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English Version

# FS Arzneimittelindustrie e.V.



## Kodex

für die Zusammenarbeit der  
pharmazeutischen Industrie mit  
Ärzten, Apothekern und anderen  
Angehörigen medizinischer Fachkreise



**FSA Code of Conduct  
on the Collaboration with Healthcare  
Professionals  
(FSA Code of Conduct Healthcare  
Professionals)**

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<b>Table of Contents</b>		<b>Page</b>
<b>Introduction</b>		<b>4</b>
<b>Chapter 1</b>	<b>Area of Application</b>	<b>5</b>
Section 1	Area of Application	5
Section 2	Definitions	6
Section 3	Responsibility for the conduct of third parties	6
<b>Chapter 2</b>	<b>Principles of Interpretation</b>	<b>6</b>
Section 4	General principles of interpretation	6
Section 5	Promotion	7
Section 6	Collaboration	7
<b>Chapter 3</b>	<b>Promotion</b>	<b>8</b>
Section 7	Prohibition of misleading practices	8
Section 8	Prohibition of disguised promotion / requirement of transparency	9
Section 9	Prohibition of promoting medicinal products or indications without marketing authorization	9
Section 10	Compulsory information	9
Section 11	Reference to publications	10
Section 12	Comparative advertising	10
Section 13	Unreasonably abusive advertising	11
Section 14	The “red hand” symbol	11
Section 15	Samples	11
Section 16	Prohibition of distant treatment / response to individual requests	12
<b>Chapter 4</b>	<b>Collaboration with Healthcare Professionals</b>	<b>12</b>
Section 17	Prescriptions and recommendations	12
Section 18	Contractual collaboration with healthcare professionals	12
Section 19	Non-interventional studies with authorised medicinal products	14
Section 20	Invitation to job-related, science-oriented training events	16
Section 21	Gifts	18
Section 22	Hospitality	19
Section 23	Sweepstakes for healthcare professionals	19
Section 24	Collaboration with healthcare professionals in their function as civil servants and/or employees of medical institutions	19
Section 25	Donations and other benefits to institutions	19
Section 26	Mutually relationships with institutions	20
<b>Chapter 5</b>	<b>Commitment and training of employees and third-party contractors</b>	<b>20</b>

Section 27	Qualification and duties of employees	20
Section 28	Commitment and training of employees and third-party contractors	21
<b>Chapter 6</b>	<b>Effectiveness</b>	<b>22</b>
Section 29	Effectiveness	22

## **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

**FSA Code of Conduct  
on the Collaboration with Healthcare Professionals  
(FSA Code of Conduct Healthcare Professionals)**

**Chapter 1: Area of Application**

**Section 1: Area of Application**

- (1) The Code of Conduct is applicable to the member companies and their domestic subsidiaries and the other affiliated companies, if these affiliated companies have acknowledged the binding nature of the FSA Code of Conduct Healthcare Professionals (“Code”) in a separate written agreement (“member companies” or “companies”). The accountability for infringements of affiliated dependent companies, which are neither members of the association or have not acknowledged the binding nature of the Code of Conduct, is in accordance with § 1 para. 3 of the “FS-Arzneimittelindustrie” Code of Procedure.
- (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 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**

- (1) Companies shall comply with the obligations imposed hereunder even when they commission others (e.g. consultants, hired sales forces, advertising agencies or market research companies) to design or implement the activities covered by this Code of Conduct for them.
- (2) The companies also have the responsibility to ensure in a reasonable way that others, with whom they collaborate (e.g. joint venture partners, license holders), comply with the minimum standards laid down in the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals.

## **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 FSA can also issue through its board of management binding guidelines for the interpretation of this Code, beyond the cases regulated in

this Code. 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 abusive advertising**

- (1) Healthcare professionals shall not be unreasonably molested by advertising. An unreasonable abuse 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 only supply samples of a medicinal product to healthcare professionals in the framework of § 47 para. 3 and 4 as well as § 10 para. 1 No. 11 AMG. The healthcare professionals must be

qualified to prescribe such a product; the samples are for them to familiarize themselves with the product.

- (2) The supplying of samples is not to be misused as an incentive to influence therapy-, prescribing- and procurement decisions.

