



**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

19th edition
July 2008

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N.B. Any approved changes between the 18th and 19th 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

**Nineteenth Edition
July 2008**

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 36 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, which is set out on pages 17 to 21. 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.

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 of results 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 Code is reproduced in the NOAH Code of Practice booklet.
- j. **The promotion of a medicine is controlled by law, including the Veterinary Medicines Regulations: this Code is not a substitute for the law, but in addition to it.**
- k. **The Code, therefore, represents an act of self-discipline and participants are encouraged to resolve differences between themselves. 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 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.

- 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. 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.** **Conciliators are available to provide informal advice and guidance in relation to the requirements of the Code and to assist in resolving inter-company differences. Member Companies wishing to seek the assistance of a conciliator may approach the Secretary to the Code of Practice Committee for advice and assistance.**
- p.** **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 Definitions

1.1 The term ‘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, 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 web sites 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.¹

1.2 The term ‘animal medicine’ means any ‘veterinary medicinal product’ as defined in the Veterinary Medicines Regulations in force at the time, together with zootechnical feed additives, coccidiostats and histomonostats as defined in Regulation (EC) No. 1831/2003.

In the case of products marketed under the Small Animal Exemption Scheme, clauses 4.7 and 7.2(iii) shall not apply.

1.3 The term ‘business user’ means any person who uses animal medicines during the course of his business or occupation, e.g. a farmer or farm manager.

1.4 The term ‘lay user’ means all those to whom promotion may be directed other than veterinary surgeons or pharmacists or the business user, as defined in Clause 1.3 above.

1.5 The term ‘participant’ refers to NOAH member companies, and to those non-member companies who have agreed to abide by this Code.

1.6 The term ‘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.

2 Application of the Code

2.1 The Code applies in its entirety in relation to promotion directed towards the veterinary and pharmaceutical professions, distributors of animal medicines, the business and lay user.

2.2 The requirements of Clauses 7.2 and 7.4 do not apply to advertisements containing only information of a commercial nature, such as announcements of changes in prices or packaging, or to adverse reaction warnings or recalls of defective products etc, always provided that no claims for the product are made.

2.3 The requirements of Clause 7.2 (except for the provisions of sub-clause vii thereof) do not apply to teaser campaigns.

3 Methods of Promotion

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

4 Nature and Availability of Information

4.1 Upon reasonable request, participants must promptly provide members of the veterinary and pharmaceutical professions, registered merchants and the business user with accurate and relevant information about the animal medicines which they market.

4.2 Information about animal medicines must reflect current knowledge or responsible opinion.

4.3 Information about animal medicines must be accurate, balanced and must not mislead, either directly or by implication, so that critical unbiased judgements and decisions can be made.

¹ See also Guidance Note 6: The Meaning of ‘Promotion’

4.4 Where promotional material refers to supporting information, such information must be available on request within 5 working days or a clear reference must be given to where it can be found. In the case of company data this must be stated as such. The phrase “Data on file” must not be used as a reference. In the case of information published in a journal, a reference to the journal must be given. In the case of information published on a website, the address must be given.

4.5 All information included in promotional material must be capable of substantiation and substantiation must be provided without delay in response to enquiries.

Such substantiation need not be provided, however, in relation to the validity of indications approved in the current marketing authorisation.

4.6 All information must be presented so as to maintain the respect and confidence of veterinary surgeons, pharmacists, Suitably Qualified Persons, the business user and the public, and to promote the correct use of animal medicines.

4.7 Promotion must not be inconsistent with the SPC, 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.²

5 Claims and Comparisons

5.1 Claims for the usefulness of an animal medicine must be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly.

5.2 Exaggerated claims must not be made and all-embracing claims and superlatives avoided. Claims must not imply that an animal medicine, or an active ingredient, has some special merit, quality or property unless this can be substantiated.

5.3 The word ‘safe’ must not be used without qualification and it must not be stated categorically that a product has no side-effects or toxic hazards.³

5.4 The word ‘new’ must not be used 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.

5.5 Comparisons of products must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, or in any other way.

5.6 Brand names of products of other companies must not be used unless the prior consent of the company has been obtained.

5.7 Care must be exercised to avoid ascribing claims or views to scientific authors in such a way as to suggest, wrongly, that these represent up-to-date opinions.

