



**Code of Practice
for the Promotion
of Animal Medicines**

Together with the
Rules of Procedure for the
Code of Practice Committee

Incorporating Guidance Notes
and The Plain Guide

27th edition
1st December 2016

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N.B. Any approved changes between the 26th and 27th edition of this booklet have been indicated by a vertical line in the right-hand margin.



Code of Practice for the Promotion of Animal Medicines Together with the Rules of Procedure for the Code of Practice Committee

**Twenty Seventh Edition
December 2016**

Preface

This Code of Practice has its origins in the Veterinary Code established in June 1974 by the Animal Health Register of the Association of the British Pharmaceutical Industry (ABPI). In September 1978 that was replaced by the ABPI's Code of Practice for the Promotion of Animal Medicines.

The National Office of Animal Health (NOAH) was formed on 1 January 1986 to represent the UK companies that research, develop, manufacture and market licensed animal health products. The association's members account for the vast majority of the UK animal health market.

In 1987 NOAH became independent from the ABPI and adopted its own Code of Practice for the Promotion of Animal Medicines in October 1987. As technologies, strategies and expectations in the marketing world continue to evolve, so too have the Rules of this Code, which has been amended regularly in accordance with Article 42 of NOAH's Articles of Association.

The Code also incorporates the provisions of the European Code of Practice for the Animal Health Industry, adopted by IFAH-Europe. The European Code, together with the Introduction to the NOAH Code are deemed part of the Constitution and Rules of the Code of Practice Committee.

As with any industry, marketing animal health products is a key factor in spreading information about the benefits of their use, as well as promoting sales. All advertising is subject to the Rules of the Advertising Standards Authority, but – as with human pharmaceuticals – promotion of animal medicines is regulated. There are special requirements in the law, in addition to which this industry Code of Practice is obligatory on all NOAH members and has also been endorsed by several non-member companies who place their product Datasheets/SPCs in the NOAH Compendium.

Members who are in doubt as to whether a contemplated method of promotion would conform with the Code are invited to consult the Secretary of the Committee who will arrange, where necessary, for the Committee's view to be obtained.

Introduction

The following introductory notes do form part of the Code and the Committee may refer to and rely upon such notes when making decisions. Particularly relevant to that process are the highlighted paragraphs.

- a. This Code of Practice for the Promotion of Animal Medicines was drawn up in consultation with the British Veterinary Association and the Royal College of Veterinary Surgeons, and is reviewed in the light of revisions to the Veterinary Medicines Regulations.
- b. The Code originally owes its creation to the determination of the Association of the British Pharmaceutical Industry (of which NOAH, prior to incorporation, formed part) to secure the universal acceptance and adoption of high standards of conduct in the marketing of animal medicines.
- c. Many animal medicines owe their existence to research carried out by their manufacturers or to the development by them as the result of academic research. Before an animal medicine is placed on the market the company will have accumulated considerable toxicological, pharmacological and clinical evidence and will have met all the statutory requirements for the testing, manufacture, and marketing of that product, including compliance with the prevailing international requirements of 'Good Manufacturing Practice', 'Good Clinical Practice', and 'Good Laboratory Practice'.
- d. With the full co-operation of the industry, comprehensive national and European Community legislation has been introduced to safeguard the public by ensuring that all medicines marketed meet standards of purity, effectiveness and safety which are acceptable in the state of present knowledge and experience.
- e. It is necessary, however, for the company, operating as it does in a keenly competitive industry and providing a range of products in respect of which freedom of choice is essential, to draw attention to the existence and nature of a particular product; for example, by appropriate promotional measures and the dissemination of further knowledge and experience gained in widespread use.
- f. While it is possible to legislate satisfactorily for the testing, manufacture and control of animal medicines, appropriate standards of marketing conduct cannot readily be defined by the same means. For this reason responsible companies have concurred in the promulgation of the Code of Practice and submitted to its restraints.
- g. **The Code emphasises the importance in the public interest of providing accurate, fair and objective information on animal medicines so that rational decisions for prescribing and use can be made. Moreover, the Code accepts the principle that such information should be presented in a form and by ways and means which conform not only to legal requirements but also to ethical standards and canons of good taste.**
- h. This Code of Practice embodies the basic principles and provisions which the animal health industry believes are essential for the conduct of its marketing activities, and for the maintenance of standards which are in the interests of all those who prescribe, sell, supply or use animal medicines.
- i. In June 1992 the European Animal Health Federation (FEDESA), now IFAH-Europe, of which NOAH is a member, adopted the Code of Good Practice for the Animal Health Industry. This requires all national associations to introduce and operate a national industry code which complies with the IFAH-Europe Code. This NOAH Code was revised in 1992/93 to incorporate the principles of the FEDESA Code: the text of the IFAH-Europe Code¹ is reproduced in the NOAH Code of Practice booklet.
- j. **The promotion of a medicine is controlled by law, including the Veterinary Medicines Regulations and anti-bribery law: this Code is not a substitute for the law, but is in addition to it.**
- k. **The Code, therefore, represents an act of self-discipline and participants are encouraged to resolve differences between themselves, including engaging in conciliatory procedures where possible. Acceptance and observance of its provisions are a condition of membership of NOAH. Member companies also acknowledge that the Code itself is to be applied in the spirit, as well as in the letter. Pharmaceutical companies outside NOAH are invited to accept and observe the Code because it is considered that ethical standards should be followed throughout the whole industry if it is to maintain the confidence of all the interests which it serves. A full list of companies which have agreed to follow the Code can be obtained**

¹ The IFAH-Europe Code of Good Practice for the Animal Health Industry was revised in June 2012.

from the NOAH office. NOAH member companies recognise that for the Code to operate effectively, they must accept and abide by the decisions of the Committee without delay. If a company breaches the Code of Practice and subsequently fails to accept or agree to the decision of the Code of Practice Committee then the Board reserves the right to refuse that company's submission of data sheets or SPCs in the Compendium whether in the printed booklet or electronic formats.

- l.** The Code is administered by a Committee set up by the Board of Management of NOAH. The Committee, with an independent legally qualified Chairman from outside the industry, consists of eight independent members (including the Chairman) not engaged in the industry, and eight members who are drawn from the senior management of member companies of NOAH, including at least four veterinarians. The Chairman has general authority to obtain expert assistance in any field, and has an original and a casting vote.
- m.** The Committee will meet to deal with complaints, to secure compliance with the Code, and to make such recommendations as it deems fit for the amendment of the provisions of the Code.
- n.** The Code will be kept under review by the Board of Management and amended from time to time where necessary to clarify it and bring it up to date.

The process for amending the Code of Practice in accordance with NOAH's Articles of Association is as follows;

- Suggestions for potential changes to the Code of Practice will be considered at a review meeting of the membership, which can be held annually, if there is a need.
- Recommendations from the Code of Practice review meeting will be put forward to the NOAH Board for consideration. The views of the NOAH Code of Practice Committee on potential amendments will also be sought. Legal advice on any changes will be sought from the Chair and Secretary of the Code of Practice Committee.
- Any recommendations from the Board for the adoption, alteration or revocation of amendments to the Code of Practice shall be subject to approval by Special Resolution of the Association at a General Meeting.

Notes for the guidance of member companies will be issued periodically to keep them informed of the rulings and recommendations of the Committee and of any alterations to the Code, and will be posted on the NOAH website. The secretariat will update participants when any changes are made, but it is also incumbent on participants to ensure that they keep themselves up-to-date with both the provisions of the Code and its Constitution and Rules. NOAH sets up usually at least one seminar a year to inform and guide users of the Code and Member Companies are encouraged to send delegates to these.

- o.** **A breach of Clause 3 of the Code, that is to say, a finding of the Code of Practice Committee that a method of promotion has been such as to bring discredit on or reduce confidence in the industry, is a sign of particular censure and is reserved for such circumstances.**

Provisions of the Code

1 Clauses and Definitions of Terminologies

- 1.1** “**Promotion**” means those marketing activities under the control of the participating company, which do or may encourage the prescribing supply or use of the company’s products. It includes, for example, data sheets, the activities of representatives; various aspects of sales promotion such as journal and direct mail advertising including ‘teaser’ campaigns; the use of Internet communications including websites and email; the use of films and other audio-visual material and exhibitions; the provision of samples, gifts and hospitality; and responses to technical enquiries if such responses do or may encourage the prescribing supply or use of the company’s products. The terms ‘promotional purposes’ and ‘promotional material’ must be construed accordingly.²
- 1.2** “**Animal Medicine**” means any ‘veterinary medicinal product’ as defined in the Veterinary Medicines Regulations (VMR) in force at the time, together with specified feed additives, coccidiostats and histomonostats as defined in Regulation (EC) No. 1831/2003.
- In the case of products marketed under the Exemption for Small Pet Animals Scheme (previously referred to as the Small Animal Exemption Scheme), Clause 4.4 (iv) and Row 3 of Table 6.2 shall not apply.
- 1.3** “**Professional Keeper of Animals**” means any person whose business involves keeping animals for profit making purposes and who uses animal medicines in the course of his business or occupation, e.g. a farmer or farm manager.
- 1.4** “**Member of Public**” means all those to whom promotion may be directed other than veterinary surgeons, veterinary students, Suitably Qualified Persons (SQPs), pharmacists or Professional Keepers of Animals, as defined in Clause 1.3 above.
- 1.5** “**Participant**” refers to NOAH member companies, and to those non-member companies who have agreed to abide by this Code. Such companies are responsible for any promotional activities of products for which they hold a UK MA where a reasonable person would consider that it was directed towards the UK animal health market.
- 1.6** “**SPC**” means the Summary of Product Characteristics of a Marketing Authorisation, or in the case of a feed additive authorised through Regulation 1831/2003 shall mean the Annex listing of its EU authorisation.
- 1.7** “**Data Sheet**” means the traditional data sheet which is an abbreviated form of the SPC and contains all the essential information for the prescriber which is consistent with the SPC.
- 1.8** “**SQP**” means a Suitably Qualified Person (as defined under the Veterinary Medicines Regulations, as amended from time to time).
- 1.9** “**Broadcast Promotion**” means an audio-visual advertisement or promotion of a Participant which is communicated to the viewer via a television, radio or satellite channel, cable feed or any other medium where:
- (i) a third party is responsible for communicating the advertisement or promotion of the Participant to the viewer; and
 - (ii) the cost to the Participant, of the advertisement or promotion, is related to its duration, and the inclusion of the information prescribed for the promotion if it had not been a Broadcast Promotion (see Clause 6.2) would unreasonably increase the cost or duration of the advertisement or promotion.³
- 1.10** “**Day**” means working day; that is a day which is not a Saturday, Sunday or a public or bank holiday within the country of the United Kingdom wherein the Participant has its place of business from which the requirement will have to be carried out.
- 1.11** “**VMD Regulations**” means any regulations, statutory instruments or anything else having the force of law issued by the Veterinary Medicines Directorate governing the advertisement or promotion of animal medicines.

² See also Guidance Note 6: The Meaning of ‘Promotion’

³ See Guidance Note 9 “Information to be included in Promotions”

1.12 ‘**Suspected Adverse Event**’ means any observation in animals that is unfavourable, unintended and occurs after any use of a veterinary medicine. This includes the following: suspected lack of expected efficacy, adverse reactions in humans following exposure to a veterinary medicine or a treated animal, unexpected veterinary medicine residue failures where levels of veterinary medicine residues in tissues or food products of treated food producing animals are above the maximum residue levels when the recommended withdrawal period of the given veterinary medicine has been respected; and suspected adverse events involving the environment.

1.13 Marketing Authorisation

For the purpose of these Rules, “Marketing Authorisation” has the same meaning as given in the current UK Veterinary Medicines Regulations.

2 Application of the Code

2.1 The Code applies in its entirety in relation to any Promotion by a Participant of an Animal Medicine directed towards the veterinary and pharmaceutical professions, distributors of animal medicines, Professional Keepers of Animals and Members of Public.