### **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 healthcare professionals**

- (1) Companies may only commission services (e.g. lectures, consulting, clinical trials, drug monitoring projects, non-interventional studies including drug monitoring projects, the attendance at meetings of advisory boards, the carrying out of training events or for the participation in market research activities) in return for payment from healthcare professionals (“contractual partners”) under the following conditions:
  1. Contractual partners and companies must agree on a written contract stipulating the services to be rendered and the remuneration before the service commences.
  2. There must be a clearly ascertainable legitimate need for the services to be rendered and also the conclusion of the contract with the contractual partner. The contractually stipulated service to be rendered by the contractual partner must be scientific or medical in nature, including educational purposes (prohibition of “fictitious contracts”).
  3. The selection of contractual partners must correspond to the needs.
  4. The number of contractual partners is not to be higher than the number necessary for fulfilling the services rendered in a reasonable manner.

5. The company has to document the contractual relationship and the services rendered. The important documents are to be kept for a period of at least one year after the contractual relationship has ended. Further, the company has to use the services rendered in a suitable manner.
  6. 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. In addition, the contractual partners may be reimbursed according to paragraph 4 for their out-of-pocket and travel expenses while rendering the contractual services.
  7. The conclusion of contracts is not to be misused to influence therapy-, prescribing or procurement decisions, or merely advertising purposes. This also applies to clinical trials and drug monitoring projects, as well as all other studies or data collection (including retrospective examinations).
- (2) The companies must obligate their contractual partners to refer to their services rendered to the company in their publications, lectures and other public statements, if the subject matter of the public statement is at the same time the subject matter of the contractual relationship or any other subject matter affecting the company. This also applies to physicians employed by the company in as far as they continue to practise their profession outside their activities for the company (as private practitioner or clinic physicians). Contracts that already exist must be appropriately amended at the next opportunity (e.g. contract extension).
  - (3) The requirements laid down in para. 1 and 2 are not applicable to the performance of non-recurring, occasional services by healthcare professionals in connection with market research activities (e.g. short telephone interviews) if the payment is inexpensive. The board of management of the association is issuing binding guidelines according to § 6 para. 2 for the interpretation of the term "inexpensive" in the meaning of this clause.
  - (4) If a contractual partner participates in an in-house or external training event in the framework of providing services for the company the rules laid down in § 20 apply accordingly (e.g. the selection of the conference location and/or the conference venue, for the remuneration of travelling and accommodation expenses as well as the prohibition of entertainment and leisure time programmes). The same applies to the participation of contractual partners in so-called Advisory Board Meeting or the participation in Investigator Meetings for clinical or non-interventional trials.

- (5) The contractual partners 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: Non-interventional studies with authorised medicinal products**

- (1) Non-interventional studies, to which drug monitoring projects also belong, are prospective studies with the purpose of gaining new insights from the treatment of patients on the application of pharmaceuticals in accordance with the instructions laid down in the marketing authorisation (e.g. harmlessness or efficacy of pharmaceuticals). The principle of non-intervention applies to all therapeutic and diagnostic measures. The inclusion and treatment, including the diagnosis and supervision, do not therefore follow a previously laid down study plan, but solely the physicians medical practise. The decision to include a patient in a non-interventional study has to be clearly separated from the decision on the prescription of a medicinal product. The data obtained has to be evaluated by means of epidemiological methods.
- (2) When planning, implementing and evaluating non-interventional studies, all applicable legal regulations and the recommendations and guidelines published by the German Federal Institute for Drugs and Medical Devices (BfArM) and the Paul-Ehrlich Institut (PEI) must be observed. Irrespective of the foregoing, the planning, implementing and evaluating of non-interventional studies must in every case comply with the following conditions:
1. The study must serve a scientific purpose.
  2. The planning, supervision, evaluating and quality assurance of the study must within the company be the responsibility of the head of the medical department (§ 27 para. 6). This also includes responsibility for the budget.
  3. The implementation (e.g. the selection of study centres and addresses of physicians or other healthcare professionals) and the performance of the study (including supervision during the course of the study) must take place under the leadership of the head of the medical department. This also applies when employees from other departments are involved in implementing and performing the study.
  4. Quality assurance systems are used, which ensure that the data obtained is valid and representative.
  5. The study must be based on a written surveillance plan as well as a written agreement between the healthcare professionals and/or the institutes in which the study is to be carried out, as well as the company that is taking over the responsibility as “sponsor” of the study. The agreement must include in particular the services to be rendered and the remuneration.

