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

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I N D E X

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

Preface

The National Office of Animal Health (NOAH) was formed on the 1st of 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.

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 the UK and the world with high quality, safe and abundant food at reasonable prices.

The Association is conscious of the importance of maintaining public confidence by the responsible conduct of business from the development and manufacturing stages through to promotion and distribution, and by the transparent exchange of information with appropriate bodies.

Animal medicines go through an extremely strict scientific assessment before they are allowed to be sold. The Veterinary Medicines Directorate (VMD) is an executive agency of the Department for Food, the Environment and Rural Affairs which is responsible for the evaluation and regulation of UK animal medicines and also grants the marketing authorisations for these products. Similar controls apply to medicines authorised across the EU through the European Medicines Agency (EMA).

NOAH supports scientific approval and works to ensure regulatory controls are managed in such a way as to protect human and animal health and the environment while encouraging investment in the animal medicines of the future.

NOAH promotes self-regulation by the animal health industry in matters relating to product promotion. The Code of Practice for the Promotion of Animal Medicines ensures ethical standards are upheld when animal medicine companies market their products. Its purpose is to ensure that marketing information is fair, accurate and objective.

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 covering advertising of veterinary medicines in the law. In addition to the legal requirements, this industry Code of Practice is obligatory on all NOAH members and has also been endorsed by several non-member companies who place their product Datasheets/Summary of Product Characteristics (SPCs) in the NOAH Compendium. The Code is upheld by the NOAH Code of Practice Committee, which is chaired by an independent practising barrister, has an independent secretary and includes representatives with expertise in farm animal production and companion animals as well as members of the veterinary profession. The Code is regularly reviewed and updated.

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 43 of

NOAH's Articles of Association. NOAH also endorses the aims put forward in the Animal Health Europe Code of Good Practice for the Animal Health Industry. 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. It can be accessed on the NOAH website in the section titled 'Promotion of Animal Medicines'.

For more information about NOAH and our work please see www.noah.co.uk or email us at noah@noah.co.uk .

Provisions of the Code

Introduction

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

In this document, the phrase 'the Code' means the NOAH Code of Practice for the Promotion of Animal Medicines. The phrase 'the Committee' refers to the NOAH Code of Practice Committee.

a. This Code of Practice for the Promotion of Animal Medicines is reviewed regularly in the light of revisions to the UK Veterinary Medicines Regulations.

b. The Code aims to secure the universal acceptance and adoption of high standards of conduct in the marketing of animal medicines.

c. While it is possible to legislate satisfactorily for the testing, manufacture and control of animal medicines, appropriate standards of marketing conduct cannot easily be defined by the same means. For this reason, participating companies have agreed to the requirements of the Code of Practice.

d. **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.**

e. This Code embodies the basic principles and provisions which NOAH member companies (and non-members who agree to abide by the Code) believe 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.

f. **The promotion of a medicine is controlled by law, including the Veterinary Medicines Regulations and anti-bribery law: the Code is not a substitute for the law, but is in addition to it.**

g. **The Code represents an act of self-discipline and participants are encouraged to resolve differences between themselves, including engaging in conciliatory procedures where possible. Acceptance and observance of its provisions are a condition of membership of NOAH. Member companies also acknowledge that the Code itself is to be applied in the spirit, as well as in the letter. Pharmaceutical companies outside NOAH are invited to accept and observe the Code because it is considered that ethical standards should be followed throughout the whole industry if it is to maintain the confidence of all the interests which it serves. A full list of companies which have agreed to follow the Code can be obtained from the NOAH office. NOAH member companies recognise that for the Code to operate effectively, they must accept and abide by the decisions of the Committee without delay. If a company breaches the Code and subsequently fails to accept or agree to the**

decision of the Committee then the Board reserves the right to refuse that company's submission of data sheets or SPCs in the Compendium electronic formats. The NOAH Board also has the right to suspend or terminate membership of NOAH as a result of non-compliance with the Code and the judgements of the Committee, should they see fit.

h. 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 employed in the animal medicines industry, and eight members who are appropriately experienced members of staff 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.

i. The Committee will meet to adjudicate on 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. Such proposals will be considered by the NOAH membership at reviews of the Code of Practice.

j. The Code will be kept under review by the Board of Management and amended from time to time where necessary to clarify it and bring it up to date.

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

- Suggestions for potential changes to the Code, from both the membership, the Committee and other relevant stakeholders, will be considered at a review meeting of the membership, which can be held annually, if the consensus among the membership that there is a need for a review.

- The Committee may also recommend changes to guidance notes or additional guidance notes to aid Code Participants on compliance. Such guidance notes will be considered and approved by the NOAH membership as outlined below.

- Recommendations from the Code of Practice review meeting and for changes to guidance notes will be put forward to the NOAH Board for consideration and approval. The views of the Committee on potential amendments will also be sought. Legal advice on any changes will be sought from the Chair and Secretary of the Committee.

k. Notes for the guidance of Code Participants will be issued periodically to keep them informed of the rulings and recommendations of the Committee and of any alterations to the Code. 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.

l. A breach of Clause 3 of the Code, that is to say, a finding of the 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.

m. **When considering alleged breaches of the Code, the Secretary of the Committee will consider what are referred to as 'items' of complaint.** An 'item' is the individual statement, form of activity by a company, or promotional graphic under complaint.

Definitions

1 Clauses and Definitions of Terminologies

1.1 **"Promotion"** means those marketing activities under the control of the participating company, which do or may encourage the prescribing supply or use of the company's products. It includes, for example, data sheets, the activities of representatives; various aspects of sales promotion such as journal and direct mail advertising including 'teaser' campaigns; the use of Internet communications including websites, social media 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 "**Animal Medicine"** means any 'veterinary medicinal product' as defined in the Veterinary Medicines Regulations (VMR) in force at the time.

In the case of products marketed under the Exemption for Small Pet Animals Scheme (previously referred to as the Small Animal Exemption Scheme), Clause 4.4 (iv) and Row 3 of Table 6.2 shall not apply.

1.3 Definitions of Target Audience for Promotions

- "**Professional Keeper of Animals"** means any person whose business involves keeping animals for profit making purposes and who uses Animal Medicines in the course of his/her business or occupation for whom accessing information about Animal Medicines assists them with the performance of their professional duties, e.g. a farmer or farm manager.

- **"Veterinary Professional"** means the following classes of person:

    - Veterinary Surgeon is a person registered on the Royal College of Veterinary Surgeons (RCVS) register of veterinary surgeons and offering services in the UK.

    - A Veterinary Student is a student studying a degree that once obtained, deems them eligible for entry on to the RCVS register of veterinary surgeons.

    - A Veterinary Nurse is a person registered on the Royal College of Veterinary Surgeons (RCVS) register of veterinary nurses and offering services in the UK.

    - A Veterinary Nursing Student is a student studying a qualification that once obtained, deems them eligible for entry on to the RCVS register of veterinary nurses.

- A **"Suitably Qualified Person (SQP)"** (sometimes referred to as Registered Animal Medicines Advisor) is the legal term for an animal medicine advisor who is qualified to prescribe and/or supply certain animal medicines under the Veterinary Medicines Regulations.

[1] See Guidance Note 6: The Meaning of 'Promotion'

- A "**Suitably Qualified Person (SQP) student"** is a student studying a qualification that once obtained, deems them eligible for entry onto a register of Suitably Qualified Persons.

- A **"Pharmacist"** is a person registered with the General Pharmaceutical Council and permitted to work as a pharmacist in the UK.

- "**Member of Public**" means all those to whom promotion may be directed other than Professional Keepers of Animals, Veterinary Professionals, Suitably Qualified Persons (SQPs), SQP students or Pharmacists as defined in Clause 1.3 above.

- **"Distributors of Animal Medicines"** means all intermediaries involved in supply and retail of veterinary medicines.

1.4 "**Participant**" refers to NOAH member companies, and to those non-member companies who have agreed to abide by this Code.

1.5 "**SPC**" means the Summary of Product Characteristics of a Marketing Authorisation.

1.6 **"Data Sheet"** means the traditional data sheet which is an abbreviated form of the SPC and contains all the essential information for the prescriber which is consistent with the SPC. Any changes to the SPC must, within 30 calendar days of approval by the relevant regulatory authority, be reflected in the Data Sheet, in the online NOAH Compendium of Data Sheets, and in any printed copies of the datasheet issued to the prescriber subsequent to the change in the SPC. In certain circumstances it may not be appropriate for the changes in the SPC to be reflected in the datasheet e.g. when the product or change has been approved but not yet placed on the market by the Marketing Authorisation holder. The NOAH Board has agreed that it considers data sheets to be Promotional Material in themselves, and thus within the scope of the Code.

Any significant changes to the SPC that require updates to existing datasheets that are important for prescribers and end users to be aware of must also, within 30 days, be added to the 'new and updated datasheets' section of the NOAH online compendium at the time of updating.[2]

1.7 "**Broadcast Promotion"** means an audio-visual Promotion of a Participant which is communicated to the viewer via a television, radio or satellite channel, cable feed or any other medium where:

(i) a third party is responsible for communicating the Promotion of the Participant to the viewer; and

(ii) the cost to the Participant, of the Promotion, is related to its duration, and the inclusion of the information prescribed for the promotion if it had not been a Broadcast Promotion (see Clause 6.2) would unreasonably increase the cost or duration of the Promotion.

