CODE OF PRACTICE FOR THE ANIMAL HEALTH INDUSTRY (2024)

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, in respect of livestock, to enable the farming community to supply high quality food at reasonable prices.

The Animal & Plant Health Association (APHA) is a member of Animal Health Europe which is the representative body of the animal health industry in Europe. The members of Animal Health Europe established the European Code of Good Practice which forms the basis of the APHA Code (Herein after referred to as the Code). The Code as outlined incorporates and supersedes all previous APHA 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 Code as a voluntary supplement in support of these laws and regulations.

The adoption of this voluntary Code by members of APHA 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 APHA.

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 APHA. All companies are bound by the law as enacted in the Republic of Ireland, whether as Primary National legislation or the implementation of European legislation.

Definitions:

Veterinary Medicine – Any product authorised by the European Medicines Agency (EMA) or Health Products Regulatory Authority (HPRA) for use as a veterinary medicine.

Veterinary Practitioner – any person registered to practice as a veterinarian by the Veterinary Council of Ireland (VCI)

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 of its principles and procedures by voluntary agreement. In addition to compliance with legal obligations, this Code shall be observed and enforced in the spirit as well as the letter.

2.1 Application of the Code:

The Code applies in its entirety in relation to promotion directed towards those personnel involved in the prescribing, dispensing and use of veterinary medicinal products.

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. MANUFACTURING

Production of 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 consider operator and environmental safety.

6. PHARMACOVIGILANCE

Companies shall establish procedures to monitor the use of their products in accordance with the legislation and 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 of veterinary medicinal products shall be fair and in accordance with the Summary of Product Characteristics (SPC) and encourage the responsible use. It shall not mislead, include exaggerated claims or lead to incorrect use of veterinary medicines. Promotional advantages or benefit to persons qualified to prescribe or supply medicinal products shall not lead to an improper inducement to prescribe or supply particular 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 ensure adherence to Good Distribution Practice EMA (EU) 2021/1248.

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

This Code of 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 Regulation 2019/06).

It covers all methods of promotion including journal, online, social media 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, hospitality and other pecuniary advantages or benefit in kind.

Promotion under this Code does not cover Price Lists, Labelling, Packaging Leaflets, and SPC's, approved by the competent authorities and communication that does not pursue advertising purposes.

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

1. A veterinary medicinal product must not be promoted if it is not authorised for use in Ireland.
2. A veterinary medicinal product must not be promoted prior to the grant of the marketing authorisation permitting its sale or supply.
3. A veterinary medicinal product subject to a suspension of its authorisation must not be promoted during that suspension.
4. Promotional activities must be consistent with the terms of the marketing authorisation and be restricted to the approved indications and directed at permitted audiences.
5. Promotional information which appears on exhibition stands or is communicated to participants at international events may, unless prohibited or otherwise regulated by local laws and regulations, refer to veterinary medicinal products which are not registered in Ireland, provided that the event has a truly international nature in terms of organisation, speakers and participants, the promotion is not targeting the Irish market and the promoted veterinary medicinal products is authorised in at least one major international market.

2. Animal Welfare

The use of veterinary medicines should support the use of good husbandry and good animal management.

3. Mandatory Information in Promotional Material

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 not promotional items)

- Product Packaging Leaflets

	Category of Information
1	**Brand Name**
2	**Active Ingredient(s)**
3	**Legal Category of Product**
4	**Company Name**
5	**Company Contact Details**
6	**Include "Use Medicines Responsibly"**
7	**An Indication that further information is available from the SPC or Datasheet or Package Leaflet**
8	**A clear instruction that advice should be sought from prescriber if product is POM when promoting to persons other than prescriber**

4. Information and its Substantiation

1. Information about a veterinary medicinal product must be accurate, balanced, fair and objective. It must not mislead by distortion, undue emphasis, omission or in any other way.
2. Information should be based on an up-to-date evaluation of scientific evidence and reflect that evidence clearly. When it refers to published studies, clear references must be given as to where they can be found.
3. All information included in promotional material must be capable of substantiation and substantiation must be provided in response to enquiries. Such substantiation need not be provided however in relation to the validity of indications approved in the marketing authorisation.
4. The word "safe" must never be used without proper qualification. It must not be stated that a product has no side effects.
5. 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.

5. Acceptability of Material

1. Promotional material must be clearly recognisable as such through layout, presentation, content or otherwise.
2. The promotion shall not be formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide.
3. 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 information can reasonably be justified.
4. 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.
5. 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.
6. Promotional material must be reviewed by nominated officials of the company with the appropriate technical expertise.
7. 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.

6.Websites and social media

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

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

10. 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

.

11. Any Irish-based website under the control of a participant, which links to another site which may include information about Animal Medicines not authorised in the ROI, or to conditions not relevant to the ROI, must provide suitable and prominent warning of this to readers. Participants shall ensure that text presented in search results relating to websites under their control will be compliant with the requirement of the Code

12. 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.

