Animalhealth CZ/SK

CODE OF PRACTICE

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FOREWORD

The pharmaceutical industry (industry) promotes health and a positive healthy attitude to everyday life. By acknowledging that medicines play an important role in prevention, improvement and treating various stages of diseases the industry recognizes its commitment to:

- provide veterinary medical medicines (medicines) that comply with the highest standards in the areas of safety, efficacy and quality
- ensure that medicines are provided with extensive pharmaceutical and information services in keeping with the current scientific know-how and findings
- act as professionals when dealing with veterinary practitioners, state officials and the public.

The industry promotes reasonable and rational use of medicines and it assists in their use being in agreement with the instructions and advice of health care professionals. In order to provide for availability of the information that serves as the basis in the decision making on the medicine's use it is necessary that the producer provides more specialized information on the medicine gained in the process of research and development and in the experience acquired while its clinical use. By doing so, the producer notifies of the existence and the properties of the given medicine with suitable instructional and promotional methods.

The industry took part in drafting of the existing legislation created to protect the public health and the wellness of animals. The legislation provides for the fact that all medicines on the market meet the requirements on quality, efficacy and safety that are acceptable with respect to the current know-how and practice.

Whereas it is possible to adopt acceptable legislation on medicine testing, production and use in veterinary medicine, the same method can not be employed while defining the suitable standards for marketing conduct. Being aware of this fact, a group of producers have agreed on declaring this Code of Practice and on complying with its limitations.

A member of the AHCZSK (member) vows to comply with the Statute of the AHCZSK and the Code of Practice of the AHCZSK.

Complaints about any member's activities are to be submitted to the Board of Directors of the AHCZSK as specified in the Code of Practice.

INTRODUCTION

(a) Code of Practice defines the rules of conduct for the activities of companies that market veterinary medicines used in ways legalised by the Czech legislation.
Code of Practice was drafted thanks to the determination of the AHCZSK members to provide for the general acceptance and adoption of high standards in the marketing of medicines intended for use.

(b) Adoption of and adherence to the Code of Practice is stipulated in the AHCZSK membership and every members must adhere to the Code of Practice in its entirety, verbatim et literatim. The members shall ensure that all representatives on its part are fully informed of the provisions of this Code of Practice. In pharmaceutical companies that are not members of the AHCZSK, the adoption of and adherence to this Code of Practice shall be appreciated.

(c) The Board of Directors of the AHCZSK shall enforce and supervise this Code of Practice. The Board can issue a decision from time to time interpreting certain sections of the Code of Practice. Complaints about alleged breaches of the Code of Practice shall be reported to the Board of Directors of the AHCZSK.

(d). Adherence to this Code of Practice in no way diminishes the responsibility of the members to act in compliance with the Czech legislation. The promotion of medicines that are dispensed only on the prescription of a veterinary practitioner aimed at the public is prohibited by law.

BASIC ROLES & PRINCIPLES

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.

SUMMARY OF PROMOTIONAL PRINCIPLES (based on IFAH Code of Good Practice)

The Code of Practice for AHCZSK. members 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.

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.

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 mktg authorisation.

v) AnimalhealthEurope 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.

PROVISIONS OF THE CODE OF PRACTICE

1. The nature and availability of information and claims

Responsibility
It is the responsibility of the members, their employees and expert advisors to ensure that correct pharmaceutical content be provided in all promotional material, fully supported by the valid SPC. All information supporting a claim must be easily accessible so that it can be provided on request within 15 days. A claim of alleged confidentiality of the information shall not be accepted. The activities of company representatives must at all times comply with the Code of Practice.

Untruthful or misleading claims
Information on a medicine and its graphic representation must be up-to-date, exact and balanced and it must not mislead either directly or by implication or as a result of error of omission.

Not registered medicines and indications
Medicines which have not been registered in the Czech Republic/Slovak Republic or which are not in the registration process must not be promoted actively. This limitation applies also for registered medicine indications that have not been approved.

Good taste
Promotional material (including graphic and other visual designs) should comply with generally accepted standards of good taste and it should recognize the professional positions of those for whom it is intended.

Unqualified use of superlatives
Unsubstantiated superlatives must not be used. Claims must not indicate that a medicine or its active agent is unique or that it has some special value, quality or property unless it can be proved. The use of the word “bezpečný” (safe) must not be unsubstantiated.

Claims based on comparisons
Comparisons of medicines must not be derogatory but it must be exact, fair and substantiated, including the citation of the source of such a claim. When comparing medicines, it must be ensured that the comparison is not misleading due to misinterpretation, unsuitable emphasis or any other cause. Clear claims, such as that the product is better, stronger, prescribed more, etc. must not be used.