[2] See Guidance Note 11: Significant Datasheet Changes

1.8 **"Day"** means working day; that is a day which is not a Saturday, Sunday or a public or bank holiday within the country of the United Kingdom wherein the Participant has its place of business from which the requirement will have to be carried out.

1.9 **"VMD Regulations"** means any regulations, statutory instruments, or anything else having the force of law issued by the Veterinary Medicines Directorate governing the Promotion of animal medicines.

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

1.11 **"Marketing Authorisation"** For the purpose of this Code, "Marketing Authorisation" has the same meaning as given in the current UK Veterinary Medicines Regulations.

1.12 **"Antimicrobials"** For the purpose of the Code of Practice, antimicrobials mean antibiotics, which are antibacterial in their action. All antibiotic products authorised in the UK are POM-V.

Code Clauses

2 Application of the Code

2.1 The Code applies in its entirety in relation to any UK directed Promotion of an Animal Medicine by a Participant that is directed towards Veterinary Professionals, Suitably Qualified Persons (SQPs), SQP students, Distributors of Animal Medicines, Professional Keepers of Animals, Pharmacists and Members of the Public.

3 Methods of Promotion

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

4 Promotion of Animal Medicines

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

(i) classified as POM-V (unless for educational purposes as set out in Clause 4.2) may only be promoted to Veterinary Professionals, Pharmacists and Professional Keepers of Animals, unless otherwise prohibited by the VMR e.g. the promotion of Antimicrobials to farmers is prohibited.

(ii) classified as POM-VPS (unless for educational purposes as set out in Clause 4.2) may only be promoted to Veterinary Professionals, Pharmacists, SQPs, SQP students and Professional Keepers of Animals. The promotion of POM-VPS products to horse owners that are not Professional Keepers of Animals is not permitted.

(iii) classified as NFA-VPS and AVM-GSL may be promoted to any class of person.

(iv) are prohibited if such Animal Medicines are not authorised for use in the United Kingdom i.e. do not hold a UK Marketing Authorisation or an authorisation from the European Medicines Agency (EMA) which is valid in the UK. This prohibition will not apply to the promotion of non-UK authorised Animal Medicines and/or indications at a truly international event which is recognised as being for the benefit of international attendees. The display and provision of Promotional Material for such Animal Medicines and/or indications is permitted at international meetings in the UK provided that the following conditions are met:

- The meeting must be a truly international meeting of high scientific standing with a significant proportion of the attendees from countries outside the UK in which the product and/or indication is licensed.

- The medicine or indication must be relevant and appropriate for the purpose of the meeting.

- Promotional material for a medicine or indication that does not have a UK marketing authorisation must be clearly and prominently labelled to that effect.

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

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

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

4.3 A Promotion of Animal Medicines must:

(i) be fair;

(ii) be balanced;

(iii) not be misleading (directly or by implication);

(iv) not directly or by implication disparage the products or services of other companies;

(v) not directly or by implication disparage the clinical and scientific opinions of members of the veterinary and allied professions;

(vi) not contain exaggerated claims, all-embracing claims or superlatives of a general nature;

(vii) not state directly or by implication that an Animal Medicine, or an active ingredient, has some special merit, quality or property over other products unless this can be substantiated;

(viii) not use the word 'new' to describe any product or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than twelve months in the United Kingdom;

(ix) not use Veterinary Surgeons' names or photographs in any way that is contrary to the Royal College of Veterinary Surgeons' *Code of Professional Conduct;*[3]

(x) not use devices, copy, slogans, trademarks or get-up which are the same or are likely to be confused with those of other holders of Marketing Authorisations for Animal Medicines save where such use is for the purpose of comparing Animal Medicines;

(xi) not be contrary to the VMD Regulations;

[3] Available via the RCVS website.

(xii) encourages responsible use of the substance while presenting its characteristics in an objective manner;

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

(i) be accurate;

(ii) be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly;

(iii) be capable of substantiation;

(iv) not be inconsistent with the SPC, except that a Veterinary Surgeon or other appropriately qualified person employed or engaged by a participating company may in appropriate circumstances give information about cascade use in response to a technical enquiry from another Veterinary Surgeon. Requests about cascade use posted on online forums must be responded to via a private message to the person requesting the information;[4]

(v) not use the word 'safe' without qualification;

(vi) not state that an Animal Medicine has no side-effects or toxic hazards;[5]

(vii) not use any comparative safety information unless such is limited to information taken directly from the approved SPC or that obtained from a well-controlled clinical study of products and in either case must not be presented in a misleading manner. The use of Suspected Adverse Event data originating from regulatory authorities regarding other companies' products is not permitted. The use of a Participant's (or Marketing Authorisation Holder's) own Suspected Adverse Event data is also not permitted.

(viii) Not, where company information, data or studies are used, use the phrase "data on file". The data referred to must have an identifiable internal company reference.

4.5 Participants shall ensure that the SPC or Data Sheet is available online via the VMD's Product Information Database or the NOAH online compendium before promoting a product.

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

4.7 Post-prescription information is information made available to animal owners and end users of Animal Medicines after a product has been prescribed, for example, instruction to assist with correct use of the product. Such information should only be made available to animal owners and end users of Animal Medicines after a product has been prescribed.[6]

[4] See Guidance Note 5: Responses to Technical Enquiries
[5] See Guidance Note 2: The Concept of 'Safety' in Promotions
[6] See Guidance Note 12: Limiting Access to Online Promotional Material and Post-Prescription Information

5 Requests for Information and Northern Ireland

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

(i) information or data referred to in the Promotion and/or
(ii) information or data to substantiate any claim in the Promotion.

If there are reasonable grounds to believe that there has been a breach of the Code, a participant must also provide within 5 Working Days of receipt of the written request from a lawfully intended recipient of the Promotion or other Participant: copies of the relevant parts of the Promotion (for Promotions done electronically this could include a copy of any email and/or relevant parts of an e-detailer);

In the case of genuine extenuating circumstances, a short extension to the 5-working day limit can be requested with an explanation and an estimate of the additional time required.

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

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

5.4 A Participant must use reasonable efforts

(i) not to actively promote Animal Medicines that are authorised only in Great Britain (GB) in Northern Ireland (NI);[7]
(ii) not to actively promote Animal Medicines that are not permitted to be promoted under EU law to Professional Keepers of Animals in Northern Ireland.[7]

6 Mandatory Information in Promotional Material

6.1 The provisions of this Clause shall apply to all Promotional Material other than

(i) material which is not intended by the Participant to be a Promotion of Animal Medicines but contains information such as changes in price or packaging or adverse reaction warnings, recalls of defective products;

(ii) Promotions which only contain brand name, generic name, company name or logo including educational material;

(iii) Company Datasheets (which are considered to be promotional items).

6.2 The following information must be included in all Promotions (save those set out in clause 6.1 above);

[7] See Guidance Note 13: Promotions in Northern Ireland

	Category of Information
1	Brand Name
2	The Active Ingredient(s)
3	Legal Category of Product
4	Company Name
5	Company Contact Details
6	The strapline "prescription decisions are for the person issuing the prescription alone'' (this is not required for products classified as NFA-VPS or AVM-GSL). The strapline "Use Medicines Responsibly"[8] can still be retained but is optional. The strapline 'authorised in UK (GB) only' in adverts where a UK (GB) authorised product is advertised in a UK wide publication. The strapline 'authorised in UK (NI) only' in adverts where a UK (NI) authorised product is advertised in a UK wide publication. The strapline 'this promotion is only intended for farmers in England, Scotland and Wales' in promotions where a product that is being marketed to professional keepers of animals in a UK-wide publication is a product which cannot be promoted in Northern Ireland (NI).[9]
7	An indication that further information is available from the SPC or datasheet or pack leaflet
8	A clear instruction that advice should be sought from prescriber if product is POM-V or POM-VPS when promoting to persons other than the prescriber

Further Requirements for Promotions Other than Broadcast Promotions

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

Requirements for Broadcast Promotions

6.4 In the case of Broadcast Promotions, the information required under Clause 6.2 can be provided either by voice or by the written word on the screen. If the written word is used on the screen, the information must be provided for a sufficiently long period of time and be sufficiently large so that the reasonably observant person can read it and understand it without undue difficulty. The information can be provided either by way of a separate frame or by way of overlay (e.g. as a static or rolling banner at the bottom of the screen).

7 References to Official Bodies

7.1 Unless specific requirements, statutory or otherwise, have been imposed, manufacturers must not include in any announcement or Promotional Material a reference to the Veterinary Products Committee, the Department for Environment, Food and Rural Affairs (DEFRA), the Veterinary Medicines Directorate, European Medicines Agency or similar official bodies.

[8] See Guidance Note 8: "Prescription decisions are for the person issuing the prescription alone" Strapline
[9] See Guidance Note 13: Promotions in Northern Ireland

7.2 It shall not be a breach of this Clause to refer to the fact that a product is authorised by the relevant body, nor to refer to general publications of those bodies.