5.8 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.

6 Disparaging References

6.1 The products or services of other companies must not be disparaged either directly or by implication.³

6.2 The clinical and scientific opinions of members of the veterinary and allied professions must not be disparaged either directly or by implication.

² See also Guidance Note 5: Responses To Technical Enquiries

³ See also Guidance Note 2: The Concept of ‘Safety’ in Promotions

7 Printed Promotional Material

7.1 Participants shall provide a member of the veterinary profession with an SPC or data sheet before promoting a product directly to him.

All other printed material (including journal advertising) which is issued for promotional purposes by the participant or with his authority must contain certain information specified in this Code.

7.2 Except for journal advertisements and posters subject to Clause 7.4, the following information must be given clearly and concisely on printed or otherwise published promotional material including websites email and the like, and on journal advertisements which include particulars of dosage:

- (i)** The brand name of the product.
- (ii)** A quantitative list of the active ingredients, using the approved or other non-proprietary names.
- (iii)** One or more indications for use consistent with the SPC.
- (iv)** At a minimum, side-effects, precautions, contra-indications and withdrawal periods of the product in the recommended dosage, and any other warnings relevant to the advertised indication(s) and the species of animal to which reference is made, consistent with the SPC.
- (v)** A form of words which indicates clearly that further information is available on request to the company or is to be found in the SPC relating to the product.
- (vi)** The legal category of the product.
- (vii)** The company name and address.
- (viii)** When promoting POM-V or POM-VPS medicines to people other than those legally allowed to prescribe them, the promotion must include the clear instruction that advice on the use of this or alternative medicines must be sought from the medicine prescriber. This wording must not be undermined by the rest of the promotion.⁴
- (ix)** Promotions for POM-V medicines aimed at people other than those legally allowed to prescribe them must include a focus on education and/or disease information.⁴

7.3 If an SPC or data sheet accompanies the promotional material, the requirements of Clause 7.2(i) – (iv) will be satisfied provided that the promotional material displays boldly and prominently a statement to the effect that it is accompanied by the SPC or data sheet.

7.4 The requirements of Clause 7.2 do not apply in the case of a journal advertisement, or poster, intended as a reminder advertisement (this will generally mean an advertisement that does not include particulars of dosage). Such advertisement or poster must always contain the following information:

- (i)** The brand name of the product.
- (ii)** The approved or other non-proprietary names of the active ingredients.
- (iii)** A form of words which indicates clearly that further information is available on request.
- (iv)** The company name and address.
- (v)** When promoting POM-V or POM-VPS medicines to people other than those legally allowed to prescribe them, the promotion must include the clear instruction that advice on the use of this or alternative medicines must be sought from the medicine prescriber. This wording must not be undermined by the rest of the promotion.⁴
- (vi)** Promotions for POM-V medicines aimed at people other than those legally allowed to prescribe them must include a focus on education and/or disease information.⁴

⁴ See also Guidance Note 1: Promotion of Prescription Only Medicines

- (vii) The legal category of the product.
- 7.5 The requirements of Clause 7.2 or Clause 7.4 do not apply if an article designed as a promotional aid bears no more, in relation to the product, than the brand name, generic name and company name and logo.
- 7.6 Promotional material, such as mailings and journal advertisements, must not be designed to disguise its real nature.
- 7.7 Promotional material must conform, both in text and illustration, to canons of good taste.
- 7.8 Veterinarians' names or photographs must not be used in promotional material in any way that is contrary to the Royal College of Veterinary Surgeons' *Guide to Professional Conduct*.
- 7.9 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other manufacturers in a way that is likely to mislead or confuse.
- 7.10 Where appropriate, for example in technical and other informative material, the date of printing or of the last review must be stated.
- 7.11 Extremes of format or size of printed material must be avoided.
- 7.12 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which could be considered unsuitable for public view.
- 7.13 The requirements of Clause 7.2 do not apply in the case of journal advertisements or product leaflets which appear to be aimed at the lay owner of companion animals. Such information must comply with Clause 7.4(i) – (v).

8 References to Official Bodies

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 or similar official bodies.

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.

9 Distribution of Printed Promotional Material

- 9.1 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.
- 9.2 Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.
- 9.3 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 his permission.