6. 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. The company has, in as far as it concerns drug monitoring projects, in the framework of its duty of disclosure in accordance with § 67 para. 6 AMG to the Confederation of German Physicians, the Central Association of Health Insurance Funds and the competent Federal Governing Authorities also to disclose the location, time, aim and plan of the study. The names of the participating physicians have to be disclosed to the Confederation of German Physicians and the Central Association of Health Insurance Funds. If the physicians involved render services that are charged to the health insurance funds then the informing in accordance with § 67 para. 6 AMG also has to include the type and amount of remuneration paid to them. A copy of the agreement is also to be handed over. Notifications to the appropriate Federal Governing Authorities are excluded from this (§ 67 para. 6 sentence 4 AMG).

7. The remuneration agreed must be in an appropriate relationship to the services rendered. With regard to the amount remunerated, § 18 para. 1 no. 6 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. The performance of the study is not allowed to be misused to influence therapy-, prescription or procurement decisions.

8. It is recommended that before a study is carried out the scientific head of the study obtains advice from an independent ethics committee formed under federal state law.

9. The participation in a study is conditional on a prior written informed patient consent, if this is necessary for data protection reasons. Moreover, a prior written confirmed information and consent is recommended (on the involvement of the study centre and the physician or other healthcare professionals, the intended role of the patient and the planned use of the data).

10. Within 21 days of starting to recruit patients information on the planned study must be entered in a publicly accessible register (title of study, aims, name of the study leader, planned number of study centres and the number of cases involved), in accordance with the joint declaration of the IFPMA, EFPIA, JPMA and PhRMA on the registering of clinical trials.

11. The results of the study must be evaluated by the company or a third party authorised by it. The responsibility for the evaluation within the company lies with the head of the medical department. A summary of the results must therefore be made available to the head of the medical department within a responsible period of time; who is to keep the appropriate reports for a period of 10 years. The company has to make available a summary of the results to all healthcare professionals who participated in the study at the latest 12 months after the study is finalised (last patient/last visit). The summary of the study results is to be made public at the latest 12 months after finalisation (e.g. per Internet). If the results of the study are of importance for the use-risk analysis the summary

is also to be sent to the competent pharmaceutical authority. The companies must observe the responsibilities set forth in para. 2 no. 11 for all non-interventional studies which will be concluded after 1 July 2008.

12. Medical sales representatives may only be used for administrative purposes when studies are carried out. Their participation has to be under the supervision of the head of the medical department (§ 27 para. 6). The participation of medical sales representatives in the study is not to be associated with advertising activities for pharmaceuticals.

13. The basic principles and the in-house procedures to be observed in the planning, carrying out and evaluating, as well as suitable quality assurance measures (in particular for the verifying of data collected), are to be elaborated in detail in the company's "Standard Operating Procedures". In doing so, besides the general legal framework conditions the recommendations of the BfArM and the PEI and also the relevant regulations of the Code are to be implemented.

- (3) The companies must observe the criteria listed in para. 2 not only for the non-interventional studies which fall under para. 2, but also for other retrospective studies if these criteria can be sensibly used for such studies. In either case, the regulations of § 26 are applicable to this study.

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

- (1) The member companies may invite such healthcare professionals to their own, continual professional development events (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- and leisure time 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. Further, the companies are to avoid conference locations which are known for their entertainment value or are considered extravagant.

- (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 (if necessary including hotel breakfast) 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. Member companies must not support directly or indirectly any entertainment programs by paying participation fees for healthcare professionals.
- (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. With international events logistical reasons could speak for an event location abroad, if it concerns an established event of a recognised national or international medical-scientific association or a consortium of such associations at a suitable location for the holding of such events in the country of the headquarters of one of the associations (e.g. joint traditional events of recognised German speaking association from Germany, Austria or Switzerland in suitable event locations in Austria and Switzerland). 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 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. The invitation and support of the participating healthcare professionals in international events is subject to besides the code of the country in which the supporting company is domiciled, the code of the country in which this healthcare professional is active. Code within the meaning of sentence 1 of this provision is the FSA Code Healthcare Professionals as well as the individual Code applicable at the place of the event, through which the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals is implemented. Code within the meaning of sentence 2 of this provision is the FSA Code Healthcare Professionals as well as the Code valid in the country of origin of the healthcare professional, through which the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals is implemented. 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 domiciled in the country where the event takes place (in the case of sentence 1) or domiciled in the country of origin of the healthcare professionals (in the case of sentence 2), 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.
- (11) The board of management of the FSA may also issue binding guidelines according to § 6 para. 2 on the interpretation of the terms “appropriate”, “known for their entertainment value” and “extravagant” in the meaning of these provisions.

