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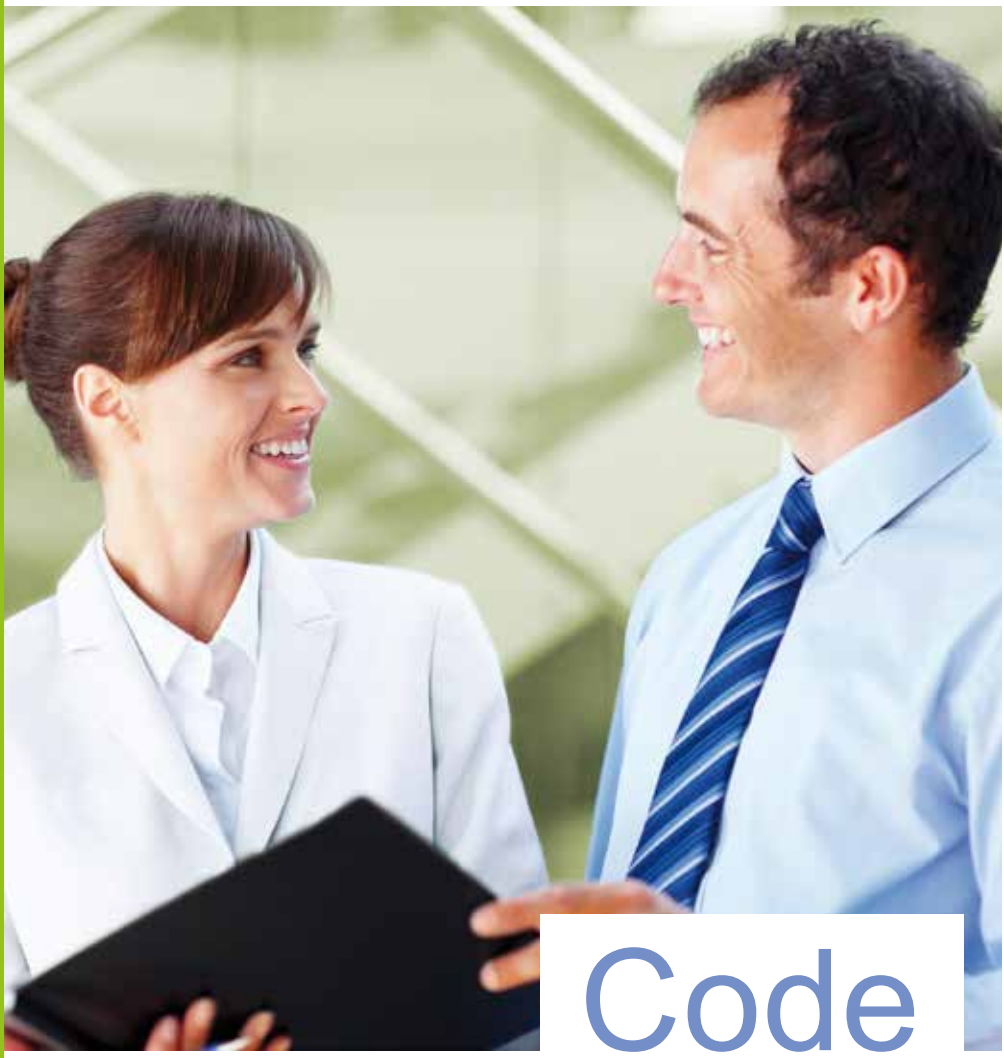
Healthcare Professionals



Code

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

New edition 2018

Report Code of Conduct violations:
www.fsa-pharma.de

Contents

Foreword

The patient always comes first. For the development of effective drugs and best possible patient care, it is essential that the pharmaceutical industry and medical healthcare professionals work together. As witnessed in the past, this cooperation is prone to a certain level of public skepticism and distrust. That is why it is important to organize this collaboration in a logical and transparent way.

