CODE OF PRACTICE FOR THE ANIMAL HEALTH INDUSTRY (April 2017)

1. INTRODUCTION

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 high quality food at reasonable prices.

The Animal & Plant Health Association is a member of the International Federation for Animal Health (IFAH) which is the representative body of the animal health industry in Europe. The members of IFAH established the European Code of Good Practice which forms the basis of the Association's Code. The Code as outlined incorporates and supersedes all previous Codes dating from 1988.

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

The adoption of this voluntary Code by members of the Animal Health Division has as its objective, the acceptance and adoption of high standards of conduct.

Compliance with the provisions of this Code is a condition of membership of the Animal Health Division of the Animal & Plant Health Association.

Subscribing companies have given an Undertaking on behalf of their company whereby failure to abide by the provisions of the Code may result in their suspension or expulsion from the Animal & Plant Health Association. All companies are bound by the law as enacted in the Republic of Ireland, whether as domestic legislation or as the adoption of European legislation.

Definitions.

The term "promotion" means those marketing activities under the control of the participating company, which do or may encourage the prescribing supply or the use of the company's products. It includes, for example, activities of representatives, various aspects of sales promotion such as journal and direct mail advertising including "teaser" campaigns; the use of films and other audio-visual material and exhibitions; the provisions 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.

The term "lay user" means all those to whom promotion may be directed other than members of the veterinary and pharmaceutical professions or the business user.

The term "participant" refers to APHA members.

The term "Business user", means any person who uses animal medicines during the course of their business or occupation. e.g. a farmer or farm manager

The term "SPC" means the Summary of Product Characteristics of a marketing authorisation.

The term "nominal value" is currently agreed at €25.00

The term "expert panel" means the agreed panel nominated in December of each year to the Code of Practice Appeals committee

2. PHILOSOPHY OF VOLUNTARY CODES

A voluntary Code is not intended to be read or construed as a document giving rise to legal rights or obligations; nor does a voluntary Code envisage that rules of legal procedure should apply in the operation of its provisions. The essence of a voluntary Code is the unequivocal acceptance by subscribers to its principles and procedures by voluntary agreement. This Code is governed by, and subscribers adopt, these considerations in the Code. In addition to compliance with legal obligations, this Code shall be observed and enforced in the spirit as well as the letter.

2. (a) Application of the Code.

2.1 The Code applies in its entirety in relation to promotion directed towards those personnel involved in the prescribing and dispensing of veterinary medicinal products relevant to the particular class of remedy.

2.2 The requirements of Clauses 9.1(i) and (ii) do not apply to advertisements containing only information of a commercial nature, such as announcements of changes in prices or packaging, or to adverse reaction warnings or recalls of defective products, etc., always provided that no claims for the product are made.

3. LEGISLATION

The principal legislation applicable to Veterinary Medicinal Products is given in Appendix E.

4. DEVELOPMENT

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

5. PRODUCTION

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

6. PHARMACOVIGILANCE

Companies shall establish procedures to monitor the use of their products in accordance with good standards of pharmacovigilance.

7. GOOD COMMERCIAL PRACTICES

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

8. PROMOTION

Promotion shall be fair and shall not include exaggerated claims or inappropriately encourage the use of particular veterinary medicinal products (see Appendix C).

9. DISTRIBUTION

Companies shall ensure that they supply their products only to those permitted in law to receive such products and shall co-operate with the appropriate authorities to encourage the proper distribution and use of such products.

10. CODE EVOLUTION AND COMPLIANCE

IFAH will establish a Committee to ensure the evolution of the European Code as desired. This Committee will also ensure that the Code is adequately applied at national level. National members of IFAH will ensure that the Code is complied with at national level by its members (see Appendix D).

APPENDIX A
GOOD LABORATORY PRACTICE

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

APPENDIX B
GOOD MANUFACTURING PRACTICE

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

APPENDIX C
PROMOTIONAL CODE

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

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

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

1. Marketing Authorisations

(i) A veterinary medicinal product must not be promoted prior to the granting of the marketing authorisation permitting its sale or supply except where permission has been granted to supply the product in an emergency situation.

