

**Code of Conduct  
of the Members of the Association  
“Freiwillige Selbstkontrolle für die  
Arzneimittelindustrie e.V.” (FSA)  
(FSA Code of Conduct)**

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## **Introduction**

Health is mankind's most precious possession, and pharmaceuticals make a key contribution to every individual's health and well-being. The research, development, production and distribution of pharmaceuticals impose great demands on the companies within the pharmaceutical industry. The patients are at the centre of the industry's efforts to prevent, cure or relieve the consequences of diseases through effective pharmaceuticals.

The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-regulation for the Pharmaceutical Industry") have made a commitment to communicate the knowledge required for the appropriate selection and application of pharmaceuticals by disseminating accurate and objective scientific information. Pharmaceuticals are technically sophisticated and complex goods requiring comprehensive explanation. It is, therefore, an indispensable task of any pharmaceutical undertaking to provide healthcare professionals with all necessary and suitable information regarding the significance and characteristics of medicinal products by considering both the possible applications and benefits of pharmaceuticals as well as the limits and risks of their application by taking account of the latest findings of medical sciences. In addition, both the research and the development of effective pharmaceuticals would be virtually impossible without close expert collaboration with the medical profession, pharmacists and other healthcare professionals. The trust-based relationship between physician and patient is the foundation of each therapy. The therapy decision is the sole responsibility of the medical profession. Pharmacists guarantee the provision of appropriate advice in the supply of the medicinal product prescribed by the physician in charge.

Advertising is a key element of market economy and an expression of intense competition within the pharmaceutical industry. This Code of Conduct is not intended to restrain fair competition. Rather, for the members of the FSA, the principle applies that pharmaceuticals are to be adequately advertised, avoiding unfair practices and conflicts with healthcare professionals in relation to professional ethics. All measures in advertising and collaborating with physicians and other healthcare professionals must remain within certain appropriate bounds and in accordance with the law. In this respect, the principles of separation, transparency, documentation and, for mutual services, the principle of equivalence as stipulated in the "Common Position" of the associations (Common Position of the Associations for assessing the Collaboration between Industry, Medical Facilities and their Employees in Reference to German Criminal Law) for the clinical sector also outline valuable reference points for the collaboration of the pharmaceutical industry with office-based physicians and other healthcare professionals.

With the objective of promoting professional conduct in accordance with these principles, fostering an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients and ensuring fair competition in

advertising as well as in the collaboration with physicians and other healthcare professionals, the general assembly of the FSA has passed the following

**Code of Conduct of the Members of the Association  
“Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.” (FSA)**

**Chapter 1: Area of Application**

**Section 1: Area of Application**

- (1) The Code of Conduct is applicable to the member companies as well as to any companies affiliated with the member companies, if these affiliated companies have acknowledged the binding nature of the FSA Code of Conduct in a separate written agreement (“member companies” or “companies”).
- (2) The Code of Conduct is applicable
  1. to the product-related promotion of medicinal products within the meaning of Section 2 of the German Drugs Act (AMG) as regulated in Chapter 3 of this Code of Conduct, if
    - a) the products are prescription-only medicinal products for human use pursuant to Section 48 AMG, and
    - b) the promotion is directed to healthcare professionals within the meaning of Section 2 of this Code of Conduct,and
  2. to the collaboration of the member companies with healthcare professionals in the field of research, development, production and distribution of prescription-only and non-prescription-only pharmaceuticals for human use as regulated in Chapter 4 of this Code of Conduct.
- (3) The Code of Conduct is not applicable to non-promotional information, including, within the meaning of this Code of Conduct, in particular:
  1. the labelling of medicinal products and accompanying package leaflets;
  2. correspondence and documents of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
  3. factual information such as announcements relating to pack changes, adverse-reaction warnings as well as reference material

(e.g. trade catalogues and price lists, provided they include no product claims);

4. factual information relating to diseases or human health;
5. information about companies, e.g. information directed to investors or to current or prospective employees, including financial data, descriptions of research and development programmes as well as information about regulatory developments affecting the company and its products.

## **Section 2: Definitions**

“Healthcare professionals” are physicians and pharmacists as well as any member of the medical, dental, pharmacy or other nursing professions or any other person who in the course of his or her professional activities may prescribe or apply or lawfully trade in medicinal products for human use.

## **Section 3: Responsibility for the conduct of third parties**

The company shall comply with the obligations imposed hereunder even if it commissions others (e.g. advertising agencies or market research companies) to design or implement the activities covered by this Code of Conduct.