3 Methods of Promotion

3.1 A Promotion must never be such as to bring discredit upon, or reduce confidence in, the animal medicines industry.

4 Promotion of Animal Medicines

4.1 Without prejudice to other provisions of this Code, the Promotion of Animal Medicines:

- (i) classified as POM-V (unless for educational purposes as set out in Clause 4.2) may only be promoted to veterinary surgeons, pharmacists, veterinary nurses, veterinary students and Professional Keepers of Animals, unless otherwise prohibited by the VMR e.g. the promotion of antimicrobials to farmers is prohibited.
- (ii) classified as POM-VPS (unless for educational purposes as set out in Clause 4.2) may only be promoted to veterinary surgeons, pharmacists, veterinary nurses, veterinary students, SQPs or other veterinary health care professionals and Professional Keepers of Animals. The promotion of POM-VPS products to horse owners is not permitted.
- (iii) classified as NFA-VPS and AVM-GSL animal medicines may be promoted to any class of person.
- (iv) are prohibited if such animal medicines are not authorised for use in the United Kingdom i.e. do not hold a UK Marketing Authorisation or an authorisation from the European Medicines Agency (EMA) which is valid in the UK. This prohibition will not apply to the promotion of non-UK authorised products and/or indications at a truly international event which is recognised as being for the benefit of international attendees. The display and provision of promotional material for such medicines and/or indications is permitted at international meetings in the UK provided that the following conditions are met:
 - The meeting must be a truly international meeting of high scientific standing with a significant proportion of the attendees from countries outside the UK in which the product and/or indication is licensed
 - The medicine or indication must be relevant and appropriate for the purpose of the meeting
 - Promotional material for a medicine or indication that does not have a UK marketing authorisation must be clearly and prominently labelled to that effect

The names must be given of countries in which the medicine or indication is authorised which must include at least one major developed country and it must be stated that registration conditions differ from country to country.

4.2 For POM-V and POM-VPS medicines, educational information, designed to give a balanced overview of the disease, may be made available to the general public. Such shall not include the brand name of a POM-V or POM-VPS product in relation to treatment but it may (although is not required to) name active substances* and contain a small, non-prominent strapline at the top or bottom of the article stating 'this information was provided by [company] makers of product [Brand XXX]'. If active substances* are referred to in the educational information, then all active substances* with the relevant indication in the species and condition for which the educational feature refers must be stated.

**For the purposes of this Code of Practice active substances include vaccine antigens.*

4.3 A Promotion of Animal Medicines must:

- (i) be fair;
- (ii) be balanced;
- (iii) not be misleading (directly or by implication);
- (iv) not directly or by implication disparage the products or services of other companies;
- (v) not directly or by implication disparage the clinical and scientific opinions of members of the veterinary and allied professions;
- (vi) not contain exaggerated claims, all-embracing claims or superlatives of a general nature;
- (vii) not state directly or by implication that an Animal Medicine, or an active ingredient, has some special merit, quality or property over other products unless this can be substantiated;
- (viii) not use the word 'new' to describe any product or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than twelve months in the United Kingdom;
- (ix) not use veterinarians' names or photographs in any way that is contrary to the Royal College of Veterinary Surgeons' *Code of Professional Conduct*;⁴
- (x) not use devices, copy, slogans, trademarks or get-up which are the same or are likely to be confused with those of other holders of Marketing Authorisations for Animal Medicines save where such use is for the purpose of comparing Animal Medicines;
- (xi) not be contrary to the VMD Regulations.

4.4 Any information or claim in a Promotion of Animal Medicines must:

- (i) be accurate;
- (ii) be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly;
- (iii) be capable of substantiation;
- (iv) not be inconsistent with the SPC ⁵, except that a veterinary surgeon or other appropriately qualified person employed or engaged by a participating company may in appropriate circumstances give information about off-SPC use in response to a technical enquiry from another veterinary surgeon. Requests about off-SPC use posted on online forums must be responded to via a private message to the person requesting the information;⁶
- (v) not use the word 'safe' without qualification;

⁴ The Royal College of Veterinary Surgeons' *Code of Professional Conduct* was revised in 2012

⁵ See also Guidance Note 7: Clause 4.4 (iv): "Promotion must not be inconsistent with the SPC"

⁶ See also Guidance Note 5: Clause 4.4 (iv): "Responses To Technical Enquiries"

- (vi) not state that a product has no side-effects or toxic hazards;⁷
- (vii) not use any comparative safety information unless such is limited to information taken directly from the approved SPC or that obtained from a well-controlled clinical study of products and in either case must not be presented in a misleading manner. The use of Suspected Adverse Event data originating from regulatory authorities regarding other companies' products is not permitted. The use of a Participant's (or Marketing Authorisation Holder's) own Suspected Adverse Event data is also not permitted.

4.5 Participants shall provide the prescriber of the medicine with an SPC or Data Sheet before promoting a product directly to them. The placement of the SPC/Datasheet online via the VMD's Product Information Database or the NOAH online compendium is an acceptable way to fulfil this requirement.

4.6 Promotions for POM-V and POM-VPS Animal Medicines aimed at veterinary students and Professional Keepers of Animals must primarily be concerned with education and/or disease information.⁸

5 Requests for Information

5.1 Upon written request, a Participant must provide within 5 Days of receipt of the written request from a lawfully intended recipient of the Promotion or other participant:

- (i) information or data referred to in the Promotion;
- (ii) information or data to substantiate any claim in the Promotion unless there are genuine extenuating circumstances requiring a short extension. In that event, an explanation must be supplied within 5 days with an estimate of time in which substantiation will be supplied.

5.2 The Participant may provide information or data referred to in Clause 5.1 either directly to the requester or alternatively by informing the requester where such information can be found e.g. a particular web page.

5.3 Such substantiation need not be provided, however, in relation to the validity of indications approved in the current Marketing Authorisation.

6 Mandatory Information in Promotional Material⁹

6.1 The provisions of this Clause shall apply to all promotional material other than

- material which is not intended by the Participant to be a Promotion of Animal Medicines but contains information such as changes in price or packaging or adverse reaction warnings, recalls of defective products
- Promotions which only contain brand name, generic name, company name or logo including educational material
- Company Datasheets (which are considered to be promotional items)

6.2 Clauses 6.2 (a) to (e) state what requirements from points 1 to 11 in the following table are required to be applied to different types of promotion:-

⁷ See also Guidance Note 2: Clause 4.4(vi): "The Concept of 'Safety' in Promotions"

⁸ See also Guidance Note 7: Clause 4.4: "Promotion must not be inconsistent with the SPC"

⁹ See Guidance Note 9. "Information to be included in promotions"

	<u>Category of Information</u>
1	Brand Name
2	An identification of the Active Ingredient(s)
3	An indication of the use (s) for the product that is consistent with the SPC/ datasheet
4	Side effects, precautions, warnings and contra indications or a statement advising the prescriber/user of the medicine to refer to the product packaging and leaflets for information about side effects, precautions, warnings and contra-indications
5	A notice that further information can be found and how it can be found (e.g. website)
6	Legal Category of Product
7	Company Name
8	Company Address
9	The strapline “Use Medicines Responsibly” ¹⁰
10	An indication that Further information is available from SPC or datasheet
11	A clear instruction that advice should be sought from Medicine Prescriber if Animal Medicine is POM-V or POM-VPS when promoting to persons other than Medicine Prescriber

(a) Broadcast Promotion with Dosage

Categories 1-11

(b) Broadcast Promotion without Dosage

Categories 1-2, 5-7, 9-11

(c) Non-Broadcast Promotions with SPC/ Datasheet attached (with or without Dosage)

Categories 1, 6-11

(d) Non-Broadcast Promotion without SPC/ Datasheet attached with Dosage

Categories 1-11

(e) Non-Broadcast Promotion without SPC/ Datasheet attached without Dosage

Categories 1-2, 5-10

Further requirements for Promotions other than Broadcast Promotions

- 6.3** In the case of Promotions other than Broadcast Promotions, the information in Clause 6.2 must be set out clearly, concisely and the font size must be sufficiently large so that a reasonably observant person can read it without undue difficulty. The date of printing or where relevant, the date of the academic or technical review must be stated in technical and other informative material.

Requirements for Broadcast Promotions

- 6.4** In the case of Broadcast Promotions, the information required under Clause 6.2 can be provided either by voice or by the written word on the screen. If the written word is used on the screen, the information must be provided for a sufficiently long period of time and be sufficiently large so that the reasonably observant person can read it and understand it without undue difficulty. The information can be provided either by way of a separate frame or by way of overlay (e.g. as a static or rolling banner at the bottom of the screen).
- 6.5** Where a Broadcast Promotion does not include particulars of dosage, the information not required in Clause 6.2 (e.g. contra-indications and address) shall be accessible from a web page under the Participant’s control whose web address is displayed during the course of the Broadcast Promotion where shall also be accessible the SPC/Datasheet.

¹⁰ See also Guidance Note 8: ‘Use medicines responsibly’ strapline

7 References to Official Bodies

- 7.1** Unless specific requirements, statutory or otherwise, have been imposed, manufacturers must not include in any announcement or promotional material a reference to the Veterinary Products Committee, the Department for Environment, Food and Rural Affairs (DEFRA), the Veterinary Medicines Directorate, European Medicines Agency or similar official bodies.
- 7.2** It shall not be a breach of this Clause to refer to the fact that a product is authorised by the relevant body, nor to refer to general publications of those bodies.

8 Distribution of Promotional Material

- 8.1** Promotional material must only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.
- 8.2** Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.
- 8.3** Mailing lists must be kept up to date. A request for a name to be removed from one of these lists must be complied with promptly and no name may be restored except at the individual's request or with their permission.

9 Reprints, Abstracts and Quotations

(such use is, of course, subject to the law of copyright)

- 9.1** Quotations from articles of a scientific or technical nature in Promotions must:
- be accurate
 - cite the author(s), the title of the article and its publication reference
 - not mislead by being out of context
- 9.2** Reprints of articles or quotations of a substantial nature must not be included in mailings without permission of the author and/or copyright owner (if different).

10 Websites, social media and out of date Promotional Material

- 10.1** Participants shall use all reasonable endeavours to ensure that promotional material which is under their control shall not be made available to or be accessible by veterinary surgeons, Professional Keepers of Animals or members of the public (e.g. via a website) where such promotional material contains information which would contravene this Code.
- 10.2** Any UK-based website under the control of a participant, which links to another site which may include information about products not authorised in the UK, or to conditions not relevant to the UK, must provide suitable and prominent warning of this to readers.
- 10.3** On social media websites, where a Participant moderates the content, third party posts or comments must be edited where necessary to ensure compliance with the requirements of the Code of Practice and the Veterinary Medicines Regulations. Such edits must be completed within 5 working days of the non-compliant material being posted.

11 Sales Representatives

- 11.1** Participants must ensure that all their representatives that are involved in the direct technical selling of animal medicines undergo thorough training and possess sufficient legal, veterinary and technical knowledge to present information on the company's products in an accurate and responsible manner, consistent with this Code of Practice. In particular the following requirements must be met unless any exception or extensions of timing to those as set out below is announced by the Board and/or NOAH executive during a particular period where course and examination scheduling makes compliance difficult:

- (i) Except in the case of representatives solely selling AVM-GSL medicines, Marketing Authorisation Holder representatives must:
 - (a) be registered on the NOAH Certificate of Animal Health (NCAH) register within six months of commencing employment;
 - (b) thereafter be on the current year's NOAH Certificate of Animal Health (NCAH) Marketing Authorisation Holders' Representatives register;
 - (c) within two years of commencing employment sit the NCAH examination; and
 - (d) within 3 years of commencing employment, pass the NCAH examination.
- (ii) For all Participants, an annual declaration of compliance with rule 11.1 shall be required, signed by the chief executive.
- (iii) Veterinary surgeons who are registered with the Royal College of Veterinary Surgeons and are employed as Marketing Authorisation Holder representatives are exempt from the requirement to obtain the NCAH qualification.

11.2 Representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties.

11.3 Representatives must not employ any subterfuge to gain an interview.

11.4 Representatives must ensure that the frequency, timing and duration of calls, together with the manner in which they are made, are such as not to cause inconvenience.

11.5 Representatives must take adequate precautions to ensure the safe-keeping of animal medicines in their possession.

11.6 Representatives must transmit to their companies forthwith any information which they receive in relation to the use or properties of the products which they promote, which appears to reflect upon the safety or efficacy of such products. In particular, having regard to the companies' commitment to pharmacovigilance, they must transmit reports of Suspected Adverse Events.

12 Samples

12.1 Samples of products whose supply is restricted by law may be made available only to persons legally permitted to supply them and must not be sent to them except in response to their instructions.