(ii) Promotional activities must be consistent with the terms of the marketing authorisation and be restricted to the approved indications.

2. Animal Welfare

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

3. Information and its Substantiation

(i) All advertisements shall be easily intelligible to the consumer, and be accurate and truthful.

(ii) The word "safe" must never be used without proper qualification. It must not be stated that a product has no side effects.

(iii) When promotional material refers to published studies, clear references must be given as to where they can be found.

(iv) The word "new" should not be used to describe any product or presentation which has been generally available or any therapeutic indication which has been generally promoted, already for more than 12 months in the Republic of Ireland.

(v) The words "magic", "mystical", "miracle" or expressions of similar import, should not be used in connection with the claims made for the product or treatment.

(vi) Brand names of products of other manufacturers must not be used unless the prior consent of the manufacturers has been obtained. This does not preclude reference to brand names where the reference is to a brand name contained in and as part of a scientific paper.

(vii) No advertisement should rest on claims that a product does not contain a given ingredient which is in common use in licensed competitor products in such a way as may give the impression that the ingredient is unsafe or harmful.

(viii) Testimonials used in advertising should be limited to the genuine views of the user and the original or a certified copy should be available, together with a signed release from the person giving it. A testimonial should not contain anything contrary to the provisions of the Code.

4. Methods of Promotion

Methods of promotion and advertising shall not bring disrepute upon the Animal Health Industry, undermine confidence in Veterinary Medicinal Products, or denigrate or attack unfairly any other products, goods or services.

5. Nature and Availability of Information

5.1 Upon reasonable request, participants must promptly provide members of the veterinary and pharmaceutical professions, registered merchants and business users and other professionals with accurate and relevant information about the VMPs which they market.

5.2 Information about VMPs must reflect current knowledge or responsible opinion.

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

5.4 Where promotional material refers to supporting information (including data on file), such information must be available on request without delay or a clear reference must be given to where it can be found. In the case of information published in a journal, a reference to the journal must be given. In the case of information published on a website, the address must be given.

5.5 All information (including unpublished data) in promotional material must be capable of substantiation and substantiation must be provided in response to enquiries. However, such

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

5.6 All information must be presented so as to maintain the respect and confidence of the veterinary and pharmaceutical professions, registered merchants, the business user and the public, and to promote the correct use of VMPs.

5.7 Promotion must not be inconsistent with the SPC, except that a veterinary practitioner or other suitably qualified person employed or engaged by a participating company may in appropriate circumstances give information about off-SPC use in response to a technical enquiry from another veterinary practitioner. The company representative should not canvas a request for this off-SPC use.

6. Acceptability of Material.

6.1 Promotional material must be of a nature which recognises the standing of the recipient and does not offend against the canons of good taste of the market in which it is distributed or encourage incorrect use of the product.

6.2 Notwithstanding companies' obligations to supply adequate information to users, promotional material should only be sent or distributed to those categories of persons entitled in law to receive it and whose need for and interest in the particular information can reasonably be assumed.

7. Claims and Comparisons

7.1 Claims for the usefulness of a VMP must be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly.

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

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

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

7.5 No reference may be made to any individual or official body or to unpublished material without the consent of the individual, body or any author concerned.

8. Disparaging References

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

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

9. Mandatory Information in Promotional Material

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

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

- Promotions which only contain brand name, generic name, company name or logo including educational material

- Company Datasheets (which are considered to be promotional items)

9.2 Clauses 9.2 (a) to (e) state what requirements from points 1 to 11 in the following table are required to be applied to different types of promotion:-

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

(a) Broadcast Promotion with Dosage
Categories 1-11

(b) Broadcast Promotion without Dosage
Categories 1-2, 5-7, 9-11

(c) Non-Broadcast Promotions with SPC/ Datasheet attached (with or without Dosage)
Categories 1, 6-11

(d) Non-Broadcast Promotion without SPC/ Datasheet attached with Dosage
Categories 1-11

(e) Non-Broadcast Promotion without SPC/ Datasheet attached without Dosage
Categories 1-2, 5-10

Further requirements for Promotions other than Broadcast Promotions
9.3 In the case of Promotions other than Broadcast Promotions, the information in Clause 9.2 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:

9.4 In the case of Broadcast Promotions, the information required under Clause 9.2 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).