## **Chapter 2: Principles of Interpretation**

### **Section 4: General principles of interpretation**

- (1) When applying the present Code of Conduct, not only the letter of the individual provisions, but also their spirit and intention as well as all applicable laws must be observed, especially the regulations of the German Drugs Act (AMG), the German Advertising in the Health Care System Act (HWG), the German Fair Trade Practices Act (UWG) and the German Penal Code (StGB), and the generally recognized legal principles applicable to healthcare professionals and the conduct recommendations of the participating associations of the pharmaceutical industry, which are based on these principles by considering their wording as well as their meaning and purpose.
- (2) The companies must maintain high ethical standards at all times. In particular, their conduct must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry or to cause offence. Additional regard must be paid to the special nature of medicines and the professional standing of the healthcare professionals addressed.

### **Section 5: Promotion**

When applying Chapter 3 of this Code of Conduct, particular attention is to be paid to the following principles of interpretation:

1. Promotion must enable the healthcare professionals addressed to form their own opinion of the therapeutic value of the medicinal product concerned. It must, therefore, be accurate, balanced, fair, objective and sufficiently complete to give a correct overall impression. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly.
2. Promotion must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties.
3. Medical sales representatives must approach their duties responsibly and ethically correct.

### **Section 6: Collaboration**

(1) When applying Chapter 4 of this Code of Conduct, particular attention is to be paid to the following principles of interpretation:

1. Healthcare professionals must not be unfairly influenced in their decisions regarding therapy, prescriptions or procurement. Therefore, it is unlawful to offer, promise or grant them or any third party any unfair advantages. Especially the forms of collaboration described in Chapter 4 below must not be used in any unfair manner to influence the decision-making freedom of healthcare professionals regarding therapies, prescriptions or procurement.
2. Considered unfair are in particular those advantages that are granted in violation of the provisions of the German Advertising in the Health Care System Act (HWG), the German Fair Trade Practices Act (UWG), the German Penal Code (StGB), or the generally recognized legal principles applicable to healthcare professionals.

(2) The board of management of the FSA may issue guidelines for the interpretation of this Code of Conduct, in particular for the interpretation of the terms “reasonable”, “socially acceptable” and “inexpensive” within the meaning of Chapter 4 hereof. The association will publish such guidelines on the internet ([www.fs-arzneimittelindustrie.de](http://www.fs-arzneimittelindustrie.de)).

## **Chapter 3: Promotion**

### **Section 7: Prohibition of misleading practices**

- (1) Misleading promotion is inadmissible, irrespective of whether it is misleading by distortion, exaggeration, undue emphasis, omission or in any other way.
- (2) A misleading practice is in particular found to exist if
  1. medicinal products are attributed with therapeutic efficiency, effects or an application they do not possess,
  2. the false impression is given that success is guaranteed,
  3. it contains improper or misleading information concerning the composition or properties of medicinal products.
- (3) When evaluating the question of whether the non-disclosure of a fact is misleading, special regard is to be paid to the potential influence such a non-disclosure may have on the decision of the healthcare professionals addressed regarding prescriptions.
- (4) Promotion must be based upon sufficient scientific evidence and must be consistent with the information addressed to healthcare professionals. This rule applies in particular to advertising claims referring to specific benefits, qualities or properties of a medicinal product or an active substance. Promotion about side-effects must also reflect all available findings or be capable of substantiation by clinical experience. Claims that are already included in the marketing authorization of the medicinal product do not require further scientific evidence. If so requested by healthcare professionals, the relevant scientific evidence must be directly made available to an appropriate extent.
- (5) The word “safe” must never be used to describe a medicinal product without proper scientific evidence.
- (6) General claims that a medicinal product has no side-effects, toxic hazards or risks of addiction or dependency are inadmissible. Claims that specific side-effects, toxic hazards or risks of addiction or dependency have so far not become known are permitted only if they are based upon sufficient scientific evidence.
- (7) The word “new” must not be used to describe any medicinal product which has been generally available, or any therapeutic indication which has been generally promoted, for more than one year.

### **Section 8: Prohibition of disguised promotion / requirement of transparency**

- (1) Promotion must not be disguised.
- (2) Where a company pays for or arranges the publication of promotional material in journals, it must make sure that such promotional material cannot be confused with independent editorial matter.
- (3) In the case of any publications made by third parties about medicinal products and their use which are either wholly or partially sponsored by a company, particular care must be taken to ensure that such publications clearly indicate that they have been sponsored by that company.

### **Section 9: Prohibition of promoting medicinal products or indications without marketing authorization**

Medicinal products being subject to a marketing authorization must not be promoted prior to the grant of such marketing authorization. Any promotion going beyond the indications or pharmaceutical forms approved in the marketing authorization is inadmissible.