10 Reprints, Abstracts and Quotations

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

- 10.1 Quotations must accurately reflect the meaning of the author and the significance of the study.
- 10.2 Reprints of articles must not be included in mailings without permission of the author or original publisher.

11 Audio-Visual Material

- 11.1 Audio-visual material, except for radio and television advertising, must comply with all relevant requirements of the Code, with the exception of Clause 7.2.

11.2 When audio-visual material is used to promote a product, copies of the relevant SPC, or a document incorporating the information required by Clause 7.2, must be made available to all persons present or to whom the material is sent or delivered. Alternatively, the material must bear a form of words indicating that further information is available from the company and giving the name and address of the company.

12 Material Reproduced on Television Apparatus, Visual Display Units and the like⁵

12.1 Promotional material which is made available by systems which enable the material to be accessed and reproduced on to television apparatus, visual display units and the like, must comply with all relevant requirements of the Code. Such material includes viewdata systems, memory disks and the like, but not video-tapes, DVDs and the like which come within the scope of Clause 11, or radio and television broadcasting which comes within the scope of Clause 13.

12.2 Where it is reasonably practicable to do so, the obligatory information required by Clause 7.2 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.

12.3 In the case of any promotional material which includes a website address, the material on that website must comply with the Code.

12.4 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.

13 Radio and Television Promotion

13.1 Information about animal medicines broadcast on radio or television must be accurate, balanced and must not mislead, either directly or by implication.

13.2 All such information must be presented so as to maintain the respect and confidence of the professional, business and lay viewer or listener, and to promote the correct use of animal medicines.

14 Sales Representatives

14.1 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. Except in the case of representatives solely selling AVM-GSL medicines, such representatives must be registered with the Animal Medicines Training Regulatory Authority (AMTRA) within six months of commencing employment, thereafter be on the current year's Manufacturers' Representatives register and within two years of commencing employment hold the relevant AMTRA Certificate. For all participants, an annual declaration of compliance with rule 14.1 shall be required, signed by the chief executive.

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

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

14.4 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.

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

14.6 They 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

⁵ See also Guidance Note 3: Promoting Animal Medicines on the Internet

products. In particular, having regard to the companies' commitment to pharmacovigilance, they must transmit reports of side effects.

15 Samples

- 15.1** 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.
- 15.2** 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.
- 15.3** 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.
- 15.4** Samples sent by post or other courier must be packed so as to be reasonably secure against the package being opened by young children.

16 Market Research

- 16.1** 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 his behalf.
- 16.2** Access to respondents must not be gained by subterfuge.
- 16.3** Any incentives given must be kept to a minimum and be commensurate with the work involved.
- 16.4** Questions intended to solicit disparaging references to competing products or companies must be avoided.
- 16.5** Market research must not be used as a form of disguised sales promotion.

17 Relations with the General Public and the Communication Media

- 17.1** Information about scientific progress or discovery in the field of animal medicines must be presented in a balanced way.
- 17.2** Promotion directed to the lay user 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 lay user.
- 17.3** If it is intended to promote a new product to the veterinary profession as well as to other users, then the veterinary profession must be informed of the availability of the product before promotion is directed towards other users.

18 Sponsorship, gifts, hospitality ⁶

- 18.1** Sponsorship, gifts and hospitality must not be such as to bring discredit upon, or reduce confidence in, the industry.
- 18.2** 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 medicine, by the person to whom it is offered, or the intended end user of the medicine.