9.5 Where a Broadcast Promotion does not include particulars of dosage, the information not required in Clause 9.2 (e.g. contra-indications and address) shall be accessible from a web page under the Participant's control whose web address is displayed during the course of the Broadcast Promotion where shall also be accessible the SPC/Datasheet.

10. References to Official Bodies

Unless specific requirements, statutory or otherwise, have been imposed, manufacturers must not include in any announcement or promotional material a reference to the Irish Medicine Board, Department of Agriculture and Food and Fisheries or similar official bodies.
It shall not be a breach of this clause to refer to the fact that a product is authorised by the relevant body, nor to refer to general publications of those bodies.

11. Distribution of Printed Promotional Material

11.1 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.

11.2 Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.

11.3 Mailing lists must be kept up to date. A request for a name to be removed from one of these lists must be complied with promptly and no name may be restored except at the individual's request or with his permission. As in compliance with current legislation.

12. Reprints, Abstracts and Quotations (such use is, of course, subject to the law of copyright)

12.1 Quotations must accurately reflect the meaning of the author and the significance of the study.

12.2 Reprints of articles must not be included in mailings without permission of the author or original publisher.

13. Audio-Visual Materials

13.1 Audio-visual material, except for radio and television advertising, must comply with all relevant requirements of the Code, with the exception of Clause 9.1.

13.2 When audio-visual material is used to promote a product, the material must bear a form of words indicating that further information is available from the company and giving the name and address of the company.

14. Material Reproduced on Television Apparatus, Visual Display Units and the like

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

14.2 Where it is reasonably practicable to do so, the obligatory information required by Clause 9.1 (ii) must be included as part of the promotional material. In other cases it must be available through the system conveying the promotional material and instructions for accessing that information must be displayed with the promotional material.

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

15. Radio and Television Promotion

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

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

16. Sponsorship, Gifts and Hospitality.

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

16.2 No gift or hospitality shall be offered for the prescription of a VMP, other than price or product itself, unless it is directly related to the correct use, administration or disposal of that medicine, by the person to whom it is offered, or the intended end user of the medicine.
In the case of a Licensed Merchant (LM) classified product, any gift or reward should not be excessive and should be in line with the agreed nominal value.

16.3 Entertainment and other hospitality must be modest, reflect good taste and be secondary to the main purpose of the meeting. Such hospitality should not be extended beyond the veterinary healthcare representative.

17. Company Staff

17.1 Participants must ensure that all their representatives that are involved in the direct technical selling of VMPs undergo thorough training and possess sufficient legal, veterinary and technical knowledge to present information on the company's products in an accurate and responsible manner, consistent with this Code of Practice.

17.2 They must approach their duties responsibly and ethically.

17.3 They must comply with all relevant requirements of the Code.

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

17.5 All members of staff who are concerned in any way with the preparation or approval of promotional material or other information for dissemination beyond the company's own employees must be fully conversant with the requirements of the Code.

17.6 Promotional material must be cleared by nominated officials of the company with appropriate technical expertise.

17.7 Representatives must take adequate precautions to ensure the safe-keeping of VMPs in their possession.

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

18. Samples

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

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

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

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

19. Market Research

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

19.2 Access to respondents must not be gained by subterfuge.

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

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

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

20. Relations with the General Public and the Communication Media

20.1 Information about scientific progress or discovery in the field of VMPs must be presented in a balanced way.

20.2 Promotion directed to the lay user must never be such as to bring discredit upon, or reduce confidence in, the animal health industry or those persons permitted to prescribe such VMPs to the lay user.

20.3 If it is intended to promote a new product to the veterinary profession as well as to other users, then the veterinary profession must be informed of the availability of the product before promotion is directed towards other users.