8 Distribution of Promotional Materials

8.1 Promotional Material must only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.

8.2 Restraint must be exercised on the frequency of distribution and on the volume of Promotional Material distributed.

8.3 Mailing lists must be kept up to date.

9 Reprints, Abstracts and Quotations

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

9.1 Quotations from articles of a scientific or technical nature in Promotions must:

- be accurate;

- cite the author(s), the title of the article and its publication reference;

- not mislead by being out of context.

9.2 Reprints of articles or quotations of a substantial nature must not be included in mailings without permission of the author and/or copyright owner (if different).

10 Websites and Social Media

10.1 Participants shall ensure that Promotional Material which is under their control shall not be made available to or be accessible by Veterinary Professionals, Suitably Qualified Persons (SQPs), SQP students, Pharmacists, Professional Keepers of Animals or members of the public (e.g. via a website) where accessing such promotional material would contravene this Code.

It is acceptable for Marketing Authorisation Holder product portfolio pages to be accessible to the general public without limitations on access, subject to such material not being used in a promotional manner.

Access to online Promotional Material and educational information where the target audience should be limited as specified in clause 4.1 should have appropriate 'gate keeping' measures in place to limit access to the material.

Access to post prescription information should have appropriate 'gate keeping' measures in place to limit access to the material and should only be made available to animal owners and end users of Animal Medicines after a product has been prescribed. [10]

[10] See Guidance Note 12: Limiting Access to Online Promotional Material and Post-Prescription Information

10.2 Any UK-based website under the control of a participant, which links to another site which may include information about Animal Medicines not authorised in the UK, or to conditions not relevant to the UK, must provide suitable and prominent warning of this to readers.

10.3 Participants shall ensure that text presented in search results relating to websites under their control will be compliant with the requirement of the Code.

10.4 On social media websites, where a Participant moderates the content, third party posts or comments must be edited where necessary to ensure compliance with the requirements of the Code and the Veterinary Medicines Regulations. Such edits must be completed within 5 working days of the non-compliant material being posted.

11 Sales Representatives

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

(i) Except in the case of representatives solely selling AVM-GSL medicines, Marketing Authorisation Holder representatives must:

(a) be registered on the NOAH Certificate of Animal Health (NCAH) register within six months of commencing employment;

(b) thereafter be on the current year's NOAH Certificate of Animal Health (NCAH) Marketing Authorisation Holders' Representatives register;

(c) within two years of commencing employment sit the NCAH examination; and

(d) within 3 years of commencing employment, pass the NCAH examination.

(ii) For all Participants, an annual declaration of compliance with rule 11.1 shall be required, signed by the chief executive.

(iii) Veterinary Surgeons who are registered with the Royal College of Veterinary Surgeons and are employed as Marketing Authorisation Holder representatives are exempt from the requirement to obtain the NCAH qualification.

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

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

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

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

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

12 Samples

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

12.2 Where samples of Animal Medicines 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 their behalf. A similar practice must be adopted for Animal Medicines which it would be unsafe to use except under veterinary supervision.

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

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

13 Market Research

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

13.2 Access to respondents must not be gained by subterfuge.

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

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

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

14 Relations with the General Public and the Communication Media

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

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

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

15 Sponsorship, Gifts, Hospitality[11]

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

15.2 Without prejudice to Clause 15.1, Sponsorship and hospitality must be associated with the general business area, business discussions, Continuing Professional Development (CPD) or otherwise have an educational component.

15.3 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 inexpensive and relevant to the practice of veterinary medicine or pharmacy.

15.4 Entry into prize draws must not be linked with purchase or prescription of an Animal Medicine.

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

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 to help inform members as to how the Code of Practice rules are intended to be operated in practice. Nevertheless, members are expected to abide by the 'spirit' of the message.

Guidance Note 1: Promotion of Prescription Only Medicines

Over the last 30 years the ability to promote medicines has been beneficial in enabling companies to appraise veterinary surgeons, veterinary students, veterinary nurses, veterinary nursing students, SQPs and professional keepers of animals 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 Promotion of each particular Prescription Only Medicine is appropriate to its status and to the image of the industry.

2. Whether it is legally permitted and appropriate to promote certain animal medicines, in accordance with the regulations, to the animal owner; and

3. Given the importance of responsible use of antibiotics, whether offering of any gift or similar inducement to veterinary surgeons is helpful to the long-term position of such products.

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

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

Industry Guidance for Antibiotic Promotion and Use

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

1. *Farm health plans include Standard Operating Procedures (SOPs) for hygiene and vaccination programmes. Good animal husbandry, hygiene and use of vaccines or other appropriate immunotherapies where possible should be implemented to reduce the occurrence of disease and the need to use therapeutic antibiotics.*

2. *Antibiotics should be used only where the prescribing Veterinary Surgeon believes they are needed for an infection specified in the UK or European Medicines Agency (EMA) Marketing Authorisation and in accordance with current UK and EU legislation:*

(i) Antibiotics can only be administered following a prescription by a veterinary surgeon: they are classified as POM-V (Prescription Only Medicine - Veterinary).

(ii) Vets may only prescribe antibiotics (subject to the professional obligations of a veterinary surgeon to ensure the health and welfare of animals under their care) when satisfied that the product is not:

- *used routinely;*
- *used to compensate for poor hygiene, inadequate animal husbandry, or poor farm management practices; or*
- *used to promote growth or increase yield.*

(iii) They are prescribed on the basis of the veterinary surgeon's knowledge of the individual case or farm and, ideally, following susceptibility testing of the causative bacteria to determine the most suitable treatment. When used in anticipation of emergency diseases outbreaks where there is no time to conduct sensitivity testing of target pathogens (e.g. E.coli), regular susceptibility monitoring is carried out.

Vets can only prescribe antibiotics for prophylactic use in exceptional circumstances where the risk of an infection or of an infectious disease is very high and where the consequences of not prescribing the product are likely to be severe.

For group prophylaxis - vets can only prescribe if:

- *The rationale for prescribing the product to the group of animals is clearly recorded by the vet prescribing it.*
- *A management review is carried out by a vet after administration of the product in order to identify factors and implement measures for the purpose of eliminating the need for any future such administration.*

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

Since the earliest days of the Code of Practice the use of the word 'safe' has been severely proscribed. The Code states in Clause 4.4 that Participants must:

(v) not use the word 'safe' without qualification

(vi) not state that an Animal Medicine has no side-effects or toxic hazards.

(vii) not use any comparative safety information unless such is limited to information taken directly from the approved SPC or that obtained from a well-controlled clinical study of products and, in either case, must not be presented in a misleading manner. The use of Suspected Adverse Event data originating from regulatory authorities regarding other companies' products is not permitted. The use of a Participant's (or Marketing Authorisation Holder's) own Suspected Adverse Event data is also not permitted.

<u>Background</u>

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

I. All Animal Medicines when licensed have to demonstrate 'safety, quality and efficacy' – popularly interpreted as "safe when used as directed". Thus, it has long been argued that to claim a licensed product is 'safe' is not only tautology but could be interpreted as implying that other licensed products are unsafe.

II. The implication that other Animal Medicines are unsafe reduces confidence in the licensing system – a cornerstone of our industry.

III. The implication that rival Animal Medicines are unsafe is disparaging and so also indicates a breach of 4.3(iv) & (v).

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

Guidance Note 3: Promoting Animal Medicines on the Internet

The Promotion of Animal Medicines by 'electronic' means has been covered by the Code for many years – clause 6 covers the requirements and exemptions for various types of Promotional Materials. See also Guidance note 9 which makes the distinction of internet promotions to those by Broadcast media.

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

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

(i) In the case of any Promotional Material which includes a website address, the material on that website must comply with the Code.

(ii) Any UK-based website under the control of a Participant which links to another site which may include information about Animal Medicines not authorised in the UK or to conditions not relevant to the UK must provide suitable warning of this to readers.

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

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

Clause 3 of the Code, which refers to all licensed categories of Animal Medicines states:

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

Clauses 15.1 to 15.4 also state the following:

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

15.2 *Without prejudice to Clause 15.1, sponsorship and hospitality must be associated with the general business area, business discussions, Continuing Professional Development (CPD) or otherwise have an educational component.*

15.3 *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 inexpensive and relevant to the practice of veterinary medicine or pharmacy.*

15.4 *Entry into prize draws must not be linked with purchase or prescription of an Animal Medicine.*

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

1. Any gift with the exception of price or product itself offered in relation to sales Promotion should be modest in cost. The exception of "price or product itself" means that Participants are not restricted in the pricing of products or in promotional offers whereby a buyer receives free products

2. Examples of inexpensive gifts that are likely to be considered acceptable would include items with a clear business use and items directly related to the correct use, administration or disposal of that product, by the person to whom it is offered, or the intended end user of the medicine. This could include educational events including modest hospitality, educational items, diagnostic aids or veterinary equipment whose value is not excessive.

3. Items that have a clear business use such as branded mugs, branded pens, notepads or computer accessories are likely to be considered acceptable.