⁶ 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

- 1a** The Code of Practice Committee shall be responsible for the administration of the Code of Practice for the Promotion of Animal Medicines. Members of the Committee who are Directors or Senior Executives of a company or firm which is in membership of the National Office of Animal Health Limited (NOAH) shall be elected by the General Meeting of the Association upon nomination from the NOAH membership. Such members are referred to as industry members. The Board of Management shall appoint the Chairman, Secretary, Assistant Secretary and Independent Members. 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 from outside the industry. In so far as the Constitution and Rules hereafter provide for any charge, they shall be interpreted as only applying to industry participants.
- 1b** In the event that, for whatever reason, the appointed individual is unavailable, the Chief Executive of NOAH shall have power to appoint for temporary purposes only any individual (including himself) to carry out the functions of the Chairman, the Secretary or the Assistant Secretary 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(a). Any such temporary appointment will cease with the next meeting of the Board of Management unless approved by that meeting.
- 2** 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;
 - Four persons each being a director or senior executive of a company or firm which is in membership of NOAH;
 - Four veterinary surgeons each being a director or senior executive of a company or firm which is in membership of NOAH;
- 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 shall 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).
- 3** 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.
- 4** A minimum of five members of the Committee shall constitute a quorum, provided that these members always include (1) the Chairman; and (2) an independent member who is a veterinary surgeon. 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.
- 5** 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.
- 6** Any such expert adviser may, by invitation of the Chairman, attend meetings of the Committee but shall have no vote.
- 7** Where a participant wishes to assert that any other participant (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 resolved with expedition 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). The Committee has power to dismiss an application if:-

- (a) It is at least two years after the event first giving rise to the complaint; and
- (b) The Committee considers it is fair to do so.

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 15(iii), rule 17 or rule 19. 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.

- 8** After receiving an allegation that there has been a breach of the Code, whether from a participant or any other person (hereinafter referred to as the 'complainant') the Secretary shall:-

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.

The Secretary will also consider whether the complaint has been made with reasonable expedition after the events giving rise to the complaint and (if the complaint is more than 2 years after the event) refer the matter in the first instance for a decision as to whether the complaint should be heard, and seek from the Complainant (to the extent it has not already been provided) why the complaint was not made within the two year time limit.

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, he may within 10 working days of receipt of the Secretary's decision, request in writing to the Secretary that the Chairman's confirmation of the Secretary's decision be sought. If the complainant makes such a request, the Secretary shall forward this to the Chairman for his decision, which shall be final. If the Secretary considers the complaint can be properly dealt with under the Code of Practice, or the Chairman determines that it can, following a request to refer the issue to him, 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, 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 working days nor more than ten working 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 by the number of items to be forwarded to the Committee.

- 9** 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.

- 10** 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 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.
 - (e) require payment from each of the parties of the charge arising from the number of items of complaint being reported to the Committee.
- 11** 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 working days, which period may be extended at the discretion of the Secretary upon application.
- 12** 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.
- 13** The respondent and complainant shall each have the right to attend separately at the meeting referred to in paragraph 10 (d) above. The complainant's oral clarification must be consistent with their written submission. Each party may present oral clarification of written material providing that:-
- (a) the Secretary has received payment from the party for the charge due, and,
 - (b) the Secretary has received from the respondent the written material required under paragraph 11 above within the time limits set out; or
 - (c) the Chairman, in his discretion, permits such oral representation with such written material as he may permit.

If the respondent or complainant requires to attend the meeting, it shall notify the Secretary of that intention, not less than three working days before the date of the meeting. Failure to comply may result in the Committee refusing to allow attendance.

If a participant who is concerned in the case either as complainant or respondent is represented on the Committee, that participant's representative shall withdraw from any meeting of the Committee during the discussion of the case and shall not take part in any representation of the participant before the Committee.

- 14** The Chairman may adjourn, at any time, any meeting of the Committee at his discretion. The respondent may ask for an adjournment if it believes that additional information is required. Such requests shall be considered by the Committee – the Committee's 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. In the event of an item of complaint not being heard by the Committee either because the item is withdrawn by the complainant, or accepted by the respondent to the satisfaction of the complainant, no charge will be made for that item and an appropriate refund will be made as necessary.
- 15(i)** 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) to give such assurances regarding the steps to be taken to avoid a breach of the Code occurring in future as the Committee may require.

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

The respondent shall make a reply within ten working days, but this period may, exceptionally, upon the respondent's request, be extended at the discretion of the Chairman.

- (ii) Where the Committee decides that a breach of the Code has occurred, the Chairman may, at his discretion, provide the Committee any information he considers appropriate to assist the Committee in reaching a judgement in relation to Rules 15(iii), 17 and 19, including any information provided by the complainant under the last paragraph of Rule 7.