APPENDIX D, COMPLIANCE

A. Compliance at European Level

(i) IFAH will establish a Committee to ensure the evolution of the European Code as desired. This Committee will also ensure that the Code is adequately applied at national level. National members of IFAH will ensure that the Code is complied with at national level by its members.

(ii) The Committee shall only consider complaints that a national association's Code does not fully comply with the European Code or that the practices of a national association's Code Committee, including its interpretation of the IFAH Code, are inconsistent with that Code. Such allegations may be brought by any member of that national association, by any member of IFAH or by any outside party.

(iii) The Committee shall not consider allegations of non compliance by national association members of a national Code. Any such case that is brought before the Committee shall be remitted to the national Code Committee concerned.

(iv) The procedures for the operation of the Committee are available on request from the Association.

(v) The European Code of Good Practice for the Animal Health Industry is binding upon members of the Animal Health Sector of the Animal & Plant Health Association.

B. Compliance at National Level

(i) Any complaints as to lack of compliance from whatever source shall be heard by a Code Committee.

(ii) The Code Committee shall be constituted as follows:

- An independent Chairman at the invitation of the Association (retired Barrister/Legal Representative).
- The present Chairman, past Chairman and vice-chairman of the Animal Health Division with the provisions that neither of the above nominees does not have a direct relationship nor interest in the proceedings.
- At least two but no more than three nominees from the "expert group" of the Animal Health Division of the Association. The nominees will be agreed individuals who, in the opinion of the above AH Division grouping, have a knowledge and appreciation of the Animal Health Industry and of the use of Veterinary Medicinal Products, and mutually agreed by both parties.

(iii) The Code Committee shall settle its own rules and procedures and may at its discretion seek opinion and information and guidance from any source on any matter they consider relevant in deciding any complaint placed before them.

(iv) A complaint shall not be decided upon by the Code Committee unless it shall have been submitted in writing with supporting reasons.

(v) The Code Committee shall have an absolute discretion to order time periods for steps to be taken by parties involved in complaints and shall also have an absolute discretion to order the cessation of any activity where they are of the opinion that the interests of the Animal Health Industry or consumer safety justifies it.

(vi) The final decisions of the Committee shall be made as appropriate by the code Committee, but could include as follows;
a) Immediate cessation and/or retraction of the activity
b) Withdrawal of all promotions deemed in breach.
c) To complete written circulation of the final decision and recommendation of the code committee, in all media, public and direct mail, to which the complaint refers.
c) Public written apology, recognising the breach of the code, correcting the breach as notified by the code committee, in the media or area were the breach of the code was promoted or used.
d) Public written apology, recognising the breach of the code, correcting the breach as notified by the code committee, and the breach notified in all media as nominated by the code committee.
e) All of the above penalties to be paid for and facilitated by the company in breach within 14 days of notification of a breach of the code.

(vii) All expenses of whatever nature involved in convening the Code Committee shall be paid by the parties involved in the dispute as apportioned by the Committee.

(viii) Compliance with the provisions of this Code is a condition of membership of the Animal Health Division of the Animal & Plant Health Association.

(ix) Where either party disagrees with the outcome of the Code Committee, then they have an option to appeal the decision to the Code of Practice Appeal Committee within 14 days.

(x) Each party shall be afforded the opportunity to personally represent their case at a meeting of the code committee.

Rules of Procedure for the Code of Practice APPEAL Committee.

(1a) The "Code of Practice Appeal Committee" shall be responsible for the administration of the Code of Practice for the Promotion of VMPs. Members of the Committee will be drawn from Directors or Senior Executives of a company or firm which is in membership of the Animal and Plant Health Association (APHA), Animal Health Division. Such members are referred to as industry members.
The Chairman of the Appeals committee will be drawn as appropriate and in the order of Current Chair, Vice Chair and Past Chair.

The Chairman of the Appeals Committee is responsible for notification to the Committee of the level of charge per item payable from time to time by 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.

In so far as the Constitution and Rules hereafter provide for any charge, they shall be interpreted as only applying to industry participants.