12.2 Where samples of products restricted, by law, to supply on prescription are distributed by a representative, the sample must be handed direct to the person legally permitted to prescribe it or given to a person authorised to receive the sample on his behalf. A similar practice must be adopted for products which it would be unsafe to use except under veterinary supervision.

12.3 An accurate accounting system must be established for samples of products, restricted by law to supply on prescription, which are made available to representatives for distribution.

12.4 Samples sent by post or other courier must be packed so as to be reasonably secure against the package being opened by young children.

13 Market Research

13.1 Methods used for market research must never be such as to bring discredit upon, or reduce confidence in, the animal medicines industry. The following provisions apply whether the research is carried out directly by the Participant or by an organisation acting on their behalf.

13.2 Access to respondents must not be gained by subterfuge.

13.3 Any incentives given must be kept to a minimum and be commensurate with the work involved.

13.4 Questions intended to solicit disparaging references to competing products or companies must be avoided.

13.5 Market research must not be used as a form of disguised sales promotion.

14 Relations with the General Public and the Communication Media

14.1 Information about scientific progress or discovery in the field of animal medicines must be presented in a balanced way.

14.2 Promotion directed to the Member of Public must never be such as to bring discredit upon, or reduce confidence in, the animal medicines industry or those persons permitted to prescribe such medicines to the Member of Public.

14.3 If it is intended to promote a new product to the veterinary profession or to other prescribers for POM-VPS/NFA-VPS, as well as to other users, then the prescriber must be informed of the availability of the product before promotion is directed towards other users.

15 Sponsorship, gifts, hospitality ¹¹

15.1 Sponsorship, prizes, gifts and hospitality must not be such as to bring discredit upon, or reduce confidence in, the industry.

15.2 No gift shall be offered or issued with the sale or purchase or for the prescription of an animal medicine, other than price or product itself, unless it is directly related to the correct use, administration or disposal of that product, by the person to whom it is offered, or the intended end user of the medicine, or unless it is an educational item, diagnostic aid or veterinary equipment whose value is not excessive.

¹¹ See also Guidance Note 4: Provision of Gifts and Inducements in Relation to Sales Promotion of Animal Medicines

Rules of Procedure for the Code of Practice Committee

1. Purpose and structure

1.1 The Code of Practice Committee (“Committee”) shall:-

- (a) Decide whether complaints that the Code of Practice for the Promotion of Animal Medicines (“Code”) has been contravened by a company or firm which has a Marketing Authorisation (“Member”) which is in membership of the National Office of Animal Health Limited (“NOAH”) (“Complaint”) are justified and impose sanctions on any Member which has contravened the Code in accordance with these Rules (“a Case”).
- (b) Advise the Board of Management of NOAH (“Board of Management”) on the content and administration of the Code and on contraventions of the Code by any Member in accordance with these Rules.
- (c) By its Officials (“Officials”) (as defined below) administer the Code and the procedures laid down by these Rules.

1.2 The Officials responsible for the administration of the Code and dealing with complaints for the benefit of the Committee are:-

- (a) The Chairman,
- (b) The Secretary; and
- (c) The Assistant Secretary

who shall be appointed by the Board of Management for such term as the Board may think appropriate. Additionally the NOAH Chief Executive shall be available, with the assistance of the NOAH Head of Technical and Regulatory Affairs, to provide advice, strictly in a confidential manner, to the Committee and its Officials as may be required from time to time. The Chief Executive and other NOAH staff cannot be involved in any discussion relating to a Case with any person (other than the Chairman, the Secretary, other NOAH Staff and [when in Committee meetings] members of the Committee).

1.3 The roles of the Officials are as follows:-

- (a) The Chairman:
 - (i) to Chair meetings of the Committee;
 - (ii) to advise the Committee as to the proper application of the Rules in relation to the Code;
 - (iii) to carry out his or her duties as set out by these Rules;
 - (iv) to assist and advise the other Officials in their respective functions and as requested, from time to time by the Board of Management, as to the application and the content of the Code and these Rules.
- (b) The Secretary:
 - (i) to administer the procedures for dealing with Complaints, and carry out his or her duties, as set out by these Rules;
 - (ii) to advise the Board of Management and the Committee as to the application and content of the Code and these Rules;

- (c) The Assistant Secretary;
- (i) to assist the Secretary as necessary, particularly with clerical support, to enable the Secretary to fulfil his or her role effectively.

1.4 Members of the Committee

The Committee shall consist of fifteen members in addition to the Chairman, as follows:

- Seven independent members not engaged in the industry, four being practising veterinary surgeons, and two being livestock farmers as appointed by the Board;
- Eight industry members of which a minimum of four shall be veterinary surgeons;

provided that no company or firm and no group of such companies or firms under the same financial control shall have more than one representative among the members of the Committee.

Industry members of the Committee shall:-

- i. be Directors or Senior Executives of a Member
- ii. be elected by the General Meeting of the Association upon nomination from the NOAH membership; and
- iii. serve for five years and thereafter shall be immediately eligible for nomination and re-election.

In the event of any vacancy, the Committee shall be deemed to be properly constituted pending the appointment of new member(s).

1.5 Temporary Appointments

In the event that, for whatever reason, the appointed individual is unavailable, the Chief Executive of NOAH shall have power to appoint, on a temporary basis only, any individual (including himself) to carry out the functions of the Chairman, the Secretary or the Assistant Secretary (save that he or she should have no vote) whether in respect of individual cases or for a limited period of time and whether or not any person is still appointed in that office pursuant to paragraph 1.4. Any such temporary appointment will cease with the next meeting of the Board of Management unless approved by that meeting.

1.6 Charges

- (a) The Board of Management is responsible for notification to the Committee of the level of charge per item payable from time to time by industry Complainants and Respondents in accordance with the procedures following. Any “charge” for this purpose in these Rules will be subject to any Value Added Tax payable. No charge is payable by Complainants unless they were eligible to be a NOAH member company in which case, they shall pay the same charge as a NOAH member company would have done. In so far as the Constitution and Rules hereafter provide for any charge, they shall be interpreted as only applying to industry Participants i.e. holders of veterinary Marketing Authorisations.
- (b) An “item” for the purpose of these Rules and charges relates to a discrete set of words and/or images and/or activities or group of words and/or images and/or activities which form a discrete message of which complaint is made. It is not the message given by the words or images; the number of Clauses of the Code it is alleged such words or images breach; or the different types of media containing those words or image.

1.7 Meetings and quorum

- (a) The Committee will meet with such frequency as the amount of business requires. Its proceedings, and all papers other than published reports, are confidential. Members of the Committee will be required to make a declaration that they will keep proceedings and all such papers confidential.

- (b) Subject to Rule 2.5(b) (special meetings to consider whether complaint brought with sufficient expedition) a minimum of five members of the Committee shall constitute a quorum, provided that these members always include (1) the Chairman; (2) an independent member who is a veterinary surgeon and (3) an industry member. Voting at all meetings shall be by show of hands or ballot at the Chairman's discretion and all motions shall be determined by a majority of those members voting. The Chairman of the Committee shall have an original and also a casting vote. The Chief Executive, Head of Technical and Regulatory Affairs, Secretary and Assistant Secretary shall attend meetings of the Committee in an advisory and administrative capacity but shall not vote on any decision taken by the Committee.

1.8 Information

- (a) The Chairman shall have general authority to obtain expert assistance in any field. The Chief Executive of NOAH shall be entitled to attend meetings of the Committee to provide such information and advice as the Committee may require.
- (b) Any such expert adviser may, by invitation of the Chairman, attend meetings of the Committee but shall have no vote.
- (c) The Secretary may at any stage after receipt of a complaint, ask either party to supply in writing further information or comments. The Secretary shall inform that party of the period within which it shall supply such further information or comments, such period to be not less than five days, which period may be extended at the discretion of the Secretary upon application.

1.9 Timings

Where a time limit is provided in these Rules, in "Days", these are working days as defined in the Code.

1.10 Marketing Authorisation

For the purpose of these Rules, "Marketing Authorisation" has the same meaning as given in the current UK Veterinary Medicines Regulations.

2. Procedures prior to the Committee Meeting

- 2.1** Anyone may make a complaint under this Code ("**the Complainant**") save that if the Complainant is eligible to be a NOAH member company but as of the date of making the complaint, is not a NOAH member company ("**Non-Member Industry Complainant**"), the complaint shall not be considered unless the Complainant agrees in writing to be bound by these Rules of Procedure.
- 2.2** Where a Complainant wishes to assert that a Participant (as defined in Clause 1.5 of the Code) (hereinafter referred to as '**the Respondent**') has contravened the Code, its Chief Executive shall notify the Secretary in writing and shall indicate with such notification whether in its view the matter is one which should be urgently resolved and the grounds for such view. Complainants must present their complaints with reasonable expedition, taking into account all the circumstances of each case, and bearing in mind good practice (especially note 'k' of the introduction). Where a complaint has not been pursued with reasonable expedition, the Committee may dismiss the complaint if the Committee considers it is fair to do so.
- 2.3** The Complainant may where appropriate draw to the attention of the Secretary in writing any previous cases heard by the Committee, previous agreements reached between the Complainant and Respondent, and any other information which may help the Committee in reaching a judgement on whether to invoke Rule 4.8 and 4.10. Any such information under this paragraph shall be communicated separately from the letter of complaint, and shall be provided by the Secretary to the Chairman.
- 2.4** After receiving an allegation that there has been a breach of the Code, the Secretary shall:-
- (i) Examine the allegation to determine if the complaint can properly be dealt with under the Code of Practice and whether sufficient information has been provided to enable the case to be considered and if not request it.
- (ii) In the event that the Secretary does not consider the complaint can properly be dealt with under the Code of Practice, he shall inform the Complainant accordingly, at the same time informing the Complainant that if the Complainant does not accept the Secretary's decision, the Complainant may

within 10 Days of receipt of the Secretary's decision, request in writing to the Secretary that the Chairman reviews the Secretary's decision. If the Complainant makes such a request, the Secretary shall forward this to the Chairman for his or her decision, which shall be final.

- (iii) If the Secretary considers the complaint can be properly dealt with under the Code of Practice, or pursuant to the review under Rule 2.4(ii), the Chairman determines that it can, then the Secretary shall:
 - (a) determine the number of items of complaint by reference to the subject matter of the complaint, each part of the subject matter, as determined by him or her, being an item;
 - (b) invite the Respondent to state whether or not the complaint is justified and whether any information relating to it supplied by the Complainant is correct and to give any answer or explanation that may be necessary. The Secretary shall inform the Respondent of the period within which it shall reply, such period to be not less than five Days nor more than ten Days;
 - (c) inform the parties of the charge which will fall due from each of them in the event that any items of complaint are forwarded to the Committee, such charge to be determined by the multiplication of the charge per item notified by the Board of Management as of the date of the complaint by the number of items determined by the Secretary pursuant to Rule 2.4 (iii)(a) to be forwarded to the Committee.
- (iv) Fees will be paid by Complainants who are Participants or Non-Member Industry Complainants and Respondents.
- (v) Where a case is settled or withdrawn prior to being adjudicated upon by the Committee for any reason, the Fees will be borne equally by the Complainant and Respondent unless otherwise agreed by both parties or in exceptional circumstances e.g. where the complaint was manifestly well-founded or manifestly unfounded and such shall be determined via written submissions to the Chairman in his or her sole and absolute discretion.

- 2.5**
- (a) The Respondent's Chief Executive shall make its written reply, which shall include the current SPC and all the material on which it relies in support of its response, together with a statement of its arguments, within the time notified to it by the Secretary. Such reply shall be signed by the Respondent's Chief Executive. The period may, upon its request, be extended at the discretion of the Secretary. The reply shall contain a statement of the facts and matters, if any, upon which the Respondent bases its view that there has been no breach of the Code.
 - (b) In the event of a Respondent submitting that the complaint has not been brought with reasonable expedition and it is unfair for the Committee to adjudicate upon the complaint contrary to Rule 2.2, any such allegation shall be made in writing and supported by due facts and data and communicated to the Complainant. The Secretary will consider such an allegation as a preliminary issue utilising (if he or she sees fit to do so) Rule 1.8(c) to obtain any necessary supporting information or to seek clarification of the information supplied and, if the Secretary considers that it is appropriate to determine the matter at a preliminary meeting prior to the meeting to adjudicate upon the complaint, he or she will arrange for the holding of a preliminary meeting of the Committee to consider whether the complaint should be dismissed pursuant to Rule 2.1. If the Secretary determines that the matter should be considered at a preliminary meeting separate to adjudication of the complaint, the quorum shall be three including the Chairman.