4. 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 laws on the supply of Animal Medicines are followed.

5. The wording in Clause 15.3 does not override the provisions in Clause 15.1. Therefore, it is still possible, even if the gift relates to price or product itself or is inexpensive and relevant to the practice of veterinary medicine or pharmacy, for the gift to fall foul of the requirements that it should not bring discredit, or reduce confidence in, the industry.

6. Care needs to be taken when offering discounts or rebates to an end user (e.g. farmer) to ensure that the discount or rebate does not encourage the purchase of unnecessary Animal Medicines or unnecessary volumes of Animal Medicines and also, that the welfare of the animal is at all times never adversely affected either actually or potentially by the discount or rebate offer.

7. For the purpose of Clauses 15.1 to 15.4 the word 'gift' is construed by the Code as including any pecuniary advantage being provided, with the exception of price or product itself.

8. For the purposes of Clauses 15.1 to 15.4 a prize draw is a competition where the winner is chosen at random from all valid entries returned by participants.

Guidance Note 5: Responses to Technical Enquiries

1. Prior to November 2004, the Committee, by convention, accepted that responses to technical enquiries did not constitute 'promotion' and were therefore outside the ambit of the Code. 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 Animal Medicines, will be considered Promotion, and the Code will apply to such communications.

2. It is very unlikely that a genuine and accurate response given by an appropriately qualified person to a genuine technical enquiry about cascade use of the Animal Medicine from a veterinary surgeon will be in breach of the Code. Participants need to be careful in standardising the reply to queries which are frequently received. If the reply indicates that the Animal Medicine can be used in a certain way, then that is likely in practice to be 'Promotion' although not necessarily a breach of the Code.

3. Sales representatives should not provide technical responses for cascade use 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 Participant is appropriate.

4. Participants must ensure that their technical advisors are capable of ascertaining whether any enquiry for a use of an Animal 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 7 below).

5. Clause 4.4, whilst maintaining the existing requirement that Promotion must not be inconsistent with the SPC, does provide an exception, under sub clause (iv) to information being supplied regarding cascade 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 Participant 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 Participant in question. Participants 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.

6. To the extent that any Promotion by way of technical response could require compliance with Code of Practice Clause 6 (mandatory information), this can easily be resolved by ensuring that every written technical response includes a copy of the data sheet or SPC for the Animal Medicine in question.

7. Participants and their technical advisers should always bear in mind the importance of the Cascade principle as defined in the Veterinary Medicines Regulations. The adviser should ensure that the advice given clearly emphasises to the enquirer the importance of prescribing Animal Medicines in accordance with the Cascade principle which is a statutory requirement as well as a professional conduct requirement for veterinary surgeons.

Guidance Note 6: The Meaning of 'Promotion'

1. Definition in Clause 1.1 of the Code:-

   "**Promotion"** means those marketing activities under the control of the Participant, which encourage the prescribing, supply or use of the company's Animal Medicines. It includes, for example, data sheets, the activities and verbal communications of representatives; various aspects of sales Promotion such as journal and direct mail advertising including 'teaser' campaigns; the use of Internet communications including websites, social media 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 may encourage the prescribing supply or use of the Animal Medicines. 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 of the word in the English language. This is quite deliberate, because advances in technology will provide new forms of media, and therefore, arguably new forms of Promotion.

3. So, the starting point is that any act which has the effect (whether intended or not) of publicising and thereby potentially selling or making the Animal Medicine more likely to be sold, runs the risk of being 'Promotion' or being held to be 'Promotion'.

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

5. Responses to technical inquiries may be considered within the scope of what is considered to be Promotion - see Guidance Note 5.

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

7. Where a 3rd party, such as a retailer of Animal Medicines (e.g. a veterinary practice or veterinary online pharmacy) is promoting a Marketing Authorisation Holder's veterinary medicine, but the Promotion is not under the control of the Participant, it is nevertheless expected that the Participant, on becoming aware of such an item, would recommend to the 3rd party, that they alter any Promotion that may be considered to be in breach of the Veterinary Medicines Regulations.

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

1. This Guidance Note follows an in-depth review of Clause 4.4(iv) and its proper construction bearing in mind the Veterinary Medicines Regulations and the Animal Health Europe Code. Clause 4.4 (iv) states:

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

2. The Veterinary Medicines Regulations (VMRs) say that advertisements:-

   ''must contain no information which is incompatible with the summary of product characteristics in relation to the substance"

   And that advertisements should:

   ''encourages responsible use of the substance while presenting its characteristics in an objective manner;"

   The VMRs also requires any advertisement to contain no information which:
   - Is misleading.
   - Might encourage improper use of the substance.

3. The Animal Health Europe Code states:-

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

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

   "The Promotion of an Animal Medicine is controlled by law, including the Veterinary Medicines Regulations **and anti-bribery law*; this code is not a substitute for the law, but in addition to it".***

5. Accordingly, members are strongly urged not to consider there is any material distinction between the Code, the VMR and the Animal Health Europe Code, to the intent that:-

i) Any Promotion of a medicinal claim outside the SPC is illegal under the legislation and by definition would also constitute a breach of the Code;

ii) Notwithstanding the last phrase of the Animal Health Europe above statement as regards indications, a genuine non-medicinal claim which is not expressly referred to in the SPC is unlikely to be a breach, although Participants should be very cautious in determining what is or is not a medicinal claim given that there is no definition of "medicinal claim" within the Veterinary Medicines Regulations.

iii) It follows that Participants should be equally cautious in relying upon any perceived difference between "*not inconsistent*" and "*consistent*", bearing in mind the above guidance.

Guidance Note 8: "Prescription decisions are for the person issuing the prescription alone" Strapline

1. It is a legal requirement for promotions to include a strapline stating that "prescription decisions are for the person issuing the prescription alone''.
2. This is not required for products classified as NFA-VPS or AVM-GSL. The strapline 'Use Medicines Responsibly' can also feature should Participants choose to include this in promotions.
3. In order to give sufficient prominence to any strapline, the strapline should be separated from other text (e.g. strapline could be the final line on each advertisement).

   The font should be sufficiently large to ensure it is readable.

Guidance Note 9: Information to be included in Promotions

1. This guidance note explains what information must be included in Promotions. The fundamental policy is that all Promotions should contain all information that would be relevant to the target audience of the Promotion whilst taking account of the practicalities caused by such obligation in certain Promotions.

2. In Clause 6.2, a list of categories of information is set out which Participants must include in all types of Promotion whether in print media, online media or broadcast Promotions or otherwise.

3. The Code makes a distinction between what is defined as Broadcast Promotions and other type of Promotions. The basic principle is to differentiate between Promotions in a particular medium where the inclusion of all relevant information would mean that the Promotion was unreasonably expensive or too long (Broadcast Promotions) and other types of Promotions even if audio-visual where the inclusion of all relevant information is not unreasonable.

4. The obvious case of a Broadcast Promotion is an advertisement on a normal terrestrial, satellite television or cable channel. Another example would be a radio advertisement. A "trailer" advertisement on a third-party website will also be considered a Broadcast Promotion *if* the cost of the advertisement depends on the duration of the advertisement and the inclusion of all relevant information would be unreasonably expensive.

5. In contrast, a YouTube advertisement clip would not be considered a Broadcast Promotion if the cost of the advertisement is not related to the duration of the advertisement. Equally, any audio-visual provided on a website under the control of the NOAH member must ensure that all relevant information is available (e.g. a datasheet or SPC PDF link next to the promotional video).

6. Where a Promotion is limited by time or space, a 'click through' link or web address guiding the audience to where they can access further information should be used. In such cases, the advertiser should ensure that the audience can find out about all relevant information from the 'click through' link or web address.

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

1. The general requirement, which is as much a matter of law under the VMR (by Regulation 10) as it is a feature of the Code, is that Animal Medicines which do not have a UK Marketing Authorisation or authorisation from the EMA, which is valid in the UK, must not be promoted in UK.

2. The 26th Edition of the Code, for the first time, has provided an exception to the general prohibition in this clause 4.1 (iv), in recognition that the UK is frequently selected as the location for conferences, meetings and seminars referable to international animal health, at which manufacturers, prescribers and users from outside the UK attend. It needs to be emphasised that for the relaxation to apply and the exception validly relied upon, the event must be truly international, and not a national event at which international attendees may also be present.

3. Accordingly, any Promotion relying on this exception must be at a truly international event at which a significant proportion of the attendees will be from countries outside the UK, and it will be for the Participant to prove that the event and its Promotion falls within the exception.

Guidance Note 11: Significant Datasheet Changes

1. The NOAH Compendium is an essential and valued source of up-to-date information about veterinary medicinal products.

2. In the online NOAH compendium, a section titled 'New and Updated Datasheets' has been developed so that prescribers and end users can readily access information about any important changes.

3. In order to maximise its usefulness to prescribers and end users of veterinary medicines, clause 1.6 of the Code requires that any significant changes to datasheets must be updated in the datasheet in the online compendium and they also must be added to the 'new and updated datasheets' section of the online compendium within 30 calendar days of the change to the SPC.