The accepted level of statistical significance is $p < 0.05$. If statistically insignificant data is used, it must be done in agreement with the following conditions:

- this data must be identified as such, with e.g. a claim, not only the “p” value
- the data must not be used to generalize or to hint at superiority or inferiority

Concluding that a claim is statistically insignificant must be connected in a certain manner to the original claim, done at the same page and in reasonable proximity of the original claim in such a manner so that it does not disappear in the surrounding lay-out.

Imitation
Promotional material must not imitate ideas, patterns, slogans or graphic layout used by other producers in a manner that is misleading or confusing.
Promotional material including the names of active agents is not excepted.

2. Promotional material

If information on a medicine is included in an interactive data system, it must be furnished with clear instructions on accessing such system.

Mailings should be sent only to those members of the professional community who can be reasonably assumed to have a need or be interested in the particular information. Requests to be removed from mailing lists must be complied with promptly and no name may be restored to such a list except at the addressee's request or their permission, in writing.

3. Veterinary pharmaceutical company representatives

Veterinary pharmaceutical company representatives must use only such promotional material and verbal claims that comply with this Code of Practice.

The members are responsible for maintaining a high standard of the training for its pharmaceutical or business representatives (representatives).

Representatives should have sufficient pharmaceutical training so they can give information on the company's medicines properly, accurately and in a balanced manner and they should be informed of all the provisions of this Code of Practice.

Representatives must at all times maintain a high ethical standard of conduct when attending to their duties.

4. Medicine samples

Members should always observe that the distribution of medicine samples complies with the legislation in action.

Information on the medicine as well as patient information leaflet must be jointly offered with the product sample or it must be included in the product container.

Representatives must take measures necessary to ensure the safety of the samples. Members must keep records in compliance with the current legislation in case it is necessary to retrieve the medicine from the market, including its samples.

5. Sale promotion

Sale promotion is necessary for spreading knowledge and experience. The main objective when organizing such promotion should be the dissemination of information. If free accommodation and hospitality are supplied when organizing congresses and symposia, they should not be the purpose of this meeting.

6. Travel and sponsoring

The following concerns the members who sponsor travel expenses of their delegates to congresses and symposia to and out of Hungary and in foreign countries:

- travel expenses can be paid on condition that the particular meeting is directly in relation with the area of interest of the particular delegate
- accommodation expenses can be covered to a reasonable level

- family member or travel companion expenses must not be paid for by the member

Symposia should be devoted mainly to scientific and pharmaceutical issues and activities and hospitality should not be the main goal of these meetings.

7. Professional public relations

Members can support the pharmaceutical activities of the pharmaceutical profession financialy or in kind. Such support must be capable of coming clean in the eyes of the general public as well as the scrutiny of the profession and it must be in agreement with the ethical standards of the profession, good taste and the legislation.

Hospitality
Hospitality or any other refreshments offered to the animal health professionals should be appropriate, secondary to the educational content and in proportion to the occasion.

Honoraria
Any honoraria for services rendered should not exceed the value of the service.

Attachment:

COMPLAINTS PROCEDURE

1. THE CIRCUMSTANCES FOR SUBMITTING A COMPLAINT

The procedure for submitting a complaint as stipulated in the Code of Practice of AHCZSK can be initiated by any member of the profession, company or general public acting in good faith and within the limits of this Code of Practice. When considering submitting a complaint, both parties should at first try to arrange for conciliation.
The potential result of the conciliatory negotiations shall be reported by both parties to the Board of Directors of AHCZSK.

1.1. Complainant and respondent

1.1.1.
To serve the purpose of this Code of Practice, a natural person or a legal entity submitting a complaint shall be denoted as the complainant.

1.1.2.
To serve the purpose of this Code of Practice, a natural person or a legal entity against who or which the complaint is made and who or which allegedly breached any provision of this Code of Practice, shall be denoted as the respondent.