- 2.6** Upon receipt of the Respondent's reply or upon the expiry of the period (taking into account any extension that has been granted) within which such reply should have been received (whether or not it has been), the Secretary shall:

- (a) forward the Respondent's reply (if such exists) to the Complainant;
- (b) forward the relevant papers to the Committee as soon as is practicable.
- (c) notify both parties that the papers have been forwarded to the Committee.
- (d) inform both parties of the date on which the Committee shall meet to consider whether there has been a breach of the Code; and

- (e) require payment from each of the parties of the charge arising from the number of items of complaint being reported to the Committee.
- 2.7 If the Respondent or Complainant wishes to attend the meeting, it shall notify the Secretary of that intention, not less than three Days before the date of the meeting. Failure to comply may result in the Committee refusing to allow attendance. Reference is made to Rule 3.3 as regards supply of presentational material etc.
- 2.8 Where the Chief Executive of NOAH considers it appropriate to do so, the Chief Executive may of his or her own motion, having previously notified the Chief Executive of the company concerned, refer any promotional activity to the Committee for its preliminary consideration whether such breaches the Code.

In such circumstances, having considered the promotional activity with regard to the Code as a whole, the Committee shall take one of the following actions (or a combination thereof):

- i. (if it considers that the promotional activity is not in breach of the Code), make a report to the Board of Management to that effect
- ii. (if it considers that the promotional activity is not in breach of the Code but is otherwise undesirable) make a report to the Board of Management with a recommendation for the Code to be amended
- iii. (if it considers, following a preliminary assessment, that the promotion activity may be in breach of the Code) instruct the Chief Executive of NOAH to advise any relevant third party on how to submit a complaint via the Secretary to the Committee.

3. **The Committee Meeting**

- 3.1 The Committee will not hear any item of complaint in respect of which payment in the sum of the charge due has not been received from the Complainant, and a Respondent may not be represented at the meeting unless its payment has been received.
- 3.2 If a Member of the Committee is an employee, agent or representative of the Complainant or Respondent or otherwise has an interest in the outcome of the complaint, that Member shall offer to withdraw from any meeting of the Committee during the discussion of the case and shall not be entitled to vote on the complaint if such offer is accepted by the Chairman, who has the discretion in all the circumstances of the Case, to allow such member to remain, subject to notification to the parties' representatives and their consent being given.
- 3.3 The Respondent and Complainant shall each have the right to attend at the meeting, and make oral presentations. The Chairman shall determine the procedure to be adopted as regards such presentations, but generally the order of presentations will be the Complainant followed by the Respondent, with a brief response thereafter by the Complainant. If the Complainant or Respondent intends to rely upon any presentational written material (e.g. PowerPoint presentation) not disclosed in the written complaint or response, it shall provide a copy of such no later than 24 hours prior to the meeting to the other party and to the NOAH office.
- 3.4 Both parties' oral presentations and any written materials used must be consistent with (but may supplement) their respective written complaint and reply.
- 3.5 In exceptional circumstances, the Chairman, in his or her discretion, may permit a party to adduce written material not disclosed in the complaint or reply or (if presentational material) not supplied pursuant to Rule 3.3 where such is not unjust to the other party. Scientific papers and technical data which have not been referred to in the complaint or reply will rarely be permitted to be adduced.
- 3.6 Cross examination by parties' representatives or comment by parties' representatives whilst the other parties' representative is providing a presentation, will not be permitted.
- 3.7 The Chairman may adjourn, at any time, any meeting of the Committee at his or her discretion either at the meeting or prior to the meeting. The Respondent may ask for an adjournment if it believes that additional information is required. Such requests shall be considered by the Committee whose decision is final. If at the resumed hearing the Committee contains different members, the Committee shall consider afresh the question of whether there has been a breach of the Code.

- 3.8 Meetings may be electronically recorded but in that event such recordings are for the Secretary's and Assistant Secretary's administrative assistance only in the preparation of the Minutes and are not available to the parties or anybody else.

4. Decision and Sanctions

- 4.1 The Committee's decision will be by a simple majority of its members who are in attendance and will be limited to the items of complaint raised and the Clauses of the Code alleged to have been breached by the Complainant (with the Chairman having an original and casting vote). Notwithstanding its decision being so limited, the Committee may in its discretion, make such comment as it may think to be in the interest in the industry and the Members.
- 4.2 If the Committee decides that a breach of the Code has occurred, the Secretary shall communicate this decision in writing to the Respondent and shall ask its Chief Executive:-
- (a) to give an undertaking in writing that the practice in question (if not already discontinued) will be discontinued on or before a specified date, and
 - (b) where appropriate, to set out the steps it will take to avoid a breach of the above undertaking.
 - (c) additionally, the Committee may in its discretion require the NOAH executive to place an advertisement providing a précis of the decision in such relevant veterinary/SQP/farming press, as the Chairman of the Code of Practice Committee reasonably chooses.

The wording of the undertaking and assurances required under (a) and (b) above shall be agreed by the Committee.

The Respondent shall make its reply and undertaking within ten Days, but this period may, exceptionally, upon the Respondent's request, be extended at the discretion of the Chairman.

- 4.3 Where the Committee decides that a breach of the Code has occurred, the Chairman may, at his or her discretion, provide the Committee with any information he considers appropriate to assist the Committee in deciding whether to make a report in accordance with Rules 4.8, 4.9 and 4.10, including any information provided by the Complainant pursuant to Rule 2.2.
- 4.4 Where the Committee decides that a breach of the Code has occurred and the breach or the conduct of a Respondent in relation to the Code or a particular case before it warrants such action it may require the Respondent to suspend the advertisement or practice complained of forthwith prior to receipt of an undertaking from the Respondent.
- 4.5 At the Chairman's discretion, upon written request, a Respondent or Complainant may be given an opportunity to attend a subsequent meeting of the Committee to receive a direct explanation of the Committee's decision.
- 4.6 For each item of complaint in respect of which the Committee find a breach has occurred, the Respondent shall be charged the appropriate sum due by reference to the charge notified by the Board of Management as of the date of filing the complaint, and the Secretary shall return the equivalent sum (if paid by the Complainant) to the Complainant. For each item of complaint that the Committee dismisses as not being in breach of the Code, a Participant or Non-Member Industry Complainant (but not anyone else) will be charged the appropriate sum due by reference to the charge notified by the Board of Management, and the Secretary will return the equivalent sum paid by the Respondent to the Respondent. The Secretary will issue receipts for Value Added Tax purposes as appropriate.
- 4.7 The Secretary shall notify the Complainant and Respondent of the outcome of the Committee's deliberations.
- 4.8 Where the Committee considers that the conduct of a Participant in relation to the Code or a particular case before it warrants such action, it may make a report to the Board of Management. Such a report may be made notwithstanding that the Respondent has accepted the decision of the Committee. Such a report may

also be made where the Committee considers that a Participant is guilty of repeated offences or repeated similar activities whether or not previously brought to the Committee, or where the Participant has failed to abide by the spirit of the Code as required by (k) of the Introduction to the Code. A reference to the Board of Management under this or any subsequent paragraph will not of itself incur further charges.

- 4.9** If any Participant declines or fails to give the required undertaking and assurance or to pay any charge required by the Secretary, this shall be reported by the Secretary with the Chairman's approval to the Board of Management.

Additionally, if the Secretary with the Chairman's approval, is satisfied that there has been a clear breach of an Undertaking given by a Participant, then this may be reported to the Board of Management. In the event that there is any doubt as to whether the action amounts to a breach of an undertaking, this will be referred to the Committee for a decision. If felt necessary in that event, the Secretary or Chairman may seek either written clarification from the Respondent in advance of the meeting, or an attendance by the Chief Executive of the Respondent or his or her appointed representative, to attend the meeting. In case of such a meeting, the quorum shall be three, always to include the Chairman.

- 4.10** It shall also be the duty of the Committee to make a report to the Board of Management concerning any member whose conduct in relation to matters covered by the Code (notwithstanding that the member company may have accepted decisions of the Committee) appears to the Committee to raise doubts as to the suitability of the member to remain in membership of NOAH.

- 4.11** Where a report is made to the Board of Management under paragraphs 4.8, 4.9 and 4.10, a copy of the report shall be forwarded to the Chief Executive of the Respondent concerned, and he shall be invited to attend personally or by any other authorised representative the meeting of the Board of Management at which the report is considered.

- 4.12** After hearing such Chief Executive or authorised representative the Board of Management shall then consider, and may decide:

- (a) to reprimand the Respondent and publish details of that reprimand; and/or
- (b) to require the Respondent to publish a corrective statement, including the option of requiring the Respondent to publish at its own cost an apology of similar magnitude and in the same media as any promotion found in breach; and/or
- (c) (if the Respondent is a member of NOAH) whether or not a recommendation should be made that the Respondent's membership of NOAH be terminated or suspended in accordance with Article 26 of the NOAH constitution.

- 4.13** If a Participant who is concerned in the case either as Complainant or Respondent is represented on the Board of Management, that Participant's representative shall withdraw from any meeting of the Board of Management during the discussion of the case, and shall not take any part in any representation of the Participant before the Board of Management.

- 4.14** At the end of the Meeting one of the veterinary surgeons in attendance shall be selected to check the Minutes for their technical accuracy.

5. General

- 5.1** At the conclusion of any proceedings under the Code, the Secretary shall, subject to the authorisation of the Committee or the Board of Management as the case may require, send a report in writing on the result of the proceedings to the person or body responsible for their institution. In the event of a member ceasing to be in membership of NOAH under Article 26 as mentioned in Rule 4.12(c), the Board of Management shall consider and decide whether the fact of and the reasons for such cessation of membership should be notified to persons or bodies outside NOAH.

- 5.2** The Committee shall submit general reports of its work to the Board of Management at such intervals as the Board of Management may require and the Board of Management may authorise the publication, within and outside NOAH, of information contained in or based upon these reports.

- 5.3** In the light of its experience of the working of the Code, the Committee may make such recommendations as it deems fit for the amendment of the provisions of the Code. Any proposal for amendment of the Code shall be forwarded to the Committee before formal adoption and any comments of the Committee shall be taken into account before the proposal is adopted.
- 5.4** The Board of Management may publicise the decision in such manner and in such way as it sees fit having regard to all the circumstances of the case.

Data Sheets

Where a participant chooses to use a data sheet rather than an SPC to satisfy the obligations of Clause 4.5, at least the following information shall be included. Such information must be consistent with the SPC.¹² Any changes to the SPC must, within 30 calendar days of approval by the relevant regulatory authority, be reflected in the Data Sheet, in the on line NOAH Compendium of Data Sheets, in the next printed edition of the NOAH Compendium and in any printed copies of the datasheet issued to the prescriber subsequent to the change in the SPC. In certain circumstances it may not be appropriate for the changes in the SPC to be reflected in the datasheet e.g. when the product or change has been approved but not yet placed on the market by the MA holder.

<i>Headings</i>	<i>Particulars</i>
Name of Product	Name of the medicinal product and, if the medicinal product has an approved name, the approved name.
Presentation	<p>Description of appearance and pharmaceutical form of the medicinal product together with the following information that is to say –</p> <p style="padding-left: 40px;">(a) where the medicinal product contains active ingredients all of which can be definitively identified –</p> <p style="padding-left: 80px;">(i) a list of such ingredients, each described by its approved name or monograph name or, where it has no approved name or monograph name, any other descriptive appellation, and</p> <p style="padding-left: 80px;">(ii) the quantity of each such ingredient contained in each unit or dose of the medicinal product or, where there is no such unit or dose, the percentage of each such ingredient contained in the medicinal product;</p> <p style="padding-left: 40px;">(b) where the medicinal product contains any active ingredient that cannot be definitively identified –</p> <p style="padding-left: 80px;">(i) the information as required under (a) above in respect of each identifiable active ingredient (if any), and</p> <p style="padding-left: 80px;">(ii) a description of the material to which the activity of any other ingredient is ascribed and, where appropriate, a statement of the activity or potency of the medicinal product;</p> <p style="padding-left: 40px;">(c) where there are no active ingredients in the medicinal product, a statement indicating the material of which that medicinal product consists.</p>
Uses	Principal action (if any) of the medicinal product and the purposes for which it is recommended to be used.
Dosage and Administration	Dosage (if any) for the medicinal product together with methods and routes of administration according to species and categories within species and, where appropriate, recommendations as to diluents.
Contra-Indications, Warnings, etc.	<p>Contra-indications, warnings, precautions, and action to be taken in the event of overdose (including, where required in the interests of safety, antidote, emergency procedure or other appropriate action) relating to the medicinal product and main side effects and adverse reactions likely to be associated with the product and, where necessary, measures for the protection of –</p> <p style="padding-left: 40px;">(a) operators,</p> <p style="padding-left: 40px;">(b) consumers of the whole or any part of a carcass or any produce of an animal to which the medicinal product has been administered, including withdrawal periods, if any, and <i>(continued overleaf)</i></p>

¹² The NOAH Board has agreed that it considers data sheets to be potentially promotional items in themselves, and thus within the scope of the Code.