This is precisely where the work of the Association of Voluntary Self-Regulation for the Pharmaceutical Industry (Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V. – FSA) comes in: As a self-regulation body, the FSA spells out clear rules of conduct, monitors them consistently and sanctions any violations. With its internal sets of rules, the FSA fulfills all legal requirements and, in going above and beyond them, submits to even stricter regulations.

Since 2004, the “FSA Code of Conduct Healthcare Professionals” has been established as the guideline for collaboration of pharmaceutical companies with members of the healthcare profession. Through its recognition, the member companies pledge in particular to refrain from unethically influencing the procurement, decision-making and therapy freedom of the physician and to uphold compliance and transparency guidelines.

The “FSA Code of Conduct Healthcare Professionals” is continuously revised and expanded. That is why in this 10th and revised edition, the amendment passed by the general assembly in October 2017, is included in Section 20 Subsection 5. With the recognition decision from the Federal Cartel Office on January 31, 2018, the amendment has gone into effect.

Effective immediately, the same rules that apply to internal, in-company further training events of member companies shall also apply to the sponsoring of external events with respect to event venues and hospitality. The FSA thus fulfills public expectations and sets consistent and unified standards. At the same time, the current amendment takes into account the binding rules of Section 10.01 of the EFPIA Code on the Promotion of prescription-only Medicines to, and Interactions with, Healthcare Professionals (“EFPIA Code of Conduct”) passed by the European Federation of Pharmaceutical Industries Associations (“EFPIA”).

It is the FSA's mission to promote ethical conduct between the pharmaceutical industry and members of the healthcare profession, as well as the patient self-help organizations and to safeguard fair competition of the member companies. With this brochure, we are making these rules of the Code of Conduct available to you. You can find additional information on the web-site of the FSA www.fsa-pharma.de.

Berlin, March 2018

Peter Solberg
Chairman of the Management Board
Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V.
[Association of Voluntary Self-Regulation for the Pharmaceutical Industry]

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

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German Federal Gazette AT 23.08.2012 B4),

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German Federal Gazette AT 20.05.2014 B6),

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(announced in the German Federal Gazette on 31 January 2018,
German Federal Gazette AT 31.01.2018 B4)

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 center 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 phy-

sicians and other healthcare professionals, the general assembly of the FSA has passed the following

FSA Code of Conduct
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Chapter 1: Area of Application

Section 1: Area of Application

(1) (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 acknowledwged 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 labeling 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 catalogs 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 programes 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 offense. 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 regard-

ing 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.fsa-pharma.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 labeling 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: Blatant and excessive promotion

(1) Promotion targeting healthcare professionals in a blatant and excessive manner is not permitted. Promotion is deemed blatant and excessive in particular if the promotion is carried out despite its being apparent to the promoter that it is unwanted by the addressee.

(2) The use of faxes, automated calling systems or e-mails for promotion is prohibited except with the prior express consent of the addressee.

When using e-mail, it is not considered blatant and excessive if the company received the e-mail address from the healthcare professional as a customer during the sale of goods or services, the company uses the address for direct marketing of its own similar goods or services, the healthcare professional has not objected to the use and the healthcare professional was instructed clearly and unequivocally at the time the address was obtained and upon each instance of its use that he may object to its use at any time, without any further costs accruing other than the forwarding charges according to the base rate.

(3) Promotion via phone calls is only permitted if there is at least putative consent.

(4) Consent provided by the addressee of the promotion may 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.

(5) It is not permitted to conduct any promotion via a message that disguises or conceals the sender's identity or does not provide a valid address for the sender on whose behalf the message is being sent to which the recipient can direct an order to desist from further such messages, without any further costs accruing other than the forwarding charges according to the base rate.

(6) Mailing lists may be used for promotion purposes only if the data included therein are kept up-to-date and the relevant data protection provisions are observed. Healthcare professionals are to be removed from promotional mailing lists upon request.

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 labeled “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 authorized to prescribe the product, in order to familiarize themselves with the product.

(2) The supplying of samples is limited to a period of two years after the initial request by each healthcare professional. The period specified in Sentence 1 starts over in all instances of a new approval according to § 29 para. 3 AMG, a major change of Type II pursuant to Appendix II No. 2 letter a) or an approval extension pursuant to Appendix I No. 2 of Regulation (EC) No. 1234/2008.