(1b) In the event that, for whatever reason, the appointed Chairman is unavailable, the Director General of APHA shall have power to appoint for temporary purposes only any individual (including himself/herself) to carry out the functions of the Chairman, the Secretary or the Assistant Secretary whether in respect of individual cases or for a limited period of time and

whether or not any person is still appointed in that office pursuant to paragraph 1(a). Any such temporary appointment will cease with the next meeting of the Board of Management unless approved by that meeting.

(2) The Appeals Committee will be open to all APHA member companies including the Chairman, as follows:

- Industry Members.-At least 40% of the APHA Animal Health Division company membership, each being a director or senior executive of a company or firm who is in membership of APHA, excluding the complainant parties.

- At least four independent members drawn from the "expert panel" nominated and agreed at an Animal Health Division meeting in December of each year. These independent members shall be drawn from the "expert group" but shall not include the representatives on the original complaint hearing. These members will be chosen by the Chairman based on their appropriate expertise in relation to the particular complaint before the Appeal committee.

- If either the Chairman, vice chairman or Past chairman is one of the complainant companies, then the Chair of the appeal committee shall be held in the order of Chairman of APHA, Vice Chair and Past Chairman.

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

(4) A quorum shall be declared when at least 40% of the eligible Animal Health Division membership and at least 4 independent experts are present. Voting at all meetings shall be by show of hands or ballot at the Chairman's discretion and all motions shall be determined by a majority of those members voting. The Chairman of the Committee shall have an original and also a casting vote.

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

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

(7) Where a member wishes to assert that any other member (hereinafter referred to as 'the respondent') has contravened the Code, its Chief Executive shall notify the Secretary in writing and shall indicate with such notification whether in its view the matter is one which should be resolved with expedition and the grounds for such view. Complainants must present their complaints with reasonable expedition, taking into account all the circumstances of each case, and bearing in mind good practice. The Committee has power to dismiss an application if:-

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

(8) After receiving an allegation that there has been a breach of the Code, from a member (hereinafter referred to as the 'complainant') the Secretary shall:-
Examine the allegation to determine if the complaint can properly be dealt with under the Code of Practice and whether sufficient information has been provided to enable the case to be

considered and if not request it. The Secretary will also consider whether the complaint has been made with reasonable expedition after the events giving rise to the complaint and (if the complaint is more than 2 years after the event) refer the matter in the first instance for a decision as to whether the complaint should be heard, and seek from the Complainant (to the extent it has not already been provided) why the complaint was not made within the two year time limit. In the event that the Secretary does not consider the complaint can properly be dealt with under the Code of Practice, he shall inform the complainant accordingly, at the same time informing the complainant that if the complainant does not accept the Secretary's decision, he may within 10 working days of receipt of the Secretary's decision, request in writing to the Secretary that the Chairman's confirmation of the Secretary's decision be sought. If the complainant makes such a request, the Secretary shall forward this to the Chairman for
his decision, which shall be final. If the Secretary considers the complaint can be properly dealt with under the Code of Practice, or the Chairman determines that it can, following a request to refer the issue to him, then the Secretary shall:

(a) determine the number of items of complaint by reference to the subject matter of the complaint, each part of the subject matter, as determined by him, being an item;
(b) invite the respondent to state whether or not the complaint is justified and whether any information relating to it supplied by the complainant is correct and to give any answer or explanation that may be necessary. The Secretary shall inform the respondent of the period within which it shall reply, such period to be not less than five working days nor more than ten working days;
(c) inform the parties of the charge which will fall due from each of them in the event that any items of complaint are forwarded to the Committee, such charge to be determined by the multiplication of the charge per item notified by the Board by the number of items to be forwarded to the Committee.

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

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

(a) forward the relevant papers to the Committee as soon as is practicable.
(b) notify both parties that the papers have been forwarded to the Committee.
(c) inform both parties of the date on which the Committee shall meet to consider whether there has been a breach of the Code.
(d) require payment by cheque from each of the parties of the charge arising from the number of items of complaint being reported to the Committee.

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

(12) The Committee will not hear any item of complaint in respect of which a cheque in the sum of the charge due has not been received from the complainant.

