c) and it must not contradict the registration (sub h). By stating the date of the information, the person who takes note of it can estimate the actuality of the information (sub d). In accordance with Article 3.2 of the Code, the information must be factually correct and must not be misleading (sub e). In accordance with Article 3.3 of the Code, the information must be comprehensible for the intended target group (sub f). In accordance with Article 4.3 of the Code, if scientific studies are used, the source on which the information is based must be clearly indicated (sub g).

*Article 4*
Like veterinary medicinal product advertising, the public information must contain a number of mandatory statements. In any case, it must be stated that it is a prescription-only veterinary medicinal product (in accordance with Article 4.5, under 7 and Article 4.6 under 3 of the Code) and that instructions for use can be found on the package or in the package leaflet (sub a). In line with this, it should be stated that the information is intended to strengthen the relationship with the veterinarian, but cannot replace it, and that further information can be obtained from the veterinarian (sub b). Furthermore, it must be guaranteed that the marketing authorization holder who is responsible for the information can be identified (c ) and reached (d).

*Article 5*
Lastly, it is determined which suggestions and/or statements in the information for the public are prohibited. It is not appropriate to compare veterinary medicinal products (sub a), treatment methods (sub c) or veterinary products (sub g) in informative texts. Comparison

indicates a promotional character, to which the advertising rules apply. Furthermore, the suggestion that the use of the veterinary medicinal product makes medical examination unnecessary (sub b) or makes healthy animals healthier (sub d) should be omitted. This does not apply to information about veterinary medicines that are primarily authorized as an alternative to medical treatment (sub b, such as veterinary medicines for oestrus synchronization) and information about for example vaccination- , deworming- and anti-parasite programs (sub e). Finally, it is not permitted to use promotional methods such as a recommendation by a confidential advisor (sub f) or inducing fear (sub i).