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

(4) For pharmaceuticals that were placed on the market prior to 31 December 2011, the initial sample request by the healthcare professional occurring after 31 December 2011 shall be considered the initial request as defined by para. 2 sentence 1.

Section 15a: Scientific information

(1) In consideration of § 6 para. 1 no. 2 of this Code, and § 7 German Advertising in the Health Care System Act (HWG), Member Companies may only provide healthcare professionals with

1. informational and educational materials. Such materials must be inexpensive, constitute a direct connection with the professional activity of the healthcare professional and be genuinely linked with patients´ care.

2. items of medical utility and samples, aimed directly at the education of healthcare professionals and patient care if they are “inexpensive” and do not offset routine business practices of the recipient. Such items include inexpensive software-applications (in particular “Apps”), which support diagnostic analysis and therapy of patients as long as they are related to products and indications of the member company.

(2) 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.

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 practice 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 for contractual collaboration laid down in nos. 1 and 5 as well as in para. 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. Under these prerequisites, § 24 is not applicable either. 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 traveling and accommodation expenses as well as the prohibition of entertainment and leisure time programes). 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 or any other benefit in kind for their willingness to meet with pharmaceutical consultants or receive information from other members of the pharmaceutical company.

Section 18a Transparency for Clinical Studies

For reasons of transparency concerning the results of clinical studies, the companies must comply with the requirements of § 42b AMG and the “Joint Industry Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases”, along with the “Joint

Position on the Publication of Clinical Trial Results in the Scientific Literature" from IFPMA, EFPIA, JPMA and PhRMA in each current version.

Section 19: Non-interventional studies with authorized 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 authorization (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 physician's medical practice. 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 centers 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. The company must observe its disclosure duties according to § 67 para. 6 AMG and § 63f paras. 1 and 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 center 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 centers 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 authorized 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 finalized (last patient/last visit). The summary of the study results is to be made public at the latest 12 months after finalization (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.

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 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 center 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. theater, 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 center 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 further training events is permissible. Member companies supporting external further training events must request that the financial support be officially disclosed by the organizer when the event is announced and when it takes place. Moreover, when providing financial support to external further training events, for the selection of the conference venue and for hospitality, the provisions concerning internal further training events shall apply mutatis mutandis. The presence of the participants, as well as the agenda of the event is not to be documented.

(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 for achieving the purpose of the event (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 recognized 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 recognized 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 organization, 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 of Conduct 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 of Conduct 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. Deviating from this, hospitality provided to healthcare professionals at international events shall be subject exclusively to the limits of hospitality in the code valid in the particular event location, through which the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals is implemented.

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) It is prohibited to promise, offer or grant gifts to healthcare professionals. This applies irrespective to product-related or non-product-related advertising.

(2) The prohibition of paragraph 1 does not apply if the benefits are allowed under this Code or an exclusion under § 7 para. 1 sent. 1 no. 2 – 5 HWG is applicable.

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 assessment of what is reasonable and socially acceptable when providing hospitality to healthcare professionals shall be subject exclusively to the code valid in the particular event location, through which the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals is implemented.

(3) The board of management of the FSA may also issue binding guidelines according to § 6 para. 2 on the interpretation of the term “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, organizations 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.

Section 26: Mutually relationships with institutions

Contracts between companies on the one hand and institutions, organizations 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 organize the scientific service with the existing resources and organization 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 labeling, package insert, the information sheet for experts and the advertising must comply with the content of the marketing authorization.

(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 this 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: Transitional Regulations and Effectiveness

Section 29: Effectiveness

The FSA Code of Conduct Healthcare Professionals in the version passed by the general assembly on 15 November 2016 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 09 January 2018, received on 12 January 2018.

