CODE OF GOOD PRACTICE FOR THE ANIMAL HEALTH INDUSTRY

Approved by the General Assembly on 20 June 2012

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Introduction

The International Federation for Animal Health-Europe, IFAH-Europe, 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 medicines, vaccines and other animal health products in Europe.

The animal health industry is committed to the research and development of new and improved products to control, prevent and cure animal diseases thus contributing to improved animal welfare, and also, in respect of livestock, to enable the farming community to supply the people of Europe and the world with high quality, 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. 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 of the relevant laws and regulations. This is in line with the Statement of Principles endorsed by the members of IFAH, the International Federation of Animal Health, 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 Production

Production and all products must be in accordance with the licence specification 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 shall be fair and in accordance with the Summary of Product Characteristics. It shall not include exaggerated claims or inappropriately encourage the use of particular animal health products.

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 in Directive 2001/82/EEC as amended).

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

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

A. Marketing Authorisations

i) A veterinary medicinal product must not be promoted prior to the grant of the marketing authorisation permitting its sale or supply.

ii) Promotional activities must be consistent with the terms of the marketing authorisation and be restricted to the approved indications – see D v) also.

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

Printed promotional material must include the following information clearly and legibly:

a) the brand name of the product;

b) the active ingredient(s) using approved name(s) where such exists;

c) the name and address of the company;

d) a statement that further information is available on request;

e) the legal status for the supply of the product;

f) such instructions as are necessary for the appropriate handling of the product;

g) in the case of food producing animals, the withdrawal period;

h) when promoting a prescription-only product to non-veterinarians, a form of words indicating that further advice should be sought from a veterinary surgeon; and

j) a summary of the particulars listed in the product authorisation including contra-indications.

k) one or more indications for use consistent with the SPC

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

D. Information and its Substantiation

i) Written and oral information about veterinary medicinal products must be accurate, balanced, fair and objective. It should be based on an up-to-date evaluation of scientific evidence and reflect that evidence clearly. It must not mislead by distortion, undue emphasis, omission or in any other way.

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

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

iv) All information included in promotional material must be capable of substantiation and substantiation must be provided in response to enquiries. Such substantiation need not be provided however in relation to the validity of indications approved in the marketing authorisation.

v) IFAH-Europe member subsidiary companies are responsible, under the relevant national code, for ensuring that any material produced by its parent company, which may be located anywhere in the World, is not promoted in its market if this material is contrary to the national summary of product characteristics (SPC).

It is the responsibility of the subsidiary company and the parent company to work together to ensure that material promoted is appropriate and the subsidiary company must take responsibility, under the national code, for any promotion of inappropriate material.

It is recognised that material may be accessed, such as via the web, by individuals in a particular country where the material, including that produced by the parent company, is contrary to the national SPC. This material is not the responsibility of the local subsidiary and it cannot be held liable for the existence of this material, which may be in compliance with an SPC in another part of the World, so long as it is not promoting this material in the local market.

E. Acceptability of Material

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

ii) Promotional material must not be designed to disguise its real nature.

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

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

F. Meetings, Gifts and Hospitality

i) Hospitality must be reasonable in level and must always be subsidiary to the main purpose of the occasion in relation to which it is provided. Particular care should be taken when sponsoring scientific symposia or exhibitions to ensure that company activities do not detract from the scientific purpose of the meeting.

ii) Gifts must be inexpensive. No gift should be of a value or nature likely to induce the prescription or use of a particular product. Except where they carry all of the information stipulated in sub-paragraph C.i) above they may bear no more than the name of a product, its approved name and the name and logo of the company.

G. Company Staff

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

ii) They must approach their duties responsibly and ethically.

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

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

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

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

H. Samples

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

COMPLIANCE

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

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

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

TRANSPARENCY REGISTER OF THE EUROPEAN UNION

With IFAH-Europe being registered on the transparency register, IFAH-Europe 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:

1) 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;

2) not obtain or try to obtain information, or any decision, dishonestly, or by use of undue pressure or inappropriate behaviour;

3) 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;

4) 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;

5) not sell to third parties copies of documents obtained from any EU institution;

6) 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;

7) 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;

8) observe any rules laid down on the rights and responsibilities of former Members of the European Parliament and the European Commission;

9) 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:

10) 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;

11) 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;

12) 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.