4. Typographical errors or general administrative changes would not be considered to be significant changes that need to be added to the 'new and updated datasheets' section.

5. A non-exhaustive list of what would constitute a significant change would include the following: new indications or species being added to the Marketing Authorisation, new safety warnings, changes to contraindications or precautions for use, information about adverse events or interactions with other products or information about use during pregnancy, lactation or lay.

Guidance Note 12: Limiting Access to Online Promotional Material and Post-Prescription Information

MAH Product Portfolio Pages

1. Marketing Authorisation Holder's (MAH) product portfolio page may be accessible to the general public. A Participant's product portfolio page that lists the products for which the company holds a Marketing Authorisation would not be considered to be Promotion.

2. Such product portfolio pages should meet the following requirements:

    - Include all products that are marketed.
    - Use the same size text for all products.
    - Use consistent font size, colour and formatting.
    - Refer to the product by its full authorised name.
    - Contain one basic image of the product ('pack shot') only.
    - Product portfolio pages may contain links to publicly available product information such as the summary of product characteristics (SPC) and package leaflet.
    - Products could (but do not have to) be grouped by animal species for which the products are authorised.
    - A statement that POM-V and POM-VPS products are only accessible via the appropriate prescription routes should be included.
    - Companies should ensure that the name of each product, its image and description is in line with the product's UK authorised SPC.

Post-Prescription Information Websites Intended for Animal Owners

3. It is permissible that certain post-prescription information should be allowed to be presented on a marketing authorisation holder's (MAH) website, provided that access to this information is restricted via an appropriate gatekeeping system. Such information should

only be made available to animal owners and end users of Animal Medicines after a product has been prescribed.

4. Educational post-prescription information would include, but is not limited to, relevant product-specific information as well as scientific and technical information about the disease or condition being treated/ prevented.

5. The principles referred to in this guidance note regarding the content of post prescription information should be adhered to regardless of whether the post prescription information is provided in hard copy print or online.

6. If a company provides information for both prescribers and animal owners, the website areas providing such educational post-prescription information for animal owners should be clearly separated from that directed at prescribers with the use of specific sections intended for the respective target audiences.

7. MAHs publishing educational post-prescription product-specific information for animal owners must ensure the contents of the materials produced are compliant with both the Code of Practice and the UK Veterinary Medicines Regulations and should take into consideration the following:

    - Information concerning a particular Animal Medicine should only be available to animal owners whose animal has been prescribed that Animal Medicine.

    - Information provided must be factual and must not make any misleading claims.

    - Information should not contain product placement of other POM-V/POM-VPS veterinary medicines.

    - Access to the material should be controlled via an appropriate gatekeeping system, for example a statement stating, 'this information is for owners of an animal which has been prescribed [product name]; please click here to confirm this describes you'.

Gatekeeping on MAH Web Pages Intended for Restricted Audiences

8. To meet the requirements of clauses 4.1 and 10.1 of the Code an appropriate gatekeeping system should be in place to restrict access to online information to the appropriate audiences. This can be done by using appropriate pop-ups requiring that the person seeking to gain access to the information confirms their status.

9. Examples of what could be appropriate pop-ups with appropriate options/actions are:

    - This information should only be accessed by Veterinary Professionals or Pharmacists, click here to confirm if you are a Veterinary Professional or Pharmacist.

- This information should only be accessed by Veterinary Professionals, Pharmacists or Suitably Qualified Persons (SQPs); if this describes you please click here to confirm.

- This information should only be accessed by Professional Keepers of Animals; please click here to confirm that you are a Professional Keeper of Animals.

- This information is for owners of an animal which has been prescribed [product name]; please click here to confirm this describes you.

10. The following measures should also be in place on the company website:

- If the website user is not the intended audience, the user must be redirected to material that can legally be available to them.

- If the website user is the intended audience only information that can legally be available to them may be shown.

- The page content must not be readable around the pop-up (i.e. obscured prior to a pop-up being accepted).

Guidance Note 13: Promotions in Northern Ireland

1. Following the UK's exit from the European Union, under the terms of the UK/EU Trade and Co-operation Agreement, EU law, including laws regulating veterinary medicines, are required to be applied in Northern Ireland.
2. This requirement is set out under the terms of both the Northern Ireland Protocol and the Windsor Framework Agreement.
3. This regulatory divergence means that there can be differences relating to the range of products that are authorised in Great Britain (GB) and Northern Ireland (NI). The different types of authorisations that can exist are as follows:

UK Marketing Authorisation (MA)- a product with a UK MA has been approved for marketing in England, Wales, Scotland and Northern Ireland

UK (GB) MA - A product with a GB MA has been approved for marketing in England, Wales and Scotland.

UK (NI) MA - A product with an NI MA has been approved for marketing in Northern Ireland. These applications will be assessed against the requirements set out within the EU Regulation.

4. Furthermore, where products are authorised in both GB and NI, the indications for use in Summary of Product Characteristics can be different as the products are being authorised under different regulatory regimes.
5. Under the current European Veterinary Medicines Regulation (2019/6) advertising of veterinary medicinal products that are subject to veterinary prescription, to professional

keepers of animals, may be permitted only where advertising is limited to immunological veterinary medicinal products.

6. This differs from the requirements of the Great Britain Veterinary Medicines Regulations 2024, which permit all POM-V and POM-VPS veterinary medicines, with the exception of antimicrobials, to be promoted to Professional Keepers of Animals.
7. Accordingly, the NOAH Code of Practice contains the following requirements relating to promotions in Northern Ireland (NI):

Clause 5.4 states:

5.4 *A Participant must use reasonable efforts*

(iii) not to actively promote Animal Medicines that are authorised only in Great Britain (GB) in Northern Ireland (NI).

(iv) not to actively promote Animal Medicines that are not permitted to be promoted under EU law to Professional Keepers of Animals in Northern Ireland.

Clause 6.2 states:

a. The following information must be included in all Promotions (save those set out in clause 6.1 above);

6 The strapline 'authorised in UK (GB) only' in adverts where a UK (GB) authorised product is advertised in a UK wide publication.

The strapline 'authorised in UK (NI) only' in adverts where a UK (NI) authorised product is advertised in a UK wide publication.

The strapline 'this promotion is only intended for farmers in England, Scotland and Wales' in promotions where a product that is being marketed to professional keepers of animals in a UK-wide publication is a product which cannot be promoted in Northern Ireland (NI).

7. As many veterinary and farming publications are UK wide, the Code requires reasonable efforts to be made by animal health companies to ensure that it is made clear to the reader, who the intended audience for the material is. By way of further guidance, Participants should consider using one or more of the following means where the material is not permitted for the NI-based audience:-

- Displaying a reasonable prominent notice on the Promotion that the Promotion is only intended for veterinarians and/or Professional Keepers of Animals in England, Wales and Scotland.
- In a mass email Promotion, ensuring email addresses of veterinarians or Professional Keepers of Animals located in Northern Ireland are not included.
- Not accepting orders or inquiries from postal addresses in Northern Ireland where to do so is in breach of the Regulations.

Rules of Procedure for the Code of Practice Committee

1. Purpose and structure

1.1 The Code of Practice Committee ("Committee") shall:-

(a) Decide whether complaints that the Code of Practice for the Promotion of Animal Medicines ("Code") has been contravened by a company or firm which has a Marketing Authorisation ("Member") which is in membership of the National Office of Animal Health Limited ("NOAH") ("Complaint") are justified and impose sanctions on any Member which has contravened the Code in accordance with these Rules ("a Case").

(b) Advise the Board of Management of NOAH ("Board of Management") on the content and administration of the Code and on contraventions of the Code by any Member in accordance with these Rules.

(c) By its Officials ("Officials") (as defined below) administer the Code and the procedures laid down by these Rules.

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

(a) The Chairman,

(b) The Secretary

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

1.3 The roles of the Officials are as follows:-

(a) <u>The Chairman</u>;

(i) to Chair meetings of the Committee;

(ii) to advise the Committee as to the proper application of the Rules in relation to the Code;

(iii) to carry out his or her duties as set out by these Rules;

(iv) to assist and advise the other Officials in their respective functions and as requested, from time to time by the Board of Management, as to the application and the content of the Code, associated Guidance Notes and these Rules.

(b) <u>The Secretary</u>:

(i) to administer the procedures for dealing with Complaints, and carry out his or her duties, as set out by these Rules;

(ii) to advise the Board of Management and the Committee as to the application and content of the Code, associated Guidance Notes and these Rules.

1.4 Members of the Committee

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

- Seven independent members not engaged in the industry, four being practising veterinary surgeons with a breadth of expertise across the different species sectors, and two being livestock farmers.

- Eight industry members of which a minimum of four shall be veterinary surgeons;

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

Industry members of the Committee shall:-

i. be appropriately experienced employees of a Member company

ii. be elected by the General Meeting of the Association upon nomination from the NOAH membership; and

iii. serve for five years and thereafter shall be immediately eligible for nomination and re-election.

Independent members of the Committee shall:-

i. be appropriately experienced

ii be elected by the General Meeting of the Association upon nomination from the NOAH membership; and

iii. serve for five years and thereafter shall be immediately eligible for nomination and re-election.