### **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 claims on advertising gifts, which go further than the name of the company, the company logo or the brand of the company resp. the name of the medicinal product or the designation of its active substance are only permissible when they include the mandatory information laid down in §10.
- (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.
- (3) The board of management of the FSA may also issue binding guidelines according to § 6 para. 2 on the interpretation of the term “inexpensive”.

### **Section 22: Hospitality**

- (1) 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.
- (2) The board of management of the FSA may also issue binding guidelines according to § 6 para. 2 on the interpretation of the terms “reasonable”.

### **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 are only permissible, if entry depends on a scientific or expert service of the participating healthcare professionals and the promised prize is appropriately proportionate to the scientific or expert service rendered by the entrants.

### **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.

### **Section 25: Donations and other benefits to institutions**

- (1) Donations (monetary- or donations in kind) as well as other unilateral monetary or benefit in kind to institutions, organisations or associations, whose members are healthcare professionals (e.g. medical-scientific associations) and/or perform medical services or research (e.g. hospitals or university clinics) premise that, besides the compliance with the relevant legal requirements, such benefits:
  1. serve the aims of health care or comparable aims (including e.g. the aims of research, teaching and further training);
  2. are correctly documented, whereby this documentation is to be kept for a minimum period of 5 years after the contractual relationship has ended; and

3. are not misused as an incentive to influence therapy-, prescription or procurement decisions.
- (2) Donations to individual healthcare professionals are not permissible.
- (3) The supporting of healthcare professionals in continued professional development events is the subject matter of § 20.
- (4) The companies must publish the granting of donations or other unilateral monetary or benefits in kind in the meaning of para. 1 with a value of more than € 10,000 per benefit recipient/year. The member companies must give details of donations made from the 1 January 2008 to the 31 December 2008 for the first time by the 31 March 2009. The list is to be up-dated at least once a year (at the latest 31 March for the previous calendar year).

### **Section 26: Mutually relationships with institutions**

Contracts between companies on the one hand and institutions, organisations or associations in the meaning of § 25 para. 1 sentence 1 on the other hand, which foresee the rendering of services to the company are only permissible if such contracts:

1. serve the aims of health care or comparable aims (including e.g. the aims of research, teaching and further training); and
2. are not misused as an incentive to influence therapy-, prescription or procurement decisions.

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

### **Section 27: 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) The persons responsible for the selection of contractual partners in the meaning of § 18 must be suitably qualified to judge that they can actually render the contractual services.
- (5) Each company must establish a scientific service which is in charge of all information about its medicinal products and meets the personal and professional requirements of § 74a (2) of the German Drugs Act (AMG). The companies are free to decide how they best set up and organise the scientific service with the existing resources and organisation structure and to which operational department they issue individually or jointly the following tasks. The scientific service is in particular responsible, that
  1. the medicinal products are not given a misleading designation, information or packaging,
  2. the labelling, package insert, the information sheet for experts and the advertising must comply with the content of the marketing authorisation.
- (6) The head of the medical department shall be responsible for the correctness and supervision of the non-interventional studies carried out in the company (including the companies of medical sales representatives associated with it). Included here is also a regular and appropriate training of the medical sales representatives, other employees and third party contractors on the requirements § 19 para. 2 no. 13 to be complied with. The companies are free in their decision, how they describe the function of the head of the medical department and which further duties are also assigned to him in the individual case. The head of the medical department is, as a general rule, also responsible for the planning and performance of clinical studies. However, he is not allowed to be responsible at the same time for the marketing or distribution department. Instead, a separation from these functions has to be ensured.
- (7) 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.
- (8) 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 28: 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. The association will support the member companies with training and advisory measures in order to increase expert knowledge of the Code, the interpretation of it and to avoid infringements of it.

## **Chapter 6: Effectiveness**

### **Section 29: Effectiveness**

The FSA Code of Conduct Healthcare Professionals in the version passed by the general assembly on 27 November 2009 will become effective on the same day. However, not before 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 has acknowledged the FSA Code of Conduct Healthcare Professionals in the present version as competitive regulations with decision of 23 March 2010, received on 29 March 2010.*