(13) The respondent and complainant shall have the right to attend at the meeting referred to in paragraph 10 (c) above, to present oral clarification of written material providing that:-

(a) the Secretary has received a cheque from the respondent for the charge due, and,
(b) the Secretary has received from the respondent the written material required under paragraph 11 above within the time limits set out; or
(c) the Chairman, in his discretion, permits such oral representation with such written material as he may permit. If the respondent wishes to attend the meeting, they shall notify the Secretary of that intention, not less than ten working days before the date of the meeting. Failure to comply may result in the Committee refusing to allow attendance. If a participant who is concerned in the case either as complainant or respondent is represented on the Committee, that participant's representative shall withdraw from any meeting of the Committee during the discussion of the case and shall not take part in any representation of the participant before the Committee.

(14) The Chairman may adjourn, at any time, any meeting of the Committee at his discretion. The respondent may ask for an adjournment if it believes that additional information is required. Such requests shall be considered by the Committee - the Committee's decision is final. If at the resumed hearing the Committee contains different members, the Committee shall consider afresh the question of whether there has been a breach of the Code. In the event of an item of complaint not being heard by the Committee either because the item is withdrawn by the complainant, or accepted by the respondent to the satisfaction of the complainant, no charge will be made for that item and an appropriate refund will be made as necessary.

(15) (i)If the Committee decides that a breach of the Code has occurred, the Secretary shall communicate this decision in writing to the respondent and shall ask its Chief Executive:-

(a) to give an undertaking in writing that the practice in question (if not already discontinued) will be discontinued on or before a specified date, and
(b) to give such assurances regarding the steps to be taken to avoid a breach of the Code occurring in future as the Committee may require. The respondent shall make a reply within ten working days, but this period may, exceptionally, upon the respondent's request, be extended at the discretion of the Chairman.

(ii) Where the Committee decides that a breach of the Code has occurred 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.
(iii) At the Chairman's discretion a respondent or complainant may be given an opportunity to attend a subsequent meeting of the Committee to receive a direct explanation of the Committee's decision.
(iv) Each party shall be afforded the opportunity to personally represent their case at a meeting of the appeal code committee.
(v) For each item of complaint in respect of which the Committee find a breach has occurred the respondent will be charged the appropriate sum due by reference to the charge notified by the Board, and the Secretary will return the equivalent sum paid by the complainant to the complainant. For each item of complaint that the Committee dismisses as not being in breach of the Code, an industry complainant will be charged the appropriate sum due by reference to the charge notified by the Board, and the Secretary will return the equivalent sum paid by the respondent to the respondent. The Secretary will issue receipts for Value Added Tax purposes as appropriate.

(16) The Secretary shall notify the complainant of the outcome of the Committee's deliberations. (Suggested time frame 2-7 days). Where the Chief Executive of APHA considers it appropriate to do so, he may with the knowledge of the Chief Executive of the company concerned refer any promotional activity to the Committee for its preliminary consideration. Having considered the

promotional activity with regard to the Code as a whole, the Committee shall take one of the following actions (or a combination thereof):
i. (if it considers that the promotional activity is not in breach of the Code), make a report to the Board to that effect
ii. (if it considers that the promotional activity is not in breach of the Code but is otherwise undesirable) make a report to the Board with a recommendation for the Code to be amended
iii. (if it considers, following a preliminary assessment, that the promotion activity may be in breach of the Code) instruct the Chief Executive of APHA to advise any relevant third party on how to submit a complaint via the Secretary to the Committee.

(17) Where the Committee considers that the conduct of a participant in relation to the Code or a particular case before it warrants such action, it may make a report to the Board. Such a report may be made notwithstanding that the respondent has accepted the decision of the Committee. Such a report may also be made where the Committee considers that a participant is guilty of repeated offences, or where the participant has failed to abide by the spirit of the Code as required by (h) of the Introduction to the Code. A reference to the Board under this or any subsequent paragraph will not of itself incur further charges.