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

1.5 Temporary Appointments

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

1.6 Charges

(a) The Board of Management is responsible for notification to the Committee of the level of charge per item payable from time to time by industry Complainants and Respondents in accordance with the procedures following. Any "charge" for this purpose in these Rules will be subject to any Value Added Tax payable. No charge is payable by Complainants unless they were eligible to be a NOAH member company in which case, they shall pay the same charge as a NOAH member company would have done. In so far as the Constitution and Rules hereafter provide for any charge, they shall be interpreted as only applying to industry Participants i.e. holders of veterinary Marketing Authorisations**.**

(b) An "item" for the purpose of these Rules and charges relates to a discrete set of words and/or images and/or activities or group of words and/or images and/or activities which form a discrete message of which complaint is made. It is not the message given by the words or images; the number of Clauses of the Code it is alleged such words or images breach; or the different types of media containing those words or image.

1.7 Meetings and quorum

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

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

1.8 Information

(a) The Chairman shall have general authority to obtain expert assistance in any field. The Chief Executive of NOAH shall be entitled to attend meetings of the Committee to provide such information and advice as the Committee may require.

(b) Any such expert adviser may, by invitation of the Chairman, attend meetings of the Committee but shall have no vote.

(c) The Secretary may at any stage after receipt of a complaint, ask either party to supply in writing further information or comments. The Secretary shall inform that party of the period within which it shall supply such further information or comments, such period to be not less than five days, which period may be extended at the discretion of the Secretary upon application.

1.9 Timings

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

1.10 Marketing Authorisation

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

2. Procedures prior to the Committee Meeting

2.1 Anyone may make a complaint under this Code ("**the Complainant**") save that if the Complainant is eligible to be a NOAH member company but as of the date of making the complaint, is not a NOAH member company (**"Non-Member Industry Complainant"**), the complaint shall not be considered unless the Complainant agrees in writing to be bound by these Rules of Procedure.

2.2 Where a Complainant wishes to assert that a Participant (as defined in Clause 1.5 of the Code) (hereinafter referred to as **'the Respondent'**) has contravened the Code, its Chief Executive shall notify the Secretary in writing and shall indicate with such notification whether in its view the matter is one which should be urgently resolved and the grounds for such view. Complainants must present their complaints with reasonable expedition, taking into account all the circumstances of each case, and bearing in mind good practice (especially note 'g' of the introduction). Where a complaint has not been pursued with reasonable expedition, the Committee may dismiss the complaint if the Committee considers it is fair to do so.

2.3 The Complainant may where appropriate draw to the attention of the Secretary in writing any previous cases heard by the Committee, previous agreements reached between the Complainant and Respondent, and any other information which may help the Committee in reaching a judgement on whether to invoke Rule 4.8 and 4.10. Any such information under this paragraph shall be communicated separately from the letter of complaint and shall be provided by the Secretary to the Chairman.

2.4 After receiving an allegation that there has been a breach of the Code, the Secretary shall:-

(i) Examine the allegation to determine if the complaint can properly be dealt with under the Code of Practice and whether sufficient information has been provided to enable the case to be considered and if not request it.

(ii) In the event that the Secretary does not consider the complaint can properly be dealt with under the Code of Practice, he or she shall inform the Complainant accordingly, at the same time informing the Complainant that if the Complainant does not accept the Secretary's decision, the Complainant may within 10 Days of receipt of the Secretary's decision, request in writing to the Secretary that the Chairman reviews the Secretary's decision. If the Complainant makes such a request, the Secretary shall forward this to the Chairman for his or her decision, which shall be final.

(iii) If the Secretary considers the complaint can be properly dealt with under the Code of Practice, or pursuant to the review under Rule 2.4(ii), the Chairman determines that it can, then the Secretary shall:

(a) determine the number of items of complaint by reference to the subject matter of the complaint, each part of the subject matter, as determined by him or her, being an item;

(b) invite the Respondent to state whether or not the complaint is justified and whether any information relating to it supplied by the Complainant is correct and to give any answer or explanation that may be necessary. The Secretary shall inform the Respondent of the period within which it shall reply, such period to be not less than five Days nor more than ten Days;

(c) inform the parties of the charge which will fall due from each of them in the event that any items of complaint are forwarded to the Committee, such charge to be determined by the multiplication of the charge per item notified by the Board of Management as of the date of the complaint by the number of items determined by the Secretary pursuant to Rule 2.4 (iii)(a) to be forwarded to the Committee.

(iv) Fees will be paid by Complainants who are Participants or Non-Member Industry Complainants and Respondents.

(v) Where a case is settled or withdrawn prior to being adjudicated upon by the Committee for any reason, the Fees will be borne by the Complainant unless otherwise agreed by both parties or in exceptional circumstances e.g. where the complaint was manifestly well-founded or manifestly unfounded and such shall be determined via written submissions to the Chair in his or her sole and absolute discretion. The fees payable will depend on what stage in the process the case was withdrawn and are set out in the Plain Guide to the Code of Practice.

2.5 (a) The Respondent's Chief Executive shall make its written reply, which shall include the current SPC and all the material on which it relies in support of its response, together with a statement of its arguments, within the time notified to it by the Secretary. Such reply shall be signed by the Respondent's Chief Executive. The period may, upon its request, be extended at the discretion of the Secretary. The reply shall contain a statement of the facts and matters, if any, upon which the Respondent bases its view that there has been no breach of the Code.

(b) In the event of a Respondent submitting that the complaint has not been brought with reasonable expedition and it is unfair for the Committee to adjudicate upon the complaint contrary to Rule 2.2, any such allegation shall be made in writing and supported by due facts and data and communicated to the Complainant. The Secretary will consider such an allegation as a preliminary issue utilising (if he or she sees fit to do so) Rule 1.8(c) to obtain any necessary supporting information or to seek clarification of the information supplied and, if the Secretary considers that it is appropriate to determine the matter at a preliminary meeting prior to the meeting to adjudicate upon the complaint, he or she will arrange for the holding of a preliminary meeting of the Committee to consider whether the complaint should be dismissed pursuant to Rule 2.1. If the Secretary determines that the matter should be considered at a preliminary meeting separate to adjudication of the complaint, the quorum shall be three including the Chairman.

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

(a) forward the Respondent's reply (if such exists) to the Complainant;

(b) forward the relevant papers to the Committee as soon as is practicable.

(c) notify both parties that the papers have been forwarded to the Committee.

(d) inform both parties of the date on which the Committee shall meet to consider whether there has been a breach of the Code; and

(e) require payment from each of the parties of the charge arising from the number of items of complaint being reported to the Committee.

2.7 If the Respondent or Complainant wishes to attend the meeting, it shall notify the Secretary of that intention, not less than three Days before the date of the meeting. Failure to comply may result in the Committee refusing to allow attendance. Reference is made to Rule 3.3 as regards supply of presentational material etc.

2.8 Where the Chief Executive of NOAH considers it appropriate to do so, the Chief Executive may of his or her own motion, having previously notified the Chief Executive of the company concerned, refer any promotional activity to the Committee for its preliminary consideration whether such breaches the Code.

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

i. (if it considers that the promotional activity is not in breach of the Code), make a report to the Board of Management to that effect

ii. (if it considers that the promotional activity is not in breach of the Code but is otherwise undesirable) make a report to the Board of Management with a recommendation for the Code to be amended

iii. (if it considers, following a preliminary assessment, that the promotion activity may be in breach of the Code) instruct the Chief Executive of NOAH to advise any relevant third party on how to submit a complaint via the Secretary to the Committee.

3. <u>The Committee Meeting</u>

3.1 The Committee will not hear any item of complaint in respect of which payment in the sum of the charge due has not been received from the Complainant, and a Respondent may not be represented at the meeting unless its payment has been received.

3.2 If a Member of the Committee is an employee, agent or representative of the Complainant or Respondent or otherwise has an interest in the outcome of the complaint, that Member shall offer to withdraw from any meeting of the Committee during the discussion of the case and shall not be entitled to vote on the complaint if such offer is accepted by the Chairman, who has the discretion in all the circumstances of the

Case, to allow such member to remain, subject to notification to the parties' representatives and their consent being given. 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.

3.3 The Respondent and Complainant shall each have the right to attend at the meeting and make oral presentations. The Chairman shall determine the procedure to be adopted as regards such presentations, but generally the order of presentations will be the Complainant followed by the Respondent, with a brief response thereafter by the Complainant. If the Complainant or Respondent intends to rely upon any presentational written material (e.g. PowerPoint presentation) not disclosed in the written complaint or response, it shall provide a copy of such no later than 24 hours prior to the meeting to the other party and to the NOAH office.

3.4 Both parties' oral presentations and any written materials used must be consistent with (but may supplement) their respective written complaint and reply.

3.5 In exceptional circumstances, the Chairman, in his or her discretion, may permit a party to adduce written material not disclosed in the complaint or reply or (if presentational material) not supplied pursuant to Rule 3.3 where such is not unjust to the other party. Scientific papers and technical data which have not been referred to in the complaint or reply will rarely be permitted to be adduced.