	(c) livestock, wildlife and others, unless there are no such particulars to be given and there is a statement to that effect.
Pharmaceutical Precautions	Special requirements for the storage of medicinal products and, where appropriate, pharmaceutical precautions including recommendations as to excipients, diluents and other additives and as to suitable containers, unless there are – (a) no such requirements, or (b) no such precautions, and a statement to that effect is made.
Legal Category	References to statutory provisions relating to sale or supply of the medicinal product.
Package Quantities	Quantity or amount of the medicinal product in each size of package or container for retail sale, or for supply in circumstances corresponding to retail sale.
Further Information	Such further information (if any) as may be necessary to assist the practitioner in the proper understanding, recognition, administration and use of the medicinal product, such information not covering more than one-tenth of the total surface area of the data sheet.
Marketing Authorisation Numbers, Names and Addresses	Marketing Authorisation number of the medicinal product and the name and address of the authorisation holder. Where the MA holder is different from the distributor this information should be provided on the data sheet.
Date of Preparation or Last Review	Date of preparation of the data sheet or, where since such preparation there has been a review or revision of the data sheet, the date of the last such review or revision.

Guidance Notes

Please note that these Guidance notes are not a formal part of the Code of Practice Rules, but are issued to members as guidance in areas where inclusion is not regarded as necessary.

Nevertheless members are expected to abide by the 'spirit' of the message.

Guidance Note 1: Promotion of Prescription Only Medicines

Date of Original Issue: 14 October 1998, revised April 2011. Modified October 2013, December 2015 and December 2016.

Over the last 30 years the ability to promote medicines has been beneficial in enabling companies to appraise veterinary surgeons, SQPs and animal owners of the products available to assist them in their legal and moral duty of care for their animals. For farm and other businesses it is also as necessary for them to be directly informed of the latest medicinal products as it is for them to be informed of other business inputs.

Nevertheless such benefits and rights need to be used with care if they are not to be lost.

Against this background, the Board recommends that you seriously consider the following points:-

1. Whether the style and tone of advertising of each particular Prescription Only Medicine is appropriate to its status and to the image of the industry.
2. Whether it is legally permitted and appropriate to advertise certain therapeutic products, in accordance with the regulations, to the animal owner; and
3. Given the importance of responsible use of antibiotics, whether offering of any gift or similar inducement to veterinary surgeons is helpful to the long-term position of such products.

NOAH believes in the benefit of advertising POMs, in accordance with the VMR, to prescribers and professional keepers of animals, but believes that this can only be sustained by an approach of great care and responsibility in the preparation of advertisements and promotions.

Members are asked to bring these points to the attention of their advertising and marketing departments.

Industry guidance for antibiotic promotion and use

Antibiotics are recognised as making an important contribution to the treatment of disease in both human and animal patients. The UK Animal Medicine Industry re-emphasises the following principles which guide the responsible marketing of this important group of medicines:-

1. *Farm health plans include Standard Operating Procedures (SOPs) for hygiene and vaccination programmes. Good animal husbandry, hygiene and use of vaccines or other appropriate immunotherapies where possible should be implemented to reduce the occurrence of disease and the need to use therapeutic antibiotics.*
2. *Antibiotics should be used only where the prescribing veterinary surgeon believes they are needed for an infection specified in the UK or European Medicines Agency (EMA) Marketing Authorisation and in accordance with current UK and EU legislation:*
 - (i) *Antibiotics can only be administered following a prescription by a veterinary surgeon: they are classified as POM-V (Prescription Only Medicine - Veterinary).*
 - (ii) *They are prescribed on the basis of the veterinary surgeon's knowledge of the individual case or farm and ideally, following susceptibility testing of the causative bacteria to determine the most suitable treatment. When used in anticipation of emergency diseases outbreaks where there is no time to conduct sensitivity testing of target pathogens (e.g. E.coli), regular susceptibility monitoring is carried out.*

The use of antimicrobial products in the absence of clinical disease or specific pathogen infections and, in particular, administration to prevent disease should not be practised without a clear justification with respect to the health and welfare of the treated animals.

3. *Advertising must comply with the requirements of the NOAH Code of Practice for the Promotion of Animal Medicine and current UK Legislation.*

Guidance Note 2: The Concept of ‘Safety’ in Promotions

Date of Original Issue: 24 June 1999. Modified: Oct 2013 & Dec 2014

Since the earliest days of the Code of Practice the use of the word ‘safe’ has been severely proscribed. The Code states in “section 4.4:

- (v) not use the word ‘safe’ without qualification
- (vi) not state that a product has no side-effects or toxic hazards.¹³
- (vii) not use any comparative safety information unless such is limited to information taken directly from the approved SPC or that obtained from a well-controlled clinical study of products and in either case must not be presented in a misleading manner. The use of Suspected Adverse Event data originating from regulatory authorities regarding other companies’ products is not permitted. The use of a Participant’s (or Marketing Authorisation Holder’s) own Suspected Adverse Event data is also not permitted.

Background

There are a number of reasons for these provisions of the Code:-

- I.** All animal medicines when licensed have to demonstrate ‘safety, quality and efficacy’ – popularly interpreted as “safe when used as directed”. Thus it has long been argued that to claim a licensed product is ‘safe’ is not only tautology, but could be interpreted as implying that other licensed products are unsafe.
- II.** The implication that other products are unsafe reduces confidence in the licensing system – a cornerstone of our industry.
- III.** The implication that rival products are unsafe is disparaging and so also indicates a breach of 4.3(iv) & (v).

It is important that there is not an evasion of this basic and fundamental principle, not just by use of the ‘s’ word, but by, in other ways, indicating that the product being promoted is safer than its rivals.

Guidance Note 3: Promoting Animal Medicines on the Internet

Date of Original Issue: September 2001, revised May 2008, revised October 2013

The promotion of animal medicines by ‘electronic’ means has been covered by the Code for many years– clause 6 covers the requirements and exemptions for various types of promotional materials. See also Guidance note 9 (December 2014) which makes the distinction of internet promotions to those by Broadcast media.

Internet promotions must continue the basic theme of not being misleading, but being accurate and balanced.

The Internet, however, has a number of specific properties which need special consideration.

- 1. It is ‘stateless’ – neither the originator nor the audience can be defined by national boundaries.
- 2. It is ‘classless’ – accessible to anyone, anywhere, (with a computer) – thus the advertiser cannot restrict his audience, but has to assume the widest range of readership, interest and expertise.
- 3. It is ‘not responsible’ – unlike, say, a peer reviewed scientific journal, the internet takes no ‘ownership’ of the material it carries and gives no assurance as to the quality of its information.

To try and impose our specific, national code requirements on this essentially undisciplined medium is a challenge, but changes to the Code have attempted to achieve this balance:

- (i) Where it is reasonably practicable to do so, the obligatory information required by the relevant parts within Clause 6 must be included as part of the promotional material. In other cases it must be available through the system conveying the promotional material and instructions for accessing that information must be displayed with the promotional material.

¹³ See also Guidance Note 2: Clause 4.4(vi): “The Concept of ‘Safety’ in Promotions”

- (ii) In the case of any promotional material which includes a website address, the material on that website must comply with the Code.
- (iii) Any UK-based website under the control of a participant which links to another site which may include information about products not authorised in the UK or to conditions not relevant to the UK must provide suitable warning of this to readers.

It should also be noted that all other relevant sections of the Code, especially clauses 3, 4, 5, and 9 will apply.

Guidance Note 4: Provision of Gifts and Inducements in Relation to Sales Promotion of Animal Medicines

*Date of original issue: April 2004. Revised July 2009.
Further revised April 2010 to include points 5-7.
Modified October 2013, December 2014 & December 2016*

Clause 3 of the Code of Practice, which refers to all licensed categories of medicines states:

‘Methods of promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry’

Clauses 15.1 and 15.2 also relate:

- 15.1** Sponsorship, prizes, gifts and hospitality must not be such as to bring discredit upon, or reduce confidence in, the industry.
- 15.2** No gift shall be offered or issued with the sale or purchase or for the prescription of an animal medicine, other than price or product itself, unless it is directly related to the correct use, administration or disposal of that product, by the person to whom it is offered, or the intended end user of the medicine, or unless it is an educational item or diagnostic aid or veterinary equipment whose value is not excessive.

Points to be considered when planning to offer personal gifts and or inducements, in particular related to POM promotions (‘benefits’) include:

1. Any gift with the exception of price or product itself offered in relation to sales promotion should be modest in cost.
2. Benefits to an employee of a customer or client should be channelled through the recipient’s employer, and offered with the employer’s prior knowledge and approval. Companies should also bear in mind the problems which can be created if an offer is made to an individual member of a partnership.
3. Recipients should be advised that there may be VAT or other tax implications resulting from receipt of the proffered ‘benefit’.
4. When offering additional product as an inducement, care should be taken to ensure that the Rules on the supply of medicines are followed.
5. The wording in Clause 15.2 does not override the provisions in Clause 15.1. Therefore it is still possible, even if the gift relates to price or product itself, or directly relates to the correct use, administration or disposal, for the gift to fall foul of the requirements that it should not bring discredit, or reduce confidence in, the industry.
6. Care needs to be taken when offering discounts or rebates to an end user (e.g. farmer) to ensure that the discount or rebate does not encourage the purchase of unnecessary medicines or unnecessary volumes of medicines and also, that the welfare of the animal is at all times never adversely affected either actually or potentially by the discount or rebate offer.
7. For the purpose of Clauses 15.1 and 15.2 the word ‘gift’ is construed by the Code of Practice as including any pecuniary advantage being provided, with the exception of price or product itself.

Guidance Note 5: Responses to Technical Enquiries

Date of original issue: 1 March 2005, minor revision May 2008

1. Prior to November 2004, the Code of Practice Committee, by convention, accepted that responses to technical enquiries did not constitute 'promotion' and were therefore outside the ambit of the Code of Practice. The Code was altered with effect from 1 January 2005 such that responses to technical enquiries, if such responses do or may encourage the prescribing supply or use of the company's products, will be considered promotion, and the Code will apply to such communications.
2. Participating companies should, therefore, appreciate that all the usual requirements of the Code will apply to such communications and oral representations are as subject to the Code as written representations.
3. It is very unlikely that a genuine and accurate response given by an appropriately qualified person to a genuine technical enquiry from a veterinary surgeon will be in breach of the Code. By the same token, companies need to be careful in delegating the function of replying to enquiries to unqualified persons and/or in standardising the reply to queries which are frequently received. If the reply indicates that the company's product can be used in a certain way, then that is likely in practice to be 'promotion' under the new definition, although not necessarily a breach of the Code.
4. Sales representatives should not provide technical responses for use outwith the SPC and should certainly not initiate discussions with veterinary surgeons, the intention behind which is to encourage veterinary surgeons to make enquiries of a particular nature. Enquiries have to come from a veterinary surgeon, or under their direct instruction, and should be instigated entirely at the volition of that veterinary surgeon. That said, if sales representatives are asked for a technical response to a query by a veterinary surgeon, then referring that person to the technical department of the company is obviously entirely appropriate.
5. Participating companies must ensure that their technical advisors are capable of ascertaining whether any enquiry for a use of a medicine is within or without the product's SPC. If it is not within the SPC, then it is incumbent upon the advisor to ensure that recipient is made fully aware of the fact and the implications of such use (see paragraph 8 below).
6. Clause 4.4, whilst maintaining the existing requirement that promotion must not be inconsistent with the SPC, does provide an exception, under sub clause (iv) to information being supplied regarding off-SPC use, when responding to a technical enquiry from a veterinary surgeon, when that response comes from a veterinary surgeon or other appropriately qualified persons employed or engaged by a participating company in appropriate circumstances.