1.2. Submitting a complaint

1.2.1.
A complaint shall be submitted in writing and it must contain:

- the complainant 's identity – name (in business, the first and last names in case of a natural person), address (address of the legal entity's headquarters or the residential address of the natural person) and contact information (telephone and fax numbers, e-mail address)
- the respondent's identity – name (in business, the first and last names in case of a natural person), address (address of the legal entity's headquarters or the residential address of the natural person) and contact information (telephone and fax numbers, e-mail address)
- the name of the product or products which the complaint concerns, for every complaint case
- the particular material that will be used as evidence of breach of the Code of Practice
- a concrete reference to the source of the advertisement/activity that is the subject matter of the complaint and/or printed material or other piece of evidence, for every complaint case
- the date when the alleged breach of the Code of Practice occurred
- the date when the complaint was submitted
- a concrete reference to that section of the Code of Practice whose provision has been breached (the number of the clause)
- a brief comment accompanying the complaint, for every complaint case

1.2.2.
All correspondence should be addressed to the Board of Directors at the following address:

Animalhelth CZ/SK
Kachlíkova 882/4, 635 00 Brno
Czech Republic

2. THE PROCEDURE FOR SUBMITTING A COMPLAINT

2.1. Investigation and appeals

2.1.1.
If AHCZSK receives a complaint about an alleged breach of the Code of Practice, it first scrutinises:

- the affair's justification, having been submitted in good faith
- the sufficiency of the information to process the complaint.

2.1.2.
One complaint can involve more than one case, e.g. a complaint about more pieces of advertisements of various subject matters and/or various products. The AHCZSK processes every case separately, as specified in the main complaint details.

2.1.3.
The first step in processing every complaint is the identification of the subject matter of the complaint, resolving whether the respondent is an AHCZSK member, whether the management or affiliate company is involved and the verification of the address.
In case that the respondent is not a AHCZSK member, the Board of Directors can announce its ruling on the conduct of this non-member company and eventually inform the authorities.

2.2. Time periods

2.2.1.
On receiving information from Board, the respondent has 15 days to provide the Board with a written response. An extension in time to respond to such notifications can be granted at the discretion of the Board.

2.3. Response

2.3.1.
In case the respondent accepts that there was a breach to this Code of Practice, the respondent shall inform the Board of measures that will be or were taken in order to set the matter right, e.g. conciliation of both parties.

2.3.2.
In case these accusations are not accepted, the reasons for refusal must be presented clearly and, if practicable, data that support them (e.g. scientific evidence supporting the claims) should be provided to AHCZSK within 15 days.

2.4. Complaint and Ruling Procedures

2.4.1.
On receiving the respondent's response, the Board of Directors of AHCZSK shall deal with the complaint at its following meeting. Both parties shall be invited to take part at this meeting to be able to express their views on the matter.

2.4.2.
The Board shall rule whether there was a breach of the Code of Practice and how this breach shall be defined.

2.4.3.
The respondent shall produce an obligation in writing stating an immediate cease in using the promotional activities or material in question and declaring the liability to undertake all

available measures to prevent any such breach to the Code of Practice in the future. This obligation must be signed by a representative of the respondent party and a detailed account on measures that the respondent intends to take in order to fulfil the obligation must be attached, including the date when the promotional material in question was used last or when in came up and/or the date when the last questionable promotional activity was undertaken.

2.4.4.
If the Board rules that there was no breach of the Code of Practice, it shall notify the complainant as well as respondent of the result.

2.4.5.
The complainant or the respondent company can lodge an appeal against the Board's ruling within 15 days to be processed at the General Meeting by submitting it at AHCZSK office.

2.5. General Meeting rulings

2.5.1.
On receiving an appeal, the AHCZSK Board of Directors shall call a General Meeting within the following four weeks.

2.5.2.
Representatives of the Board and representatives of both parties shall be asked to attend the General Meeting in order to comment on the complaint.

2.5.3.
The General Meeting shall rule if there was or was not a breach of the Code of Practice, the complainant and respondent company are notified of the ruling in writing, including the reasons for such a ruling.

2.5.4.
The rulings of the General Meeting are final and no appeal may be lodged against them within the framework of the AHCZSK.

3. GENERAL PROVISIONS

3.1. Observing the Code of Practice

Observing the Code of Practice shall be supervised by the Board of Directors that is accountable to the General Meeting of AHCZSK. The Board of Directors can establish an ad hoc commission to scrutinise the given complaint or it can seek external expert advice in order to resolve whether there was or was not a breach of the Code of Practice. The respondent's representative is invariably excluded from the scrutiny and ruling of the given complaint.

3.2. Reporting

The Board of Directors makes biannual reports and sends them to all members. The Board of Directors can recommend the General Meeting of AHCZSK to publish these reports. A report shall contain the following information:

a) the names of the respondent companies in complaints in breach of the Code of Practice
b) the product name and promotional material or, as the case may be, the activity that was in breach with the Code of Practice
c) the clause of the Code of Practice that was breached and the reasons why
d) the total number of the complaints received
e) the total number of the cases in breach with the Code of Practice
f) the total number of appeals and the results thereof.