CODE OF GOOD PRACTICE FOR THE ANIMAL HEALTH INDUSTRY

Approved by the Board & General Assembly of AnimalhealthEurope on 19 June 2024
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INTRODUCTION

The AnimalhealthEurope (hereinafter referred to as the "Association") is the representative body of companies and national trade associations in the animal health industry. This industry researches, develops, manufactures, and brings to the market veterinary medicinal products and other animal health products in Europe.

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

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

1 Development

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

2 Manufacture

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

3 Pharmacovigilance

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

4 Good Commercial Practices

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

5 Promotion

Promotion of veterinary medicinal products shall be fair and in accordance with the Summary of Product Characteristics (SPC) and encourage responsible use. It shall not mislead, include exaggerated claims or lead to incorrect use. 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).

6 Distribution

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

APPENDIX A - GOOD LABORATORY PRACTICE

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

APPENDIX B - GOOD MANUFACTURING PRACTICE

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

APPENDIX C - PROMOTIONAL CODE

The European Code of Good Practice for the Animal Health Industry applies to all forms of promotion, by which is meant those informational and marketing activities undertaken by an animal health company, or with its authority, in relation to the prescribing, supply or administration of its veterinary medicinal products (as defined and covered in Regulation (EU) 2019/6 and the applicable national laws).

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.

Labelling, accompanying package leaflets that are approved by the competent authorities, and communication that does not pursue advertising purposes - for example as a response to a request for information about a particular product, or warnings for undesirable side effects in the context of pharmacovigilance - should not be considered as promotion under this Code.

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

A. Marketing Authorisations

i. A veterinary medicinal product must not be promoted in a country if it is not authorised or registered in the country in question.

ii. A veterinary medicinal product must not be promoted prior to the grant of the marketing authorisation permitting its sale or supply in the country in question.

iii. If the marketing authorisation has been suspended, it is prohibited to promote the veterinary medicinal product during that period of the suspension in the country in which it was suspended.

iv. Promotional activities must be consistent with the terms of the marketing authorisation and be restricted to the approved indications, in compliance with applicable laws and regulations in the country concerned.

v. 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 (or uses) which are not authorised in the country where the event takes place, or which are authorised under different conditions, as long as:

1. any such promotional material is accompanied by a suitable statement indicating the countries in which the veterinary medicinal product is authorised and makes clear that the veterinary medicinal product or indication is not authorised locally, and
2. any such promotional material which refers to the prescribing information (indications, warnings etc.) authorised in a country or countries where the veterinary medicinal product is authorised.

must be accompanied by an explanatory statement indicating that authorisation conditions differ internationally.

B. Animal Welfare

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

C. Information to be made available

i. Promotional material, if permissible under the laws or codes of a relevant country, a reference to an online tool such as a website or QR code must include the following information clearly and legibly:

a) the brand name of the product;
b) the active ingredient(s) using approved name(s) where such exists;
c) the name and address of the company;
d) a statement that further information is available on request;
e) the legal status for the supply of the product;
f) such instructions as are necessary for the appropriate handling of the product;
g) in the case of food producing animals, the withdrawal period;
h) when promoting a prescription-only immunological veterinary medicinal product to professional keepers of animals if permitted by the country, an express invitation to consult a veterinarian;
i) a summary of the particulars listed in the product authorisation including contra-indications;
j) one or more indications for use consistent with the SPC.

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

D. Information and its substantiation

i. Information about veterinary medicinal products must be accurate, balanced, fair, and objective. It must not mislead by distortion, undue emphasis, omission or in any other way.

ii. 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.

iii. 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 elements approved in the marketing authorisation.

iv. The word "safe" must never be used without proper qualification. It must not be stated that a veterinary medicinal product has no side effects.

E. Acceptability of material

i. Promotional material must be clearly recognisable as such through layout, presentation, content or otherwise be of a nature which considers the targeted audience and does not offend against the canons of good taste of the market in which it is distributed.

ii. 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.

iii. Promotional material should only be sent or distributed to those categories of persons entitled in law to receive it and whose need for and interest in the particular information can reasonably be assumed.

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

F. Meetings, gifts and hospitality

i. Hospitality being offered at professional and scientific events must be reasonable in level and must always be subsidiary to the main purpose of the occasion in relation to which it is provided. In principle, the value of such hospitality, including meals, should follow the reasonable standards in the country of the hospitality is being offered (the "Host Country Principle"). Particular 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.

ii. Offering or promising of gifts, pecuniary advantages, or benefits in kind to veterinarians and other persons authorised to supply veterinary medicinal products is permitted, provided that these are inexpensive and are relevant to the practice, prescription or supply of veterinary medicinal products, in accordance with the relevant applicable law.

iii. Veterinarians and other persons authorised to supply veterinary medicinal products may not seek or accept any inducements prohibited in the paragraph above (art. F, ii).

iv. The paragraphs above (art. F, i, ii, iii) shall not affect existing measures or trade practices relating to prices, margins and discounts.

i. Except for small quantities of samples (see H), veterinary medicinal products may not be distributed for promotional purposes.

G. Company staff

i. Representatives must be adequately trained and possess sufficient knowledge to present information on their company's product in an accurate and responsible manner.

ii. They must approach their duties responsibly and ethically.

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

iv. They must transmit to their companies forthwith any information, which they receive in relation to the use of the products which they promote, particularly reports of side effects in accordance with the companies' commitment to pharmacovigilance.

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

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

H. Samples of veterinary medicinal products

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

ii. Such samples may only be distributed to veterinarians and persons permitted to supply veterinary medicinal products.

iii. Antimicrobial veterinary medicinal products may not be distributed in sample forms.

COMPLIANCE

i. The European Code of Good Practice for the Animal Health Industry sets out the minimum standards which the association considers must apply. Individual national associations must adopt the European Code or ensure that their national codes fully reflect the standards of the European Code in a manner compatible with nationally applicable laws.

ii. The member associations of the Association are required to establish adequate procedures, according with its circumstances at national or regional level, for ensuring that its member companies comply with the requirements of this Code or the relevant national code and for dealing with any complaints as to non-compliance which may be made.

iii. The European Code of Good Practice for the Animal Health Industry is binding upon members of the Association and must be brought into operation by national associations as decided by the General Assembly on 23 November 2005.

TRANSPARENCY REGISTER OF THE EUROPEAN UNION

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

Code of Conduct

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

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

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

- comply strictly with the provisions of Rule 9 of, and Annex X and the second paragraph of Article 2 of Annex I to, the European Parliament’s Rules of Procedure;

- satisfy themselves that any assistance provided in the context of Article 2 of Annex I to the European Parliament's Rules of Procedure is declared in the appropriate register;

- in order to avoid possible conflicts of interest, obtain the prior consent of the member or members of the European Parliament concerned as regards any contractual relationship with or employment of a member's assistant, and subsequently declare this in the register.