3.6 Cross examination by parties' representatives or comment by parties' representatives whilst the other parties' representative is providing a presentation, will not be permitted.

3.7 The Chairman may adjourn, at any time, any meeting of the Committee at his or her discretion either at the meeting or prior to the meeting. The Respondent may ask for an adjournment if it believes that additional information is required. Such requests shall be considered by the Committee whose decision is final. If at the resumed hearing the Committee contains different members, the Committee shall consider afresh the question of whether there has been a breach of the Code.

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

4. Decision and Sanctions

4.1 The Committee's decision will be by a simple majority of its members who are in attendance and will be limited to the items of complaint raised and the Clauses of the Code alleged to have been breached by the Complainant (with the Chairman having an original and casting vote). Notwithstanding its decision being so limited, the Committee may in its discretion, make such comment as it may think to be in the interest in the industry and the Members.

4.2 If the Committee decides that a breach of the Code has occurred, the Secretary shall communicate this decision in writing to the Respondent and shall ask its Chief Executive:-

(a) to give an undertaking in writing that the practice in question (if not already discontinued) will be discontinued on or before a specified date, and

(b) where appropriate, to set out the steps it will take to avoid a breach of the above undertaking.

(c) additionally, the Committee may in its discretion require the NOAH executive to place an advertisement providing a précis of the decision in such relevant veterinary/SQP/farming press, as the Chair of the Code of Practice Committee reasonably chooses. The costs of such advertisements will be borne by the party found in breach of the Code unless the Chair decides otherwise.

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

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

4.3 Where the Committee decides that a breach of the Code has occurred, the Chairman may, at his or her discretion, provide the Committee with any information he considers appropriate to assist the Committee in deciding whether to make a report in accordance with Rules 4.8, 4.9 and 4.10, including any information provided by the Complainant pursuant to Rule 2.2.

4.4 Where the Committee decides that a breach of the Code has occurred and the breach or the conduct of a Respondent in relation to the Code or a particular case before it warrants such action it may require the Respondent to suspend the advertisement or practice complained of forthwith prior to receipt of an undertaking from the Respondent.

4.5 At the Chairman's discretion, upon written request, a Respondent or Complainant may be given an opportunity to attend a subsequent meeting of the Committee to receive a direct explanation of the Committee's decision.

4.6 For each item of complaint in respect of which the Committee find a breach has occurred, the Respondent shall be charged the appropriate sum due by reference to the charge notified by the Board of Management as of the date of filing the complaint, and the Secretary shall return the equivalent sum (if paid by the Complainant) to the Complainant. For each item of complaint that the Committee dismisses as not being in breach of the Code, a Participant or Non-Member Industry Complainant (but not anyone else) will be charged the appropriate sum due by reference to the charge notified by the Board of Management, and the Secretary will return the equivalent sum paid by the Respondent to the Respondent. The Secretary will issue receipts for Value Added Tax purposes as appropriate.

4.7 The Secretary shall notify the Complainant and Respondent of the outcome of the Committee's deliberations.

4.8 Where the Committee considers that the conduct of a Participant in relation to the Code or a particular case before it warrants such action, it may make a report to the Board of Management. Such a report may be made notwithstanding that the Respondent has accepted the decision of the Committee. Such a report may also be made where the Committee considers that a Participant is guilty of repeated offences or repeated similar activities whether or not previously brought to the Committee, or where the Participant has failed to abide by the spirit of the Code as required by (k) of the Introduction to the

Code. A reference to the Board of Management under this or any subsequent paragraph will not of itself incur further charges.

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

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

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

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

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

(a) to reprimand the Respondent and publish details of that reprimand; and/or

(b) to require the Respondent to publish a corrective statement, including the option of requiring the Respondent to publish at its own cost an apology of similar magnitude and in the same media as any promotion found in breach; and/or

(c) (if the Respondent is a member of NOAH) whether or not a recommendation should be made that the Respondent's membership of NOAH be terminated or suspended in accordance with Article 26 of the NOAH constitution.

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

5. <u>General</u>

5.1 At the conclusion of any proceedings under the Code, the Secretary shall, subject to the authorisation of the Committee or the Board of Management as the case may require, send a report in writing on the result of the proceedings to the person or body responsible

for their institution. In the event of a member ceasing to be in membership of NOAH under Article 26 as mentioned in Rule 4.12(c), the Board of Management shall consider and decide whether the fact of and the reasons for such cessation of membership should be notified to persons or bodies outside NOAH.

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

5.3 In the light of its experience of the working of the Code, the Committee may make such recommendations as it deems fit for the amendment of the provisions of the Code. Any proposal for amendment of the Code shall be forwarded to the Committee before formal adoption and any comments of the Committee shall be taken into account before the proposal is adopted.

5.4 The Board of Management may publicise the decision in such manner and in such way as it sees fit having regard to all the circumstances of the case.

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. 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
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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 Committee is not a Scientific Review Board (see 4e). It bases its judgements on the requirements of the Code and on whether the claims and statements made in a Promotional item are appropriate to the audience to which it is addressed.

c) Frequently complaints appear to result from the Participant 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 Committee follows this general approach. (See also Guidance Note 7.) Thus promotional statements outside the SPC are likely to result in a breach of the Code and could be in breach of the Regulations. Responses to technical enquiries, if these serve to encourage the prescribing, supply or use of a Participant's Animal Medicine, 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 cascade use, will not in itself constitute a breach of the Code. (See Guidance Note 5.)

e) Cases are normally heard at one of the meetings of the Committee which take place approximately every six weeks. Because of the need to collect information from both parties, clarify points of concern and circulate papers to the Committee, a minimum of three weeks is normally needed between receiving the complaint and the Committee hearing. Additional meetings can be arranged in cases of urgency, but as there are Rules governing the quorum, it is often impractical to do so – see also 2(d)(iv), below.

f) The introduction of 'charges' (not 'fines') is intended to concentrate minds on the key aspects of a case and reduce trivial items. This is designed to improve the fairness of the system to both parties and to the industry as a whole, and thus the co-operation of parties with the procedures of the Committee is encouraged and requested.

g) The Committee Secretariat is very pleased to receive enquiries from Participants or their advertising agents to give guidance on whether a particular dispute falls within the remit of the Committee. Whilst assistance can also be given as to the Code of Practice procedures, and

in highlighting parts of the Code that may be relevant and in reporting on the views of the Committee on relevant past cases, it is not possible to give a ruling on whether or not a particular promotion is consistent with the Code.

h) References to the Constitution of the Code of Practice Committee are shown in this Guide in square brackets: [ ].

2. The Complaint

A would-be Complainant should:-

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

b) Before making a formal complaint to NOAH, the two Chief Executives should have been party to the discussion, although discussions of this nature are not mandatory. (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 Participant may stipulate a reasonable timeframe within which a response is expected from the other Participant: this should not normally be less than 5 working days. Under normal circumstances a complaint should not be made to the Secretary of the Committee until there has been a dialogue between the two Participants concerned. However, if the other Participant fails to respond within a reasonable period, then the complainant is entitled to make a formal complaint about the Promotion to the Secretary. Participants should note that inter-company communications may be referred to in a Code of Practice hearing.

d) If the dispute cannot be solved: send a letter signed by the Chief Executive to the Secretary of the Committee stating:-

   i) Where and when the Promotional Material appeared or, if a leaflet, how it is being distributed.

   ii) Which Clauses of the Code are alleged to have been broken – with clearly argued explanation, addressing each 'item' under complaint.

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

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

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

   iv) If there is any special case for rapid action, it is up to the complainant to make a strong case for this, and to consider the background; for example, if an advertisement has been running for some months before a complaint is received, it would be hard to justify calling a special meeting. Under normal circumstances the case will be heard

at the next pre-booked meeting at approximately six-week intervals, bearing in mind that a minimum of three weeks is normally needed to process the papers, get a response from the Respondent, and give the Committee time to study the case.

e) Where possible, the letter of complaint referred to at (d) above should be submitted using the complaint template which is available online and from the NOAH office. Furthermore, when responding to complaints about their Promotions, respondents are also encouraged to use the complaint response template form. Letters can be submitted via email rather than hard copy.

f) 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).

g) Additionally, the complainant may, in a separate letter to the Secretary, draw attention to previous relevant cases heard by the Committee, previous agreements reached between the complainant and respondent, and any other information which may help the Committee in reaching a judgement as to whether to require respondent to suspend the promotion, or to make a report to the Board. **[2.3]**

h) The complaint letter and associated documents should all be submitted electronically by email, although the Secretary may request hard copies of some documents, for example copies of Promotional Material.

i) The complaint letter should be emailed to noah@noah.co.uk in Microsoft Word format. It is also a requirement for any hard copies of supporting documents such as Promotional Material to also be sent by email, preferably in colour (as scanned copies where necessary).