What will be 'other appropriately qualified persons' will depend on the nature of the technologies involved and the general procedures adopted and formulated by the company in question. Companies will know what is appropriate in the sense of to whom in any given case, having regard to good practice and their general obligations under the law not to provide negligent advice responsibility can properly and safely be delegated.

What will be 'appropriate circumstances' will depend on the view of the Committee dealing with the facts of any given case. But a genuine response to a genuine enquiry between professionals should not give rise to any difficulties in practice.

7. To the extent that any promotion by way of technical response could require compliance with Code of Practice Clause 6 (mandatory information), this can easily be resolved by ensuring that every written technical response includes a copy of the data sheet or SPC for the product in question.
8. Participating companies and their technical advisers should always bear in mind, in giving any technical response, the importance in prescribing medicines of the "Cascade" principle, which, through regulations implementing Directive 2001/82/EC, is a statutory requirement.
9. Finally, participating companies should always operate under the principle that the decision whether or not to use an animal medicine, whether within or without the use laid down in that product's SPC, must always be left to the veterinary surgeon and should never be assumed by the participating company.

Guidance Note 6: The Meaning of ‘Promotion’

Date of original issue: April 2005, minor revision May 2008

Modified: December 2014

1. Definition in Clause 1.1 of the Code:-

“**Promotion**” means those marketing activities under the control of the participating company, which do or may encourage the prescribing supply or use of the company’s products. It includes, for example, data sheets, the activities of representatives; various aspects of sales promotion such as journal and direct mail advertising including ‘teaser’ campaigns; the use of Internet communications including websites and email; the use of films and other audio-visual material and exhibitions; the provision of samples, gifts and hospitality; and responses to technical enquiries if such responses do or may encourage the prescribing supply or use of the company’s products. The terms ‘promotional purposes’ and ‘promotional material’ must be construed accordingly.

2. **‘Includes’** Thus the definition in the Code is not a complete list in itself; the term will include anything which is promotion in the item (i.e. at the time of consideration) understood to be promotion by the ordinary meaning the word in the English language. This is quite deliberate, because advances in technology will provide new forms of media, and therefore, arguably new forms of promotion.

3. So, the starting point is that any act which has the effect (whether intended or not) of publicising and thereby potentially selling or making by popularising the product more likely to be sold, runs the risk of being ‘promotion’ or being held to be ‘promotion’.

4. Thus, promotion is not limited by the means or media whereby the product or message is promoted: it will usually involve the written word, but not necessarily. It can and often does involve images, graphs, film or video, or even sound recordings. It can also include oral comment from (for example) representatives whether in direct one to one meetings with potential customers (e.g. veterinary surgeons) or at sales meetings, exhibitions or at conferences. Even a lecture given at a seminar could be promotion.

5. Most recently, the convention that responses to technical queries would not be treated as ‘promotion’ has been changed, and even these activities may now be promotion – see Guidance Note 5.

6. As is expressly referred to in Clause 1.1 of the Code, it will include journal and direct mail advertising, teaser campaigns **and also includes gifts and hospitality.**

7. It should be understood that there is nothing wrong with promotion – providing it meets the requirements of the Code of Practice.

Guidance Note 7: Clause 4.4 (iv) “Promotion must not be inconsistent with the SPC”

Date of original issue: April 2009 Revised October 2013 & December 2014

1. This Guidance Note follows an in-depth review of Clause 4.4(iv) and its proper construction bearing in mind the Veterinary Medicines Regulations and the IFAH-Europe Code, which is incorporated in the NOAH Code of Practice.

Clause 4.4 (iv) states:

“Any information or claim in a Promotion of Animal Medicines--- must not be inconsistent with the SPC...”

2. The Veterinary Medicines Regulations say that it is an offence if an advertisement:-

“is misleading or contains any medicinal claim which is not in the SPC”

3. The IFAH-Europe Code states:-

“Promotional activities must be consistent with the terms of the Marketing Authorisation and be restricted to the approved indications”

- Moreover the introduction to the Code, which forms part of the Constitution and is utilised by the NOAH Code of Practice Committee in its considerations in respect of any case, at paragraph 'j' states:-

“The promotion of a medicine is controlled by law, including the Veterinary Medicines Regulations and anti-bribery law; this code is not a substitute for the law, but in addition to it”.

- Accordingly, members are strongly urged not to consider there is any material distinction between the Code, the VMR and the IFAH-Europe Code, to the intent that:-
 - Any promotion of a medicinal claim outside the SPC is illegal under the legislation and by definition would also constitute a breach of the Code;
 - Notwithstanding the last phrase of the IFAH-Europe above statement as regards indications, a genuine non-medicinal claim which is not expressly referred to in the SPC is unlikely to be a breach, although members should be very cautious in determining what is or is not a medicinal claim given that there is no definition of “medicinal claim” within the Veterinary Medicines Regulations.
 - It follows that members should be equally cautious in relying upon any perceived difference between “*not inconsistent*” and “*consistent*”, bearing in mind the above guidance.

Guidance Note 8: ‘Use Medicines Responsibly’ strapline

Date of original issue: April 2011

- The strapline should state: ‘Use Medicines Responsibly.’ Members are encouraged to reference the responsible use sections of the NOAH website.
- In order to give sufficient prominence to the strapline, the strapline should be separated from other text e.g. strapline could be the final line on each advertisement.

The font should be no smaller than a limit such that a lower case letter ‘x’ is no less than 2mm high.
- The font size used for the ‘use medicines responsibly’ text should be larger than the smallest font size used in the rest of the advertisement e.g. in the section detailing the Marketing Authorisation Holder contact details.
- There is an exemption from this requirement for AVM-GSL products, although use is encouraged.

Guidance Note 9: Information to be included in Promotions

Date of original issue October 2013

Modified: December 2014

- This guidance note explains what information must be included in promotions. The fundamental policy is that all promotions should contain all information that would be relevant to the target audience of the promotion whilst taking account of the practicalities caused by such obligation in certain promotions.
- In Clause 6.2, a list of categories of information is set out which Participants must include depending on the type of promotion. The actual categories that must be included depend on whether the promotion is a Broadcast Promotion (as defined), the promotion expressly refers to dosage levels and whether or not the SPC is attached to the promotion.
- The Code makes a distinction between what is defined as Broadcast Promotions and other type of promotions. The basic principle is to differentiate between promotions in a particular medium where the inclusion of all relevant information would mean that the promotion was unreasonably expensive or too long (Broadcast Promotions) and other types of promotions even if audio-visual where the inclusion of all relevant information is not unreasonable.
- The obvious case of a Broadcast Promotion is an advertisement on a normal terrestrial, satellite television or cable channel. Another example would be a radio advertisement. A “trailer” advertisement on a third party website will also be considered a Broadcast Promotion *if* the cost of the advertisement depends on the duration of the advertisement and the inclusion of all relevant information would be unreasonably expensive. In such cases, the advertiser should ensure that the viewer can find out about all relevant information from an appropriate web page whose web page address should be included (whether visually or audio in the advertisement). By reason of the

definition of what is a Broadcast Promotion, it would be impractical to attach a SPC Datasheet to such promotions. Thus, when considering Clause 6.2, no distinction is drawn between when the SPC Datasheet is attached and when it is not.

5. In contrast, a YouTube advertisement clip would not be considered a Broadcast Promotion if the cost of the advertisement is not related to the duration of the advertisement. Equally, any audio-visual provided on a website under the control of the NOAH member must ensure that all relevant information is available i.e. a datasheet and SPC PDF link next to the promotional video.
6. Where a promotion is a Broadcast Promotion, it is accepted that not all information (eg contra indications) can be practicably included. However, viewers of such promotions should know where to find such information and accordingly, it is important that a website address is provided for the viewer to find out more about the advertised product.
7. A distinction is also made between a promotion that **attaches** the SPC/ Datasheet and those which do not. The underlying policy here is that it is not necessary for a promotion to include all relevant information where the SPC is immediately accessible by the reader or viewer of the promotion and the reader or viewer is aware of such. For example, a promotional document which staples the SPC/ Datasheet as an appendix to the printed promotion would be considered as “attached”. In the case of a website promotion, a hyperlink embedded in the text of the promotion would also be considered as “attached”. In the case of an audio-visual promotion which are not Broadcast Promotions (eg on-demand video on a web page), a reference to a web address within the audio-visual promotion would not suffice as a viewer could not click on it. However, if a web video appeared right next to a prominent hyperlink to the SPC, such would normally be considered as being “attached” to the promotion provided that the viewer of the web video would realise that the SPC relates to the web video.

Guidance Note 10: International Events, Clause 4.1(iv)

Date of original issue December 2016

1. The general requirement, which is as much a matter of law under the VMR (by Regulation 10) as it is a feature of the Code, is that medicines which do not have a UK marketing authorisation or authorisation from the EMA, which is valid in the UK, must not be promoted in UK.
2. The 26th Edition of the Code of Practice, for the first time, has provided an exception to the general prohibition in this clause 4.1 (iv), in recognition that the UK is frequently selected as the location for conferences, meetings and seminars referable to international animal health, at which manufacturers, prescribers and users from outside the UK attend. It needs to be emphasised that for the relaxation to apply and the exception validly relied upon, the event must be truly international, and not a national event, at which international attendees may also be present.
3. Accordingly any promotion relying on this exception must be at a truly international event at which a significant proportion of the attendees will be from countries outside the UK and it will be for the promoting company, to prove that the event and its promotion falls within the exception.

**A
Plain Guide
to the
Code of Practice
and
Handling Complaints**
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**Updated December 2015**

**This Plain Guide to the Code of Practice is designed solely for the purpose of providing assistance to the users. It has no constitutional effects and reliance in that regard must be limited to the Rules of Procedure for the Code of Practice Committee. Whilst every effort has been taken to ensure that the Plain Guide is accurate, no responsibility can or should be assumed as to the justification or authority given by the Plain Guide and reliance in that regard should again be limited to the Rules of Procedure.**

# A Plain Guide to the Code of Practice and Handling Complaints

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**This Plain Guide to the Code of Practice is designed solely for the purpose of providing assistance to the users. Whilst approved for that purpose by the Board of NOAH and by the Code of Practice Committee, it has no constitutional effects and reliance in that regard must be limited to the Constitution and Rules of Procedure for the Code of Practice Committee. Whilst every effort has been taken to ensure that the Plain Guide is accurate, no responsibility can or should be assumed as to the justification or authority given by the Plain Guide and reliance in that regard should again be limited to the Rules of Procedure.**

## **1. General Background**

- a) The spirit of the Code is for companies to first try and settle matters between themselves; only when this has failed should a formal complaint be made.
- b) The Code of Practice Committee is not a Scientific Review Board (see 4e). It bases its judgements on the requirements of the Code and on whether the claims and statements made in a promotional item are appropriate to the audience to which it is addressed.
- c) Frequently complaints appear to result from the company doing the promotion being too wrapped-up in its own understanding of the product and failing to ‘stand back’ and assess its promotion from the viewpoint of the outside world. This is particularly true where in-house terminology is used which may be misunderstood elsewhere.
- d) Under the Veterinary Medicines Regulations promotional items must be not be misleading or include a medicinal claim not in the SPC. The Code of Practice Committee follows this general approach. (See also Guidance Note 7.) Thus promotional statements outside the SPC are likely to result in a breach of the Code and could be in breach of the Regulations. Responses to technical enquiries, if these serve to encourage the prescribing, supply or use of a Company’s product, will be treated as ‘promotion’ although a genuine response by an appropriately qualified person to a genuine enquiry by a veterinary surgeon or a person acting under their direct instruction involving off-SPC use, will not in itself constitute a breach of the Code. (See Guidance Note 5.)
- e) Cases are normally heard at one of the meetings of the Committee which take place approximately every six weeks. Because of the need to collect information from both parties, clarify points of concern and circulate papers to the Committee, a minimum of three weeks is normally needed between receiving the complaint and the Committee hearing. Additional meetings can be arranged in cases of urgency, but as there are Rules governing the quorum, it is often impractical to do so – see also 2(d)(iv), below.
- f) The introduction of ‘charges’ (not ‘fines’) is intended to concentrate minds on the key aspects of a case and reduce trivial items. This is designed to improve the fairness of the system to both parties and to the industry as a whole, and thus the co-operation of parties with the procedures of the Committee is encouraged and requested.
- g) The Committee Secretariat is very pleased to receive enquiries from companies or their advertising agents to give guidance on whether a particular dispute falls within the remit of the Committee. Whilst assistance can also be given as to the Code of Practice procedures, and in highlighting parts of the Code that may be relevant and in reporting on the views of the Committee on relevant past cases, it is not possible to give a ruling on whether or not a particular promotion is consistent with the Code.
- h) References to the Constitution of the Code of Practice Committee are shown in this Guide in square brackets: [ ].