Guidelines by the FSA Board of Management pursuant to Section 6 Subsection 2 of the FSA Code of Conduct for Interaction with Healthcare Professionals

Effective: 15 February 2018

1. Guideline pursuant to Section 6 Subsection 2 in association with Section 15 for the interpretation of the provision of samples of centrally-approved pharmaceuticals

For a proprietary medicinal product which has been approved by the European Union in a centralized approval procedure according to Regulation (EC) 726/2004, the owner of the permit for distributing the product as the pharmaceutical entrepreneur according to Section 4 Subsection 18 of the German Medicines Act (AMG) can oneself or through a third party (e.g. local representative, distribution entities etc.) provide pharmaceutical samples to doctors under the prerequisites of Section 15 of the Code of Conduct. The distribution through such third parties does not increase the amount under the prerequisites of Section 15 of the Code of Conduct.

2. Guideline pursuant to Section 6 Subsection 2 in association with Section 15 for interpretation of the time limitation for the provision of samples

2.1 From the referral of Section 15 Subsection 1 to Section 47 Subsections 3 and 4 of the German Medicines Act (AMG) it is derived that no more than two sample packs per doctor and calendar year may be provided by a pharmaceutical entrepreneur.

2.2 According to Section 15 Subsection 2 of the Code of Conduct, the provision of samples is furthermore only permitted within a time period of 24 months (“two years”) beginning with the first request by a given healthcare professional.

3. Guidelines by the FSA Board of Management pursuant to Section 6 Subsection 2 in conjunction with Section 15a Subsection 1 No. 1 for interpreting the term “Informational and educational material”

3.1 Subject to fulfillment of the requirements stipulated in Section 15a Subsection 1 No. 1 of the Code, member companies may provide healthcare professionals with informational and educational materials. Special attention must first and foremost be paid to Section 6 Subsection 1 No. 2 of the Code in conjunction with the statutory restrictions, and especially the limits stipulated in section 7 German Advertising in the Health Care System Act (HWG).

3.2 Pursuant to Section 15a Subsection 1 No. 1 of the Code, informational and educational materials may be provided if such materials are inexpensive, have a direct connection

with the professional activity of the healthcare professional and are genuinely linked with patients' care.

3.3 A direct connection with the professional activity of the healthcare professional generally requires that the informational and educational material relate to therapeutic indications of the medicinal products or the market research activities of the company. Such materials are deemed to be genuinely linked with patients' care if the informational and educational materials provided facilitate health professionals gaining a better understanding of the company's products and the related indication and research activities in respect of the treatment of patients. In respect of the requirement that informational and educational materials have a modest or nominal value (i.e. be inexpensive), neither the Code nor these Guidelines explicitly stipulate fixed threshold amounts. Informational and educational materials within the meaning of Section 15a Subsection 1 No. 1 of the Code are always deemed to be inexpensive if the provision of such materials is in accordance with healthcare law provisions (including but not limited to, section 7 HWG), the professional regulations applicable to healthcare professionals, all other applicable statutory provisions, and also any other relevant regulations of the Code. This means that, pursuant to the Code, for example, informational and educational materials are still considered "inexpensive" even where their value exceeds EUR 5.00, unless this is contrary to section 7 HWG (e.g. because they do not pertain to the advertising of medicinal products). Pursuant to Section 15a Subsection 1 No. 1 of the Code, healthcare professionals may, as a rule, therefore only be provided with scientific (informational) brochures, rules for patient treatment (Behandlungsschemata), informational flyers, specialist publications, product monographs and guidelines and recommendations published by medical-scientific associations (provided that such guidelines and recommendations are not scientific publications within the meaning of 3.6) since such materials generally fulfill the aforementioned requirements. This provision typically covers documentation to be used for continuing education courses/events and medical congress reports. Enquiries by physicians do not justify any derogation from the said requirements. This applies to articles of a scientific nature provided free of charge independently of any specific enquiry in relation to the company's products and the related indication (e.g. for the purpose of conducting literature searches). The said requirements prescribed herein must also be complied with if informational and educational materials are provided to physicians in order to answer specific enquiries within the meaning of section 1 Subsection 5 HWG.