3. When the Secretary Receives the Complaint

a) A unique reference number is allocated – please use this in all subsequent correspondence.

b) The Secretary may seek clarification from the Complainant and may seek copies of material documentation from either party, particularly if not all the relevant matters have been enclosed with the complaint. **[1.8(c)] and [2.4].**

c) The Secretary will then make a decision as to whether the complaint falls within the jurisdiction of the Committee [**2.4**]. As long as the complaint is within the compass of the Committee's authority, the Secretary will accept the complaint as one to be determined by the Committee in accordance with the procedures set out in the Rules.

d) The Secretary will write to the Respondent, notifying the complaint, having identified the number of items, and will give a time within which the Respondent must reply, such period

being not less than 5, nor more than 10, working days **[2.4 (iii) a & b]**. The Secretary will inform the Complainant of the action they have taken.

e) In due course (usually after receipt of the Respondent's response) the Secretary will inform both the Complainant and Respondent **[2.6 (d)]** of the date of the next Committee meeting. The Secretary will require from each party payment in respect of the fee based on a charge per item of complaint (currently £8,000.00 plus VAT for the first item of complaint and £4,000.00 plus VAT for subsequent items which form part of the same case)**.** These fees will be required to be paid by NOAH members, signatories to the Code by non-members and all holders of UK Marketing Authorisations. This payment must be received from the Complainant before the meeting of the Committee, or the Committee will not consider the complaint **[3.1]**.

f) 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. There have been 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 (or UK General Manager) and must reach the Secretary within the time specified by the Secretary in his letter (not less than 5 nor more than 10 days – **[2.5 (a)]**). When responding to complaints about their Promotions, respondents are also encouraged to use the complaint response template form which is available online and from the NOAH office. Letters can be submitted via email rather than hard copy.

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. 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 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 SPC.

g) The Respondent will be asked for relevant information relating to the Promotions in question. Promotional claims should disclose the authority or source 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. Fees payable where a case is withdrawn prior to the meeting

Should a case be discontinued prior to the Committee meeting, the following fees (plus VAT) will be payable, with the fee liability specified in rule 2.4 (v) of the Rules of Procedure of the Code.

Stage of withdrawal/discontinuance:

a) Secretariat review and determination that the complaint cannot be properly dealt with under the Code - £750

b) Withdrawn by Complainant prior to Respondent being informed of the complaint by the Secretariat - £2,250

c) Withdrawn following the Respondent's reply and prior to papers being forwarded to Committee members - £3,000

d) Following papers being forwarded to the Committee and more than 5 Business Days before the date of The Committee meeting - £4,250

e) Less than 5 Business Days of The Committee meeting – subject to f) below - £5,000

f) If the complaint is withdrawn less than 48 hours before The Committee Meeting - £6,000

6. <u>The Meeting</u>

a) Both the Respondent and Complainant will be notified by the Secretary of the date when the matter will be considered by the Committee. Both the Respondent and the Complainant will be asked by the Secretary if they intend to exercise their right **[3.3]** to be in attendance at any meeting and if so, to provide the name of the person or persons attending. This right is dependent, however, on the Committee receiving payment for each item **[3.1]** and the response within the time limits **[2.6(b)]**. If the Secretary has not received the payment before the Day of the meeting, the Committee will not allow the party in question to give any oral representation at the meeting and will rely solely on the papers before it. **[3.1]**

b) If either party intends to be orally represented at the meeting of the Committee, a decision should be taken as to how that should be handled.

c) Committee members from companies directly affected by the case leave the room during the hearing **[3.2]**. It is not considered acceptable for industry Code of Practice Committee members to represent their companies in cases.

Meetings are informal, and conducted by a Chair, 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.

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 appropriately experienced members of staff of a corporate member company of NOAH, and four are veterinary surgeons being appropriately experienced members of staff of a member company of NOAH **[1.4]**. A quorum requires at least five Committee members **[1.7]** and must always include (i) the Chairman; (ii) a veterinary surgeon who is an independent member and (iii) an industry member.

e) The Chairman conducts the meetings, can adjourn meetings **[3.7]**, and can if thought appropriate call on expert assistance **[1.8(a)]**. Generally, with the authority of the Committee, representatives of the NOAH Executive attend the meetings as observers but do not vote.

f) Decisions are by simple majority vote, with the Chairman having an original and a casting vote **[4.1]**.

g) In general the practice is for the members to have received before the meeting a bundle of papers, including a case summary prepared by the Secretary, and including the written complaint and response of the parties, with all supporting material that the parties have supplied. Hence the importance of parties putting great care into their written arguments.

h) The Chairman will outline briefly the elements of each case before each party's representatives come into the room. The members of the Committee will consider the case and identify to their satisfaction the issues in question, and then invite the representatives, if any, of the Complainant and Respondent into the meeting room.

i) The Complainant's oral clarification through presentation at the Committee meeting must be consistent with their written submission. Generally Respondents will not be allowed to bring up new arguments which have not been made in their written response. If both are present, the Complainant will be invited to summarise the complaint, then the Respondent to respond, followed finally by the opportunity for the Complainant to address any points from the Respondent's oral comments. Although the two parties will be in the room together, they may not speak at the same time as each other, nor question the other party.

j) For each party, the Chairman will outline the issues, and in particular highlight any questions the Committee has identified as being particularly important. The representative(s) can then address the Committee. Questions will be asked by members of the Committee. The representative(s) are then asked to leave the room, and the members discuss the issues and come to a decision. If there are any further questions arising before the Committee feels it can properly vote, the representative(s) may be invited back into the room, but subject to that, generally they are released before the Committee comes to its final decision.

k) The decision will be: (1) no breach; (2) a breach requiring an undertaking to be supplied, or in cases which the Committee determine are sufficiently serious to warrant this; (3) a

requirement for an immediate suspension of all of the promotion constituting a breach, in addition to an undertaking. Where thought appropriate the Committee has power to refer the conduct of any participant to the Board of NOAH. **[4.8, 4.9] & [4.10]**. Undertakings must be returned within 10 working days. **[4.2]**

7. <u>After the Meeting</u>

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 <u>explanation</u> of the ruling.

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

b) The Secretary will simultaneously write to the Chief Executives of both parties as soon as possible after the meeting and will follow up with details of the hearing extracted from the minutes. For the avoidance of doubt, the Committee's deliberations are confidential and a party is not entitled to a verbatim transcript of the deliberations.

c) If a breach is found, the Respondent will also receive a "Form of Undertaking" setting out the required actions – this <u>must</u> be signed by the Chief Executive and returned to the Secretary by the due date (10 Days). A copy of the Undertaking is provided to the Complainant. A copy of the Undertaking will be added to the 'Register of Undertakings' on the NOAH website.

d) To the extent that a party has failed to convince the Committee of the justification of its arguments, the costs of that item will be borne by the party concerned, and the fee (currently £8,000.00 plus VAT for the first item of complaint and £4,000.00 plus VAT for subsequent items) will be retained and a receipt issued. The opposing party in respect of that item will have its money returned. **[4.6].** In cases where there are multiple items in a case, the fee to be returned will be calculated on a pro-rata basis. For example, a 2-item case with a total fee of £12k, will have fees set at £6000 per item, a 3-item case with a total fee of £16k, meaning £5333 per item. The fee to be returned to Participants where there are multiple items in a case will be calculated on this basis.

e) After the meeting the Complainant and Respondent will be advised of the decision within 5 working days. The full minutes will be then drafted by the Secretary before final approval by the Chairman. Unless there are exceptional circumstances prevailing, this would normally be processed within 30 working days.

f) The full minutes of the meeting are sent to all Committee members.

g) After the companies have been informed of the decision, where a breach has been found a press release shall be written by the NOAH secretariat to alert the relevant press of the breach, as well as to inform them of the publication on the NOAH website of a summary of the case together with a copy of any Undertaking where relevant.

h) A copy of the case summary and news release is sent to the Chief Executives of all Code signatories.

i) Where a company refuses or fails to accept a ruling the matter will be referred to the NOAH Board who will take whatever action is deemed necessary. Such action may include a

reprimand, an instruction to the Respondent to publish an apology of similar magnitude and in the same media as any promotion found in breach, or suspension or termination of the Respondent's membership of NOAH.

Product	**Company**	**Date**	**Promotion**
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Complainant's Check List

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1. Discussed with Respondent?
2. Chief Executives aware?
3. Letter to Secretary signed by Chief Executive? accompanied by:
   - Copy of offending material with date and place of issue?
   - Clauses alleged to have been breached?
   - Offending 'items' identified?
   - Copy of relevant Data Sheet or SPC?
   - Copies of correspondence with respondent?
   - Justification for urgency where relevant?
   - A clearly argued case?
   - Confirmation that the Complainant will forward payment of the fee once the Secretary defines the number of items raised and therefore the fee payable. This fee to be paid within the timescale given by the Secretary in the confirmation and in any event, more than 48 hours before the date of the Committee Meeting.
   - Names of representatives (if any) to attend hearing?

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 complaint?

- Relevant material under complaint (additional material may be requested by Code of Practice Secretary)?

- Fee payment made?

- Names of representatives (if any) to attend hearing?

Please see new complaint and response templates available on our website (www.noah.co.uk) or from the NOAH office. These templates have been developed to assist companies in the preparation of a Code of Practice complaint. It will be greatly appreciated if this new process could be adopted in the future. Thank you.