## **2. The Complaint**

A would-be Complainant should:-

- a) Try and sort out differences informally with the other party.

- b) Before making a formal complaint to NOAH, the two Chief Executives should have been party to the discussion. (There have been numerous instances in the past where disputes between middle-management have been solved when Chief Executives take a wider view.)
- c) A company may stipulate a reasonable timeframe within which a response is expected from the other company: this should not normally be less than 5 working days. Under normal circumstances a complaint should not be made to the Secretary of the Code of Practice Committee until there has been a dialogue between the two companies concerned. However, if the other company fails to respond within a reasonable period, then the complainant is entitled to make a formal complaint about the promotion to the Secretary. Participants should note that inter-company communications may be referred to in a Code of Practice hearing.
- d) If the dispute cannot be solved: send a letter signed by the Chief Executive to the Secretary of the Code of Practice Committee stating:-

- i) Where and when the advertisement appeared or, if a leaflet, how it is being distributed.
- ii) Which Clauses of the Code are alleged to have been broken – with clearly argued explanation, addressing each ‘item’ under complaint.

NB An ‘item’ is the individual statement or graphic under complaint – for example in an advertisement the headline, a statement in the text, a chart and an illustration may all be under complaint – these would be regarded as four separate ‘items’, albeit from a single advertisement.

- iii) Where relevant any inconsistencies with the product Data Sheet/SPC should be highlighted and a copy of the data sheet(s)/SPC supplied.

Prompt handling of the case is dependent on a clearly argued and documented complaint – all too often it is clear that the complainant is very cross, but less clear what about! This only creates delay while the Secretariat try to sort things out.

- iv) If there is any special case for rapid action, it is up to the complainant to make a strong case for this, and to consider the background; for example, if an advertisement has been running for some months before a complaint is received, it would be hard to justify calling a special meeting. Under normal circumstances the case will be heard at the next pre-booked meeting at approximately six-week intervals, bearing in mind that a minimum of three weeks is normally needed to process the papers, get a response from the Respondent, and give the Committee time to study the case.
- e) The letter of complaint should be accompanied by:-
  - i) A good quality example of the promotion under complaint (ideally an original, failing that a full colour, legible photocopy).
  - ii) Copies of the inter-company correspondence.
  - iii) Copies of any material supporting the arguments (but remembering this is not an academic forum).
- f) Additionally, the complainant may, in a separate letter to the Secretary, draw attention to previous relevant cases heard by the Committee, previous agreements reached between the complainant and respondent, and any other information which may help the Committee in reaching a judgement as to whether to require respondent to suspend the promotion, or to make a report to the Board. **[2.3]**

### **3. When the Secretary Receives the Complaint**

- a) A unique reference number is allocated – please use this in all subsequent correspondence.
- b) The Secretary may seek clarification from the Complainant, and may seek copies of material documentation from either party, particularly if not all the relevant matters have been enclosed with the complaint. **[1.8(c)] and [2.4]**.
- c) It would be appreciated if the complaint and response letter could be emailed to the secretariat (s.wells@noah.co.uk) in Microsoft Word format, as this helps to speed up the processing of the case notes to the

complainant, respondent and the Code of Practice Committee. It is also helpful if any hard copies of supporting documents such as promotional material are also sent by email, preferably in colour (as scanned copies where necessary).

- d) The Secretary will then make a decision as to whether the complaint falls within the jurisdiction of the Committee [2.4]. As long as the complaint is within the compass of the Committee's authority, the Secretary will accept the complaint as one to be determined by the Committee in accordance with the procedures set out in the Rules.
- e) The Secretary will write to the Respondent, notifying the complaint, having identified the number of items, and will give a time within which the Respondent must reply, such period being not less than 5, nor more than 10, working days [2.4 (iii) a & b]. The Secretary will inform the Complainant of the action he has taken.
- f) In due course (usually after receipt of the Respondent's response) the Secretary will inform both the Complainant and Respondent [2.6 (d)] of the date of the next Committee meeting. He will require from each party payment in respect of the fee based on a charge per item of complaint (currently £5,000.00 plus VAT). These fees will be required to be paid by NOAH members, signatories to the Code by non-members and all holders of UK Marketing Authorisations. This payment must be received from the Complainant before the meeting of the Committee, or the Committee will not consider the complaint [3.1]. There is facility for the monies to be accepted by electronic BACS transfer: please contact the NOAH office for details if required.
- g) It is seldom practical to incorporate material supplied by a Complainant after the above procedures have taken place. Any new item of complaint has to be treated as a new case, whilst additional supporting material should, in fairness, be supplied to the Respondent at the time of notifying the complaint, so as to give a full opportunity to reply. It is therefore important that Complaints are as comprehensive as possible at the outset.

#### **4. The Response**

- a) As indicated above, it is important that the parties try to resolve their differences by direct correspondence and discussion. The writer is aware of a few cases where the complaint was quite clearly justified at the outset, but the Respondent made no attempt at resolution, forcing the Complainant to officially complain. However, on receipt of the notification, the Respondent agreed to comply by withdrawing the promotion. Such behaviour is unfortunate and an unnecessary abuse of NOAH time and costs.
- b) The Respondent's reply must be signed by the Chief Executive, and must reach the Secretary within the time specified by the Secretary in his letter (not less than 5 nor more than 10 days – [2.5 (a)])
- c) “Two wrongs do not make a right” – Respondents sometimes try to justify their own incorrect action by citing examples of similar behaviour by others or with a ‘tit for tat’ attack on the Complainant – neither approach is helpful either to the Respondent's case or to the work of the Committee. If a Respondent believes it has identified a breach of the Code it should make a new and separate complaint. Allegations that a complaint is ‘commercially motivated’ do not impress the Committee and can damage the impression the Committee forms of the Respondent.
- d) The response should be directly related to the complaint documents and to the Clauses of the Code which are alleged to have been broken. General ‘tirades’ against the complainant are a waste of time and energy.
- e) We re-emphasise that this is not a scientific review body nor a substitute for the Veterinary Products Committee. Complex scientific defences are seldom necessary or helpful. If you feel that detailed scientific arguments or supporting papers are essential to your case then they should be added as appendices to your clear statement of response.
- f) The technical reference point will be the data sheet or SPC, and the Respondent must address the issues by reference to that, and not rely on perceived technical benefits of the product which are not within the terms of the data sheet or SPC.
- g) The Respondent will also be asked for 20 copies of the promotions in question and of the relevant data sheets/SPCs. The former should be original top copies (or where necessary colour photocopies to scale), as often the layout and colour can be relevant factors to be taken into account. In that regard, promotional claims should disclose the authority relied upon clearly and distinctly, particularly identifying any qualification to the benefit

claimed. Footnotes need to be clearly referred to, and references to another promotion, which in turn contains a reference has been held not to be acceptable.

- h) A copy of the written reply from the Respondent will be provided to the Complainant.

## **5. The Meeting**

- a) Both the Respondent and Complainant will be notified by the Secretary of the date when the matter will be considered by the Committee. Both the Respondent and the Complainant will be asked by the Secretary if they intend to exercise their right [3.3] to be in attendance at any meeting and if so, to provide the name of the person or persons attending. This right is dependent, however, on the Committee receiving payment for each item [3.1] and the response within the time limits [2.6(b)]. If the Secretary has not received the payment before the Day of the meeting, the Committee will not allow the party in question to give any oral representation at the meeting, and will rely solely on the papers before it. [3.1]
- b) If either party intends to be orally represented at the meeting of the Committee, a decision should be taken as to how that should be handled. Facilities can be made available for overhead or LCD projectors etc. providing the Secretary is given advanced warning.
- c) Committee members from companies directly affected by the case leave the room during the hearing [3.2].

Meetings are informal, and conducted by a Chairman, who is a senior barrister by profession. The meetings are held approximately every six weeks. Additional meetings can be arranged in cases of urgency, but as there are Rules governing the quorum, it is often impractical to do so. At present meetings are usually held at the Farmers Club in central London, but other venues may be utilised.

- d) The Committee consists of the Chairman, seven other independent members not engaged in industry, of which four must be veterinary surgeons and two must be livestock farmers. Four are a director or senior executive of a corporate member company of NOAH, and four are veterinary surgeons being a director or senior executive of a member company of NOAH [1.4]. A quorum requires at least five Committee members [1.7] and must always include (i) the Chairman; and (ii) a veterinary surgeon who is an independent member.
- e) The Chairman conducts the meetings, can adjourn meetings [3.7], and can if thought appropriate call on expert assistance [1.8(a)]. Generally, with the authority of the Committee, the NOAH Chief Executive and Head of Technical and Regulatory Affairs attend the meetings but do not vote.
- f) Decisions are by simple majority vote, with the Chairman having an original and a casting vote [4.1].
- g) In general the practice is for the members to have received before the meeting a bundle of papers, including a case summary prepared by the Secretary, and including the written complaint and response of the parties, with all supporting material that the parties have supplied. Hence the importance of parties putting great care into their written arguments.
- h) The Chairman will outline briefly the elements of each case before each party's representatives come into the room. The members of the Committee will consider the case and identify to their satisfaction the issues in question, and then invite the representatives, if any, of the Complainant and Respondent into the meeting room.
- i) The Complainant's oral clarification must be consistent with their written submission. Generally Respondents will not be allowed to bring up new arguments which have not been made in their written response. If both are present, the Complainant will be invited to summarise the complaint, then the Respondent to respond, followed finally by the opportunity for the Complainant to address any points from the Respondent's oral comments. Although the two parties will be in the room together, they may not speak at the same time as each other, nor question the other party.
- j) For each party, the Chairman will outline the issues, and in particular highlight any questions the Committee has identified as being particularly important. The representative(s) can then address the Committee. Questions will be asked by members of the Committee. The representative(s) are then asked to leave the room, and the members discuss the issues and come to a decision. If there are any further questions arising before the Committee feels it can properly vote, the representative(s) may be invited back into the room, but subject to that, generally they are released before the Committee comes to its final decision.

- k) The decision will be: (1) no breach; (2) a breach requiring an undertaking to be supplied, or in cases which the Committee determine are sufficiently serious to warrant this; (3) a requirement for an immediate suspension of all of the promotion constituting a breach, in addition to an undertaking. Where thought appropriate the Committee has power to refer the conduct of any participant to the Board of NOAH. [4.8, 4.9] & [4.10]. Undertakings must be returned within 10 working days. [4.2]

## **6. After the Meeting**

- a) The Committee may not re-open a case once a ruling is made, and so follow-up letters or phone calls with new suggestions, comments or arguments are generally redundant. However, should the need arise, it is exceptionally possible for the Chairman to invite one or other party to attend a subsequent meeting to receive a verbal explanation of the ruling.

Similarly the NOAH secretariat is forbidden from responding to ‘morning after’ calls from either party on the result of the case.

- b) The Secretary will simultaneously write to the Chief Executives of both parties as soon as possible after the meeting, and will follow up with details of the hearing extracted from the minutes. For the avoidance of doubt, the Committee’s deliberations are confidential and a party is not entitled to a verbatim transcript of the deliberations.
- c) If a breach is found, the Respondent will also receive a “Form of Undertaking” setting out the required actions – this must be signed by the Chief Executive and returned to the Secretary by the due date (10 Days). A copy of the Undertaking is provided to the Complainant. A copy of the Undertaking will be added to the ‘Register of Undertakings’ on the NOAH website.
- d) To the extent that a party has failed to convince the Committee of the justification of its arguments, the costs of that item will be borne by the party concerned, and the fee (currently £5,000.00 plus VAT) will be retained and a receipt issued. The opposing party in respect of that item will have its money returned. [4.6].
- e) After the meeting the Complainant and Respondent will be advised of the decision within 5 working days and a press release will be issued accordingly within the same time frame. The full minutes will be then drafted by the Secretary and checked for technical accuracy by one veterinary member of the Committee before final approval by the Chairman. Unless there are exceptional circumstances prevailing, this would normally be processed within 30 working days.
- f) The full minutes of the meeting are sent to all Committee members.
- g) Press releases shall be written by the NOAH secretariat to alert the relevant press to the publication on the NOAH website of the précis of the case together with a copy of any Undertaking where relevant.
- h) A copy of the Précis and News Release is sent to the Chief Executives of all Code signatories.
- i) Where a company refuses or fails to accept a ruling the matter will be referred to the NOAH Board who will take whatever action is deemed necessary. Such action may include a reprimand, an instruction to the Respondent to publish an apology of similar magnitude and in the same media as any promotion found in breach, or suspension or termination of the Respondent’s membership of NOAH.