### **Section 10: Compulsory information**

- (1) All promotional material relating to medicinal products must include the following information clearly and legibly:
  1. the name or the company name and domicile of the pharmaceutical manufacturer,
  2. the name of the medicinal product,
  3. the composition of the medicinal product pursuant to Section 11 (1) sentence 1 no. 6 d) of the German Drugs Act (AMG),
  4. the therapeutic indication,
  5. the contra-indications,
  6. the side-effects,
  7. warnings if and to the extent required for the labelling of receptacles and outer packages,
  8. the indication “verschreibungspflichtig” (prescription-only), and
  9. the date on which the information was generated or last revised.

- (2) For medicinal products that contain only one active ingredient, the information according to subsection (1) no. 2 must be followed by the name of such ingredient, including the indication “Wirkstoff:” (active substance); this rule shall not apply if the information according to subsection (1) no. 2 contains the name of the active substance.
- (3) The information according to subsections (1) and (2) above must be consistent with the information required by Section 11 of the German Drugs Act (AMG) for the package leaflet.
- (4) Subsections (1) and (2) shall not apply to an advertisement that is intended only as a reminder. An advertisement is found to be intended as a reminder if it exclusively refers to the name of the medicinal product or additionally to the name, the company name, the trademark of the pharmaceutical manufacturer or the active substance.
- (5) The medical sales representative must, when promoting individual medicinal products vis-à-vis healthcare professionals, submit a summary of the relevant product characteristics.

### **Section 11: Reference to publications**

A promotion shall be inadmissible when

1. referring to scientific, expert or other publications without indicating whether the publication concerns the medicinal product, the method, the treatment, the object or any other means being advertised and without mentioning the name of the author, the date of publication and the source reference,
2. quotations, tables, copies, other representations or expert remarks of third persons taken from scientific publications have not been faithfully reproduced, except where the modification can be based upon an objectively justified reason, in which case it must be clearly stated that it has been modified.

### **Section 12: Comparative advertising**

- (1) Any advertising which explicitly or by implication identifies the medicinal products of a competitor shall be deemed to be comparative advertising.
- (2) Any comparative advertising that fails to objectively refer to one or more essential, relevant, verifiable and typical properties of the medicinal products compared is inadmissible.
- (3) Comparative advertising must not be misleading or disparaging with regard to a competitor’s medicinal product.

### **Section 13: Unreasonably molesting advertising**

- (1) Healthcare professionals shall not be unreasonably molested by advertising. An unreasonable molestation is found to exist where advertising action can be recognized by the advertising person as not being desired by the recipient.
- (2) The use of faxes, automated calling systems or e-mails for promotion is prohibited except with the prior permission of the recipient.

When using e-mail, a putative permission can be assumed to have been given if the company has received the e-mail address from the recipient and the recipient is clearly informed in any e-mail that he may object to the use of e-mail at any time.

- (3) The permission to be given by the addressee of the advertising action must not be obtained by using any inducement or subterfuge, in particular by misleading the addressee as to the identity of the medical sales representative or the company represented by him.
- (4) Mailing lists may be used for promotion only if the data included therein are kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with.

### **Section 14: The “red hand” symbol**

- (1) For advisories of newly identified, considerable dangers caused by medicinal products or other risk-related information to be directly communicated to physicians and/or pharmacists in case of need of action to exclude risks for patients, where possible, a red-hand symbol and the text “Important information on a pharmaceutical” must be used on both the envelope and the letterhead. In sending a “red-hand” letter, it is possible to use all media available in accordance with the requirements of the largest possible degree of coverage in distribution. In particularly urgent cases, it may also be necessary to disseminate these advices orally, by fax or through public notices, e.g. via print media, radio and television.
- (2) A “red-hand” letter must not, either as a whole or in parts, have the character of promotional matter or contain advertising claims. Other scientific information, advertisements or direct marketing mail must never be sent out with the red-hand symbol and must not be labelled “Important Information”.

### **Section 15: Samples**

- (1) Pharmaceutical manufacturers may supply samples of a medicinal product to healthcare professionals who are qualified to prescribe such product in order to familiarize them with the product, but only in response to a written request, signed and dated, from the recipient.

- (2) Companies must have adequate systems of control and accountability for samples which they distribute.
- (3) Each sample shall be no larger than the smallest presentation of the relevant pharmaceutical being available on the market and no more than two samples of a medicinal product shall be provided within one year.
- (4) Each sample must be marked “unverkäufliches Muster“ (free medical sample – not for resale) and must be accompanied by the summary of product characteristics.
- (5) Samples must not contain any substances or preparations within the meaning of Section 2 of the German Narcotics Act (BtMG) listed as such in Annex II or III of said Act.