3.4 Informational and educational materials do not necessarily need to be provided in paper (hardcopy) form. The information may also be made available by media data carriers (such as USB sticks, CDs, DVDs, Apps), using the company logo if so requested, and/or with the product logo in instances where the information primarily relates to the product

insofar as the media carrier is secondary to the information stored thereon and to the main objective of disseminating information.

3.5 The provision does not preclude the provision of health apps provided that the requirements stipulated in clauses 3.1 to 3.4 are fulfilled.

3.6 Fulfillment of said requirements stipulated in clauses 3.2 and 3.3 needs to be examined on a case-by-case basis. The requirements are generally not fulfilled in the case of general reference books and journal subscriptions. In this respect, it is irrelevant whether reference books, journals or general journal subscriptions are provided in paper (hard-copy) or electronic from.

3.7 Magazines of a promotional nature and customer magazines do not, as a rule, fall within the ambit of this provision insofar as they are covered by Section 1 Subsection 3 No. 5 of the Code and thus do not fall within the scope of application of the Code.

3.8 The provision of factual information to healthcare professionals within the meaning of Section 1 Subsection 3 of the Code neither falls within the ambit of this provision, nor is it covered by the Code, insofar as all requirements stipulated in Section 1 Subsection 3 No. 3 of the Code have been fulfilled.

3.9 Basic writing pads and inexpensive pens may be provided at continuing internal education courses/events, advisory board meetings and similar events to enable participants to take notes. The value of such items may not exceed EUR 5.00 per participant per event. These items may only bear the company's name or its company logo, if at all.

4. Guidelines by the FSA Board of Management pursuant to Section 6 Subsection 2 in conjunction with Section 15a Subsection 1 No. 2 for interpreting the term "medical items of medical utility and samples"

4.1 Pursuant to Section 15a Subsection 1 No. 2 of the Code, items of medical utility and samples may be provided if they have a modest or nominal value and serve the dual purpose of providing a genuine educational function for healthcare professionals and being beneficial to patients and do not offset routine business practices of the recipient.

4.2 Items of medical utility and samples may be provided if they serve a general educational function of facilitating the health professional gain a better understanding of the company's products and how to administer medicinal products sold by the company. Providing such materials is beneficial for patients if they serve the needs of patients undergoing treatment. In respect of the requirement that items of medical utility and samples have a

modest or nominal value (i.e. be inexpensive), neither the Code nor these Guidelines explicitly stipulate fixed threshold amounts. Materials within the meaning of Section 15a Subsection 1 No. 2 of the Code are always deemed to be “inexpensive” if the provision of such materials is in accordance with healthcare law provisions (including but not limited to, Section 7 HWG), the professional regulations applicable to healthcare professionals, all other applicable statutory provisions, and also any other relevant regulations of the Code. This means that such materials are, for example, still considered “inexpensive” even where their value exceeds EUR 5.00, unless contrary to Section 7 HWG (e.g. because they do not pertain to product-related materials).

4.3 Items which are covered by this provision include objects used for demonstration purposes, teaching aids (used, for example, in instructing how medicinal products should be administered) or placebo patches as these items are intended to ensure safety and thus designed to serve the dual purpose of providing a genuine educational function for healthcare professionals and being beneficial to patients.

4.4 The provision prohibits standard medicinal products being made available to physicians free of charge as this does not serve an educational function for the healthcare professional. Sharps disposal containers, bandages, alcohol pads, syringes, hypodermic needles, filter needles, lancets, disinfectant etc. may not, therefore be provided.

4.5 Items of medical utility and samples which are provided to a physician to merely be passed on to patients do not generally fall within the ambit of the provision. General statutory laws (such as Section 7 HWG and Section 128 Social Security Code (Sozialgesetzbuch, SGB V) and the professional regulations applicable to healthcare professionals must, however, be complied with in this respect.