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## Introduction

The International Federation for Animal Health-Europe, IFAH-Europe, is the representative body of companies and national trade associations in the animal health industry. This industry researches, develops, manufactures and brings to the market veterinary medicines, vaccines and other animal health products in Europe.

The animal health industry is committed to the research and development of new and improved products to control, prevent and cure animal diseases thus contributing to improved animal welfare, and also, in respect of livestock, to enable the farming community to supply the people of Europe and the world with high quality, safe and abundant food at reasonable prices.

The Association is conscious of the importance of maintaining public confidence by the responsible conduct of business from the development and manufacturing stages through to promotion and distribution, and by the transparent exchange of information with appropriate bodies. The industry operates under stringent EU and national controls and the Association has adopted this European Code of Good Practice as a voluntary supplement in support of the relevant laws and regulations. This is in line with the Statement of Principles endorsed by the members of IFAH, the International Federation for Animal Health, worldwide.

### 1. Development

The development of animal health products shall be conducted in a responsible manner having regard to all available scientific data and in accordance with all applicable EU and national laws and regulations and Good Laboratory Practice (see appendix A). Particular attention shall be paid to animal welfare and to the effects of any residues that may result from the use of such products in food-producing animals. Results shall be reported in an honest and objective manner.

### 2. Production

Production and all products must be in accordance with the licence specification of the Marketing Authorisation and in conformity with Good Manufacturing and Good Laboratory Practices (see appendices A and B). Production procedures shall take into account operator and environmental safety.

### 3. Pharmacovigilance

Animal health companies shall establish procedures to monitor the use of their products in accordance with the legislation and the good standards of pharmacovigilance.

#### **4. Good Commercial Practices**

Companies shall maintain high ethical standards in their commercial dealings and shall not engage in any practice contrary to the spirit of fair competition or otherwise likely to bring the industry into disrepute. Complaints shall be handled responsibly and expeditiously.

#### **5. Promotion**

Promotion shall be fair and in accordance with the Summary of Product Characteristics. It shall not include exaggerated claims or inappropriately encourage the use of particular animal health products.

#### **6. Distribution**

Animal health companies shall ensure that they supply their products only to those permitted in law to receive such products and shall cooperate with the appropriate authorities to encourage the proper distribution and use of such products.

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### **APPENDIX A - GOOD LABORATORY PRACTICE**

Compliance with the rules governing Monitoring for Good Laboratory Practice of October 1989 (as amended or supplemented) shall be considered the minimum necessary to meet the obligations of this Code.

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### **APPENDIX B - GOOD MANUFACTURING PRACTICE**

Compliance with the rules governing Medicinal Products for human and veterinary use in the European Community Vol. 4 of January 1989 (as amended or supplemented) shall be considered the minimum necessary, to meet the obligations of this Code.

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### **APPENDIX C - PROMOTIONAL CODE**

The European Code of Good Practice for the Animal Health Industry applies to all forms of promotion, by which is meant those informational and marketing activities undertaken by an animal health company, or with its authority, in relation to the prescribing, supply or administration of its veterinary medicinal products (as defined in Directive 2001/82/EEC as amended).

It covers all methods of promotion including journal, online and direct mail advertising, the activities of representatives, the use of audio-visual systems such as films, video recordings, data storage services and the like, and the provision of samples, gifts and hospitality. It is not intended to inhibit the exchange of scientific information concerning the development of the product.

The following regulations detail the minimum standards, which must be met to ensure compliance with the Code. However they must be read in the light of national legislation, which in the event of conflict shall prevail.

#### **A. Marketing Authorisations**

- i) A veterinary medicinal product must not be promoted prior to the grant of the Marketing Authorisation permitting its sale or supply.
- ii) Promotional activities must be consistent with the terms of the Marketing Authorisation and be restricted to the approved indications – see D v) also.

#### **B. Animal Welfare**

The use of animal health products should support the use of good husbandry and good animal management.

#### **C. Information to be Made Available**

- i) Printed promotional material must include the following information clearly and legibly,
  - a) the brand name of the product;
  - b) the active ingredient(s) using approved name(s) where such exists;
  - c) the name and address of the company;
  - d) a statement that further information is available on request;
  - e) the legal status for the supply of the product;
  - f) such instructions as are necessary for the appropriate handling of the product;
  - g) in the case of food producing animals, the withdrawal period;
  - h) when promoting a prescription-only product to non-veterinarians, a form of words indicating that further advice should be sought from a veterinary surgeon; and

- j) a summary of the particulars listed in the product authorisation including contra-indications.
- k) one or more indications for use consistent with the SPC

ii) Notwithstanding sub-clause (j) above, where an advertisement is intended only as a reminder, it must include the information required by a), b), c) and d) of sub-clause (i) above.

#### **D. Information and its Substantiation**

- i) Written and oral information about veterinary medicinal products must be accurate, balanced, fair and objective. It should be based on an up-to-date evaluation of scientific evidence and reflect that evidence clearly. It must not mislead by distortion, undue emphasis, omission or in any other way.
- ii) The word "safe" must never be used without proper qualification. It must not be stated that a product has no side effects.
- iii) When promotional material refers to published studies, clear references must be given as to where they can be found.
- iv) All information included in promotional material must be capable of substantiation and substantiation must be provided in response to enquiries. Such substantiation need not be provided however in relation to the validity of indications approved in the Marketing Authorisation.
- v) IFAH-Europe member subsidiary companies are responsible, under the relevant national code, for ensuring that any material produced by its parent company, which may be located anywhere in the World, is not promoted in its market if this material is contrary to the national summary of product characteristics (SPC).

It is the responsibility of the subsidiary company and the parent company to work together to ensure that material promoted is appropriate and the subsidiary company must take responsibility, under the national code, for any promotion of inappropriate material.

**It is recognised that material may be accessed, such as via the web, by individuals in a particular country where the material, including that produced by the parent company, is contrary to the national SPC. This material is not the responsibility of the local subsidiary and it cannot be held liable for the existence of this material, which may be in compliance with an SPC in another part of the World, so long as it is not promoting this material in the local market**

#### **E. Acceptability of Material**

- i) Promotional material must be of a nature which recognises the standing of the recipient and does not offend against the canons of good taste of the market in which it is distributed or encourage incorrect use of the product.
- ii) Promotional material must not be designed to disguise its real nature.
- iii) Notwithstanding companies' obligation to supply adequate information to users, promotional material should only be sent or distributed to those categories of persons entitled in law to receive it and whose need for and interest in the particular information can reasonably be assumed.
- iv) No reference may be made to any individual or official body or to unpublished material without the consent of the individual body or any author concerned.

#### **F. Meetings, Gifts and Hospitality**

- i) Hospitality must be reasonable in level and must always be subsidiary to the main purpose of the occasion in relation to which it is provided. Particular care should be taken when sponsoring scientific symposia or exhibitions to ensure that company activities do not detract from the scientific purpose of the meeting.
- ii) Gifts must be inexpensive. No gift should be of a value or nature likely to induce the prescription or use of a particular product. Except where they carry all of the information stipulated in sub-paragraph C.i) above they may bear no more than the name of a product, its approved name and the name and logo of the company.

#### **G. Company Staff**

- i) Representatives must be adequately trained and possess sufficient knowledge to present information on their company's product in an accurate and responsible manner.
- ii) They must approach their duties responsibly and ethically.
- iii) They must comply with all relevant requirements of the Code.
- iv) They must transmit to their companies forthwith any information, which they receive in relation to the use of the products which they promote, particularly reports of side effects in accordance with the companies' commitment to pharmacovigilance.
- v) All members of staff who are concerned in any way with the preparation or approval of promotional material or other information for dissemination beyond the company's own employees must be fully conversant with the requirements of the Code.
- vi) Promotional material must be cleared by nominated officials of the company with the appropriate technical expertise.

#### **H. Samples**

Samples may be supplied in accordance with the relevant national law.

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## COMPLIANCE

- i) The European Code of Good Practice for the Animal Health Industry sets out the minimum standards which the association considers must apply. Individual national associations must adopt the European Code or ensure that their national codes fully reflect the standards of the European Code in a manner compatible with national laws.
  - ii) The member associations of the Association are required to establish adequate procedures, according with its circumstances at national or regional level, for ensuring that its member companies comply with the requirements of this Code or the relevant national code and for dealing with any complaints as to non-compliance which may be made.
  - iii) The European Code of Good Practice for the Animal Health Industry is binding upon members of the Association and must be brought into operation by national associations as decided by the General Assembly on 23 November 2005
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## TRANSPARENCY REGISTER OF THE EUROPEAN UNION

With IFAH-Europe being registered on the transparency register, IFAH-Europe expects all of its members to also comply with the Code of Conduct on the transparency register as follows:

### Code of Conduct

In their relations with the EU institutions and their Members, officials and other staff, registrants shall:

1. always identify themselves by name and by the entity or entities they work for or represent; declare the interests, objectives or aims promoted and, where applicable, specify the clients or members whom they represent;
2. not obtain or try to obtain information, or any decision, dishonestly, or by use of undue pressure or inappropriate behaviour;
3. not claim any formal relationship with the EU or any of its institutions in their dealings with third parties, nor misrepresent the effect of registration in such a way as to mislead third parties or officials or other staff of the EU;
4. ensure that, to the best of their knowledge, information which they provide upon registration and subsequently in the framework of their activities within the scope of the register is complete, up-to-date and not misleading;
5. not sell to third parties copies of documents obtained from any EU institution;
6. not induce Members of the EU institutions, officials or other staff of the EU, or assistants or trainees of those Members, to contravene the rules and standards of behaviour applicable to them;
7. if employing former officials or other staff of the EU or assistants or trainees of Members of the EU institutions, respect the obligation of such employees to abide by the rules and confidentiality requirements which apply to them;
8. observe any rules laid down on the rights and responsibilities of former Members of the European Parliament and the European Commission;
9. inform whomever they represent of their obligations towards the EU institutions;

Individuals representing or working for entities which have registered with the European Parliament with a view to being issued with a personal, non-transferable badge affording access to the European Parliament's premises shall:

10. comply strictly with the provisions of Rule 9 of, and Annex X and the second paragraph of Article 2 of Annex I to, the European Parliament's Rules of Procedure;
11. satisfy themselves that any assistance provided in the context of Article 2 of Annex I to the European Parliament's Rules of Procedure is declared in the appropriate register;
12. in order to avoid possible conflicts of interest, obtain the prior consent of the Member or Members of the European Parliament concerned as regards any contractual relationship with or employment of a Member's assistant, and subsequently declare this in the register.

Product

Company

Date

Promotion

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**Complainant's Check List**

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1. Discussed with Respondent?
2. Chief Executives aware?
3. Letter to Secretary signed by Chief Executive?  
accompanied by:
  - Copy of offending material with date and place of issue?
  - Clauses alleged to have been breached?
  - Offending 'items' identified?
  - Copy of relevant Data Sheet or SPC?
  - Copies of correspondence with respondent?
  - Justification for urgency where relevant?
  - A clearly argued case?
  - Cheque for £5,000 + VAT per item? (Where required to pay.)
  - Names of representatives (if any) to attend hearing?
  - Visual aid equipment needed?

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**Respondent's Check List**

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- Letter to Secretary signed by Chief Executive – by due date
- Reference number quoted?
  - Clearly argued response to each point of the compliant?
  - 20 Originals of material under complaint?
  - 20 Copies of data sheet/SPC current at the time of promotion?
  - Cheque for £5,000 + VAT per item?
  - Names of representatives (if any) to attend hearing?
  - Visual aid equipment needed?



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