#### **Section 16: Prohibition of distant treatment / response to individual requests**

The diagnosis or treatment of diseases is reserved for physicians. In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised by the company to consult a physician.

### **Chapter 4: Collaboration with Healthcare Professionals**

#### **Section 17: Prescriptions and recommendations**

It is unlawful to offer, grant or promise healthcare professionals or any third party a fee or other monetary advantage for prescribing, applying or recommending a pharmaceutical to patients.

#### **Section 18: Contractual collaboration with physicians**

- (1) Physicians may only render services for companies (e.g. lectures, consulting, clinical trials, drug monitoring projects) based on written agreements that clearly state both the nature of the service and the remuneration.
- (2) The contractually stipulated service to be rendered by the physician in question to the company must be scientific or medical in nature, including educational purposes (prohibition of “fictitious contracts”). Clinical studies and drug monitoring projects as well as any other studies or data collections must not be misused with a view to influencing therapeutic or procurement decisions or for mere promotional purposes.

- (3) The remuneration must be exclusively monetary and must be proportionate to the service rendered. When judging the appropriateness of the intended remuneration, the physician's fee schedule may serve as a reference guide. To take into account the physician's time expended, appropriate hourly rates may also be arranged.
- (4) In addition, physicians may be reimbursed for their out-of-pocket and travel expenses while rendering the contractual services.
- (5) Physicians or third parties must not be granted payment of any fees for their willingness to meet with pharmaceutical consultants or receive information from other members of the pharmaceutical company.

### **Section 19: Drug monitoring projects**

- (1) Drug monitoring projects are scientific studies following the marketing authorization or registration of a pharmaceutical with the purpose of gaining new insights on the application of the pharmaceutical and its efficacy and tolerability in practice.
- (2) With regard to therapeutic and diagnostic measures, the principle of non-intervention applies to drug monitoring projects.
- (3) When planning, designing and implementing drug monitoring projects, the recommendations and guidelines published by the German Federal Institute for Drugs and Medical Devices (BfArM) must be observed. In particular, the completed surveillance sheets should be professionally evaluated and the execution of the drug monitoring project should be subjected to appropriate quality assurance measures.
- (4) In addition, the company must justify and document the planned number of patients and the amount remunerated for each surveillance sheet in the project file.
- (5) With regard to the amount remunerated for the implementation of a drug monitoring project, Section 18 (3) applies subject to the provision that said remuneration should be set in such a manner that it does not create an incentive to prescribe the pharmaceutical in question.

### **Section 20: Invitation to job-related, science-oriented training events**

- (1) The member companies may invite such healthcare professionals to their own, job-related training events, who are particularly concerned with said companies' research areas, pharmaceuticals and their therapeutic indications (in-house training events).
- (2) The company may only pay reasonable travel and accommodation costs for the invited physicians, if the job-related, scientific character of the in-house training event clearly takes centre stage. During such training events,

reasonable hospitality arrangements for the participants are also possible. However, the company must neither finance nor organize any entertainment programs of the participants (e.g. theatre, concert or sports events). The actual participation of the invited persons and the event program must be documented.

- (3) Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue as well as the invitation of healthcare professionals must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason.
- (4) The invitation of healthcare professionals to the job-related training events of any third party (external training events) may only include reasonable travel expenses, necessary accommodations and participation fees charged by said third party, if the scientific character of these events clearly takes centre stage and if the company has a relevant interest in such a participation. The company may only assume the costs, if the event provides a link to the member company's field of activities as well as a link to the expertise of the event participant.
- (5) Within appropriate limits, financial support for the organizers of external training events is permissible. However, entertainment programs must neither be supported financially or in the form of donations nor organized. Member companies supporting external training events must request that the financial support be officially disclosed by the organizer when the event is announced and when it takes place.
- (6) If the organizer is a member of the medical profession, the nature, content and presentation of the training event must be determined solely by said medical organizer.
- (7) The invitation and assumption of the costs for in-house and external training events must not include companions. This also applies to any hospitality offered.
- (8) No member company may organize, hold and/or sponsor international events or pay for the costs of the participants unless
  1. the majority of the participants are from outside of its home country, or
  2. the relevant resource or expertise are available at the venue (e.g. for recognized medical congresses with international lecturers),

and, in view of these factors, it makes greater logistical sense to hold the event in another country. International events are in-house or external training events in which the company organizing, holding or supporting the event or supporting its participants is not domiciled in the country where the relevant event takes place.