5. Guideline by the FSA Board of Management pursuant to Section 6 Subsection 2 in connection with Section 17 on the compatibility of safe use measures with the prohibition on granting benefits for prescriptions and recommendations

5.1 Programs initiated by pharmaceutical companies to support patients in using medications safely, as intended and as approved, are widely distributed and ubiquitously known in the market. The objective of this guideline is to establish standardized rules for all FSA member companies for the conditions under which these programs are admissible. Disease awareness programs with which companies only provide information on certain illnesses do not fall under this guideline.

5.2 The prerequisite for the admissibility of safe use measures is the existence of an objectively useful reason. The basis for determining whether such an objectively useful reason

exists must involve the medical perspective and take into account the interest that patients have in good-quality and safe healthcare. An objectively justifiable reason exists in therapy situations in which above and beyond medical treatment and awareness guidance provided by the physician, the patient has a need for information and support that cannot be fully satisfied by other means. This is restricted to illnesses in which patients are impaired or unable to consistently and safely follow instructions and explanations provided by the doctor, due to physical impairments or mental limitations. This may also be the case if the use of a drug or a prescribed patient treatment is particularly sophisticated or may cause difficulties in practical use. Also beyond the above-mentioned reasons, safe use measures may be useful in special treatment situations if they promote patient compliance. Also in case of a purportedly simple application schema of a drug – such as oral application for example – there may be special circumstances that make safe use measures necessary and useful in terms of patient safety.

5.3 Accordingly, objectively justifiable reasons for safe use measures may be especially warranted

- in case of physical/mental impairments in patients;
- in case of sophisticated application schema;
- for improvement of therapy compliance among patients and special treatment situations where the promotion of therapy compliance is important for the patient and the prognosis of his treatment, without the patient having to be physically/mentally impaired or the concrete therapy based on especially sophisticated patient treatment.

5.4 The head of the company's medical department must assess and confirm the objective justification and usefulness of the safe use measure. All materials used for the supporting measures must be approved by the medical department. The involvement of employees of other departments in the implementation of safe use measures is permitted within the scope of regulations, whereby it is not mandatory for the operative responsibility for this task to lie in the medical department.

5.5 In relationship to the treating physician, it is important to remember that safe use measures are only allowed to assume a supplementary and/or reinforcing function. Pharmaceutical companies or third parties hired by them are therefore not allowed to partially or completely take over or even supplant the original explanation and instruction concerning approval-compliant therapy that must be provided by the physician. The repetition of instructive remarks by means of information materials and/or practical instruction by pharmaceutical companies or third parties hired by them is admissible under training aspects,

however, if the complete fulfillment of duty by the physician with respect to explanation and instruction of the patient has already occurred and is not being initially assumed by the company.

5.6 Safe use measures on the part of pharmaceutical companies must therefore go beyond the level of service provided by the physician as required by law, by either going into greater detail or reinforcing it. The mandatory services provided by the physician himself are geared towards the concrete therapy situation and the particular needs of the individual patient. The physician is to provide an explanation and instruction that conforms to the particular medical standard and offers the patient adequate care. Additional special services by pharmaceutical companies aimed at reinforcing and/or enhancing therapy compliance are not allowed to supplant these measures but only to supplement and optimize them. They are not permitted if the measure is aimed at relieving the physician of his obligations, especially when providing explanations and instruction to the patient concerning therapy-compliant use.

5.7 It must be ensured that the explanation and instruction of the therapy provided by the physician on the one hand, and safe use measures by pharmaceutical companies on the other hand are clearly separated from one another. As such, safe use measures by pharmaceutical companies must be communicated in a transparent manner and are not allowed to be ascribed to the physician as the physicians own service to the patient. The hiring of physicians and/or their employees by pharmaceutical companies to provide additional safe use measures for their own patients is not permitted. This also is true if the company hires third parties to carry out such programs.

5.8 The physician can provide information and explanations to the patient's concerning the content and form of the safe use measures and utilize factually informative information materials. Providing factual information directed to the patient's concerning the content of the safe use measures by the pharmaceutical companies is also possible within the scope of statutory bounds. This also includes the provision of written materials to patients in response to concrete inquiries, e.g. if they are made available in a physician's practice in the form of factually informative information materials or in digital form via a website.