- (iii) 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.
- (iv) At the Chairman's discretion 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.
- (v) For each item of complaint in respect of which the Committee find a breach has occurred the respondent will be charged the appropriate sum due by reference to the charge notified by the Board, and the Secretary will return the equivalent sum paid by the complainant to the complainant. For each item of complaint that the Committee dismisses as not being in breach of the Code, an industry complainant will be charged the appropriate sum due by reference to the charge notified by the Board, 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.

16 The Secretary shall notify the complainant of the outcome of the Committee's deliberations.

16a Where the Chief Executive of NOAH considers it appropriate to do so, he may with the knowledge of the chief executive of the company concerned refer any promotional activity to the Committee for its preliminary consideration.

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 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 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.

17 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. 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 under this or any subsequent paragraph will not of itself incur further charges.

18 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.

19 It shall also be the duty of the Committee to make a report to the Board 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.

20 Where a report is made to the Board under paragraphs 17, 18 or 19 above, 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 at which the report is considered.

21 After hearing such Chief Executive or authorised representative the Board 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 his 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 7(c) of the NOAH constitution.

22 If a participant who is concerned in the case either as complainant or respondent is represented on the Board, that participant's representative shall withdraw from any meeting of the Board during the discussion of the case, and shall not take any part in any representation of the participant before the Board.

23 At the conclusion of any proceedings under the Code, the Secretary shall, subject to the authorisation of the Committee or the Board 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 7c) as mentioned in paragraph 17 above, the Board 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.

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

25 In the light of its experience of the working of the Code, the Committee may make such recommendations as it deems fit of 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.

Data Sheets

Where a participant chooses to use a data sheet rather than an SPC to satisfy the obligations of clause 7.1, at least the following information shall be included. Such information must be consistent with the SPC.⁷

<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</p>

⁷ 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.
Licence or Authorisation Numbers, Names and Addresses	Licence or authorization number of the medicinal product and the name and address of the licence or authorisation holder.
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.

IFAH-Europe Code of Good Practice for the Animal Health Industry

November 2005

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Compliance

Introduction

The International Federation for Animal Health-Europe, IFAH-Europe is the representative body of 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 food at reasonable prices.

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

1. Development

The development of products shall be conducted in a responsible manner having regard to all available scientific data and in accordance with all applicable EC 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 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

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 shall not include exaggerated claims or inappropriately encourage the use of particular veterinary medicinal products.

6. Distribution

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.

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.

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.

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 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.

B. Animal Welfare

The use of pharmaceutical 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.

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.

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.

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.

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

The conclusion of NOAH discussions has been to re-affirm our support for the legal right, held since the 1968 Medicines Act, for companies to advertise to animal keepers, whether they be farmers, horse or pet owners. We believe that over the last 30 years this facility has been beneficial in enabling companies to appraise 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 – particularly when addressed to animal owners;
2. Whether it is appropriate to advertise certain therapeutic products to the animal owner; and
3. Given the current debate over antibiotics, whether the advertising of such products to farmers and the offering of any gift or similar inducement to farmers or veterinary surgeons is helpful to the long-term position of such products.

NOAH believes in our continued right to advertise POMs to animal owners, but believe 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.

Special guidance on promotion of fluoroquinolones antibiotics

Fluoroquinolone antibiotics are recognised to make 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 their responsible marketing and use:-

1. *As with all animal diseases, management programmes such as vaccination and appropriate animal care should be used, as relevant, to reduce disease and the need for therapeutic intervention.*
2. *To be used for indications specified in the UK Marketing Authorisation and in accordance with current UK and EU legislation:-*
 - (i) *Fluoroquinolones are classified POM (prescription only medicine – only available on veterinary prescription).*
 - (ii) *Only for therapeutic use on the basis of professional experience of the individual case or farm and, where clinical circumstances allow, following sensitivity testing to determine the most suitable treatment.*
 - (iii) *Fluoroquinolones are not licensed for use as growth promoters and should not be used in this manner, which would be contrary to the "Swann" principle of reserving non-therapeutic antibiotics for this purpose.*
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

Since the earliest days of the Code of Practice the use of the word ‘safe’ has been severely proscribed. The Code states in “section 5 – Claims and Comparisons”:

- 5.3 “The use of the words ‘safe’ must not be used without qualification and it must not be stated categorically that a product has no side effects or toxic hazards”.

Background

There are a number of reasons for this provision 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 6.1.