- (9) The organisation, holding and/or sponsoring of international events as well as the invitation of healthcare professionals to, and the support of their participation in, such events are subject to both the code of the country in which the company organizing, holding or supporting the international event is domiciled and the code of the country in which the international event takes place. Code within the meaning of this provision shall mean the FSA Code as well as the applicable code at the place of the event implementing the EFPIA Code of Practice on the Promotion of Medicines. In the event of a conflict, the more restrictive rule shall apply. The company must notify any activities within the meaning of sentence 1 in advance to its affiliated company, if any, domiciled in the country where the event takes place or obtain appropriate advice for the due and proper implementation of such activities.
- (10) If healthcare professionals are commissioned by member companies to hold lectures at in-house or external training events or provide other services, Section 18 shall apply.

### **Section 21: Gifts**

- (1) For advertising gifts offered within the scope of a product-related promotion, the limits stated in Section 7 of the German Advertising in the Health Care System Act (HWG) must be observed. Unless otherwise provided for by Section 7 of the German Advertising in the Health Care System Act, such gifts must be “inexpensive”. Advertising gifts must not, beyond the information defined in Section 10 of this Code of Conduct, contain any indications or advertising claims other than the company name, the company logo or the trademark of the company or the name of the medicinal product or the designation of its active substance.
- (2) In addition, gifts offered within the scope of a non-product-related promotion may be made only for special occasions (e.g. for practice openings or anniversaries), as long as their value is within socially acceptable limits and they are intended for use in the professional practice.

### **Section 22: Hospitality**

Hospitality is only permissible during in-house training events and work lunches/dinners to a reasonable and socially acceptable extent. The occasion for such a work lunch/dinner must be documented. Hospitality for companions is not permissible.

### **Section 23: Sweepstakes for healthcare professionals**

- (1) Sweepstakes, in which winning is solely due to chance, may not be advertised to healthcare professionals.

- (2) Sweepstakes, in which the entry depends on a scientific or expert service of the participating healthcare professionals and for which the promised prize is appropriately proportionate to the scientific or expert service rendered by the entrants, are permissible.

**Section 24: Collaboration with  
healthcare professionals in their function as civil servants  
and/or employees of medical institutions**

When collaborating with healthcare professionals who are civil servants and/or employees of medical institutions, the information and recommendations of the “Common Position” of the associations should also be observed.

**Chapter 5: Commitment and training of employees and third-party  
contractors**

**Section 25: Qualification and duties of employees**

- (1) The companies shall ensure that their sales representatives, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, hospitals or other healthcare facilities in relation to the advertising of medicinal products are adequately trained and have sufficient expert knowledge to be able to provide precise and sufficiently complete information about the medicinal products they promote.
- (2) Medical sales representatives must be familiar with the companies’ obligations hereunder and all applicable laws and regulations, and companies are responsible for ensuring their sales representatives’ compliance with these requirements.
- (3) All other company staff, and any personnel retained by way of contract with third parties who are concerned with the preparation or approval of promotional material or activities must also be fully conversant with the requirements of the applicable codes and relevant laws and regulations.
- (4) Each company must establish a scientific service which is in charge of all information about its medicinal products and meets the personal and medical requirements of Section 74a (2) of the German Drugs Act (AMG). The scientific service is in particular responsible that
  1. the medicinal products are not provided with any misleading designation, information or presentation, and
  2. the labelling, the package leaflet, the expert information and the advertising are consistent with the content of the marketing authorization.

- (5) Medical sales representatives must submit to the scientific service of their companies any information they receive in relation to the use of their company's medicinal products, particularly reports of side-effects.
- (6) Medical sales representatives must ensure that the frequency and duration of their visits to healthcare professionals, together with the manner in which they are made, do not cause unacceptable inconvenience to the practice operation.

#### **Section 26: Commitment and training of employees and third-party contractors**

- (1) Member companies must commit their employees and third-party contractors being concerned with in the advertising of medicinal products or collaborating with healthcare professionals to adhere to this Code of Conduct and ensure compliance through suitable organizational measures, including the establishment and definition of the function of a "compliance officer" by appointing one or several employees.
- (2) In addition, the employees must be informed of the most important principles of the professional regulations and obligations of the healthcare professions. Furthermore, they must be trained with regard to the content of the FSA Code of Conduct.

### **Chapter 6: Effectiveness**

#### **Section 27: Effectiveness**

The Code of Conduct of the members of the FSA in the version passed by the general assembly on, December 2, 2005, will become effective as soon as it has been acknowledged as competitive regulations by the Federal Cartel Office pursuant to Section 24 (3) of the German Restraints of Competition Act (GWB).

*[The Federal Cartel Office acknowledged the Code of Conduct as competitive regulations with decision of March 13, 2006, received on March 16, 2006.]*