7. 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.

8. Nature and Availability of Information

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.

2. Information about VMPs must reflect current knowledge and/or responsible opinion.

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.

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. 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.

6. All information must be presented 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.

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.

9. Claims and Comparisons

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.

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.

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.

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.

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.

10. Disparaging References

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

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

11. 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 HPRA, Department of Agriculture and Food and the Marine 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.

12. Meetings, Gifts and Hospitality.

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. Hospitality being offered at events for professional and scientific purposes must be reasonable in level and must always be subsidiary to the main purpose of the occasion in relation to which it is provided. Care should be taken when sponsoring scientific symposia or exhibitions to ensure that company activities do not detract from the main objectives of the event.
2. Offering or promising of gifts, pecuniary advantages or benefits in kind to veterinarians and other persons authorised to supply veterinary medicinal products is permitted, if these are inexpensive and are relevant to the practice, prescription or supply of veterinary medicinal products.
3. No gift shall be offered or issued with the sale or purchase or for the prescription of an Animal Medicine, unless it is directly related to the correct use, administration or disposal of that product, by the person to whom it is offered, or the intended end user of the medicine, or unless it is educational, an educational item, diagnostic aid or veterinary equipment whose value is not excessive.
4. Except for small quantities of samples (see 16 below), veterinary medicinal products may not be distributed for promotional purposes.

13. Company Staff

1. Representatives must be adequately trained and possess sufficient knowledge to present information on their company's product in an accurate and responsible manner.
2. They must approach their duties responsibly and ethically.
3. They must comply with all relevant requirements of the Code.
4. They must transmit to their companies forthwith any information, which they receive in relation to the use of the products which they promote, particularly reports of side effects in accordance with the companies' commitment to pharmacovigilance.
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.

14. Samples

1. Samples may be supplied in accordance with the relevant national law.
2. Samples may only be distributed to veterinarians and persons permitted to supply veterinary medicinal products.
3. Antimicrobial veterinary medicinal products may not be distributed in sample forms.

15. Market Research

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.

2. Access to respondents must not be gained by subterfuge.

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

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

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

APPENDIX D, COMPLIANCE

A. Compliance at European Level

1. 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

1. Any Complaints in the context of this code should initially be addressed by the complainant to the respondent (alleged wrongdoer). It is expected that most complaints will be resolved amicably between the complainant and the respondent promptly once the complaint is made.
2. A Reasonable response time in the context of 1) above is agreed to be one week.
3. If a complaint is not resolved between the complainant and the respondent within two weeks, it can be referred by the complainant to APHA. For the purpose of notifying APHA, this can initially be done using verbal means.
4. The complainant should document the complaint in writing to APHA, setting out the nature of the complaint, steps taken to resolve the complaint to date, and requesting the matter be referred to the Code Committee of APHA.
5. The APHA CEO will first ensure that the matter has been reviewed by both the complainant and the respondent at the highest level (of direct commercial responsibility in this market) in both organisations and that there has been a direct dialogue again at the highest level, which has failed to resolve the complaint.
6. No complaints will be entertained if the alleged offence happened more than two years prior to the notification of the complaint to APHA in writing. For the avoidance of doubt, the timeframe will be adjudicated based on the date of notification of the complaint to APHA in writing.
7. APHA will invoice both the Complainant and the Respondent a sum of €5000 each. This fund (€10,000) will be used as a deposit to fund expenses related to the case.

8. The Code Committee shall be constituted as follows:

   An independent Chairperson at the invitation of the Association (for E.G. retired Barrister/Legal Representative).

   Two of the three from the present Chairman, past Chairman and vice-chairman of the Animal Health Division provided that none of the above nominees has a direct relationship or 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 individuals who, in the opinion of the above AH Division Chair and Vice Chair have a knowledge and appreciation of the Animal Health Industry and of the use of Veterinary Medicinal Products, and mutually agreed by both parties.

9. The Code Committee 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.

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

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

12. 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.

13. 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.
    d) Public written apology, recognising the breach of the code, correcting the breach as determined by the code committee, in the media or area where the breach of the code was promoted or used.
    e) Public written apology, recognising the breach of the code, correcting the breach as determined by the code committee, and the breach notified in all media as nominated by the code committee.
    f) All of the above penalties to be paid for and facilitated by the company in breach within 30 days of notification of a breach of the code.

14. 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 to reflect the adjudication of the case.

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

APPENDIX E

PRINCIPAL LEGISLATION GOVERNING VETERINARY MEDICINAL PRODUCTS

EU Commission Reg 2019/06 and its related Implementing and Delegated Acts
EU Commission Regulation 2019/04 and its related Implementing and Delegated Acts

IE Regulation 21 of 2023 and its related Statutory Instruments.

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