(18) If any participant declines or fails to give the required undertaking and assurance or to pay any charge required by the Secretary, this shall be reported by the Committee to the Board of Management.

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

(20) Where a report is made to the Board under paragraphs 17, 18 or 19 above, a copy of the report shall be forwarded to the Chief Executive of the respondent concerned, and he shall be invited to attend personally or by any other authorised representative the meeting of the Board at which the report is considered.

(21) After hearing such Chief Executive or authorised representative the Board shall then consider, and may decide:
(a) to reprimand the respondent and publish details of that reprimand; and/or
(b) to require the respondent to publish a corrective statement, including the option of requiring the respondent to publish at his own cost an apology of similar magnitude and in the same media as any promotion found in breach; and/or
(c) (if the respondent is a member of APHA) whether or not a recommendation should be made that the respondent's membership of APHA be terminated or suspended in accordance with Article 7(c) of the APHA constitution.

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

(23) At the conclusion of any proceedings under the Code, the Secretary shall, subject to the authorisation of the Committee or the Board as the case may require, send a report in writing on the result of the proceedings to the person or body responsible for their institution. In the event of a member ceasing to be in membership of APHA under Article 7c) as mentioned in paragraph

17 above, the Board shall consider and decide whether the fact of and the reasons for such cessation of membership should be notified to persons or bodies outside APHA.

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

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

APPENDIX E

PRINCIPAL LEGISLATION GOVERNING VETERINARY MEDICINAL PRODUCTS

Poisons Act 1961 (Number 12 of 1961).

Animal Remedies (Control of Oestrogenic Substances) Regulations 1962 (S.I. No. 96 of 1962)

Animal Remedies (Control of Certain Anti-Abortion Vaccines) Regulations (S.I. No. 112 of 1965)

Poisons Regulations 1982 (S.I. No. 188 of 1982)

Poisons (Amendment) Regulations 1983 (S.I. No. 51 of 1983)

Poisons (Amendment) Regulations 1984 (S.I. No. 349 of 1984)

National Drugs Advisory Board (Establishment) Order 1966 (Amendment) Order 1985 (S.I. No. 220 of 1985)

Poisons (Amendment) Regulations 1986 (S.I. No. 424 of 1986)

Poisons (Amendment) Regulations, 1991 (S.I. No. 353 of 1991)

Animal Remedies Act, 1993 (Number 23 of 1993)

European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations, 1994 (S.I. No. 176 of 1996)

Irish Medicines Board Act, 1995 (Number 29 of 1995)

Control of Animal Remedies and their Residues Regulations, 1998	(S.I. No. 507 of 1998)
Animal Remedies Regulations, (No 2), Regulations 2007)	(S.I. No. 786 of 2007)
Animal Remedies Regulation (Poisons Act 1961) Regulation 2007	(S.I. 861 of 2007)
European Communities (Animal Remedies) (Amendment) Regulations 2009	(S.I. 182 of 2009)
European Communities (Control of Animal Remedies and their Residues) Regulations 2009	(S.I. 183 of 2009)

Note: This listing is not an exhaustive statement of legislation applicable to Veterinary Medicinal Products.

Nominations for Code Committee of Animal Health Division.

University.

- Grace Mulcahy
- Tom Barragry

Member Company Vet.

- Jim Walsh, Co-op Animal Health
- Jim Spratt, C & M Vetlink.
- Mr. Charles Chavasse MVB Pfizer Field based Vet
- Ms Alison Hughes, Boehringer Ingelheim Ltd, or alternate company vet.

Practising Vets

- Rosanna Wregor, Parklands Vet Group
- Tom Buckley, Irish Equine Centre
- *Prof Ann Cullinane, Irish Equine Centre*
- Mr Frank O'Sullivan MVB Trim
- *Mr John O'Rourke*
- *Bill Cashman, MVB, Cork*

Retired Vets.

- PJ O'Connor, Retired, Formally Dept of Agriculture
- Kevin O'Farrell, Retired, Formally Teagasc Moorepark

Expert Person Nomination.

- Frank Hughes.Pharmacist
- Mr. John Shirley, Journalist