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

The promotion of animal medicines by ‘electronic’ means has been covered by the Code for many years – clause 11 covers ‘audio visual material’, clause 12 ‘TV apparatus, VDUs and the like’ while clause 13 covers mainstream ‘radio and television promotion’.

All three clauses continue the basic theme of not being misleading, but being accurate and balanced. Clauses 11 and 13 impose “all relevant requirements of the code except 7.2”, while 12, indicating a realisation that “VDU’s” etc have more time and space, requires 7.2 to be observed.

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, any where, (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, in particular clauses 12.2 to 12.4:

- 12.2** Where it is reasonably practicable to do so, the obligatory information required by Clause 7.2 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.

12.3 In the case of any promotional material which includes a website address, the material on that website must comply with the Code.

12.4 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, 6, 8 and 10, 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 December 2006.

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 18.1 and 18.2 also relate:

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

18.2 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 medicine, by the person to whom it is offered, or the intended end user of the medicine.

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

1. Any benefit 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.

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 4.7, whilst maintaining the existing requirement that promotion must not be inconsistent with the SPC, does provide an exception 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 7.2 (production of certain particulars), 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

1. Definition in Clause 1.1 of the Code:-

1.1 The term '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, 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 web sites 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. The Concise Oxford Dictionary states that 'promotion' is the noun referable to the verb 'promote' which means (amongst other not relevant meanings) **"..... publicise and sell (product)"**.
4. The Reader's Digest Universal Dictionary, which may be felt to have a more 'new world' influence on use of the English language, provides the following material meaning for the verb 'promote':-
- "..... to attempt to sell or popularise by advertising or by securing financial support"**.
5. 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'.
6. 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.
7. 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.
8. 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.**
9. It should be understood that there is nothing wrong with promotion – providing it meets the requirements of the Code of Practice.

A
Plain Guide
to the
Code of Practice
and
Handling Complaints

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Launched at the



Code of Practice Training Seminar

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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 2diii,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 not be misleading or include a medicinal claim not in the SPC. The Code of Practice Committee follows this general approach. 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.
- f) In recent years modifications to procedures have been introduced to speed the resolution of a case. Also the introduction of 'charges' (not 'fines') is intended to concentrate minds on the key aspects of a case and reduce trivial items. All 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 the views of the Committee on relevant 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.
- 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.
- 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. [7]

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 [8] and [11].
- 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 [8]. It is no longer part of the rules that the Secretary determines whether or not there is a prima facie case disclosed by the Complainant. 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 [8a & 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 [10] 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 £3,000.00 plus VAT): however, there is no fee for complaints made by non-signatories to the Code. This payment must be received from the Complainant before the meeting of the Committee, or the Committee will not consider the complaint [12]. 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 – [9])
- 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 [13] 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 [13(a)] and the response within the time limits [13(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 [13(a)].
- 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. 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 and Respondent will be invited into the meeting separately.
- c) Committee members from companies directly affected by the case leave the room during the hearing [13(c)].

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 [2]. A quorum requires at least five Committee members [4] 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 [14], and can if thought appropriate call on expert assistance [5]. Generally, with the authority of the Committee, the NOAH Chief Executive and Technical Executive 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].
- 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. The Complainant's representatives, if any, are invited in, and after they have left, the Respondent's representatives, if any. 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.
- i) 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. [15] & [17]. Undertakings must be returned within 10 working days. [15]

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.
- 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 working days).
- 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 £3,000.00 plus VAT for Code signatories only) will be retained and a receipt issued. The opposing party in respect of that item will have its money returned.[15].
- e) The full minutes of the meeting are sent to all Committee members.
- f) A News Release is written by the NOAH secretariat as soon after the hearing as possible, and approved by the Secretary and Chief Executive, and is followed by a more detailed précis of the case. The News Release and précis will be placed on the NOAH website, together with a copy of the Undertaking.
- g) A copy of the Précis and News Release is sent to the Chief Executives of all Code signatories.
- h) 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.

Product

Company

Date

Promotion

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?

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 complainant?
- 20 Originals of material under complaint?
- 20 Copies of data sheet/SPC current at the time of promotion?
- Cheque for £3,000 + VAT per item?
- Names of representatives (if any) to attend hearing?
- Visual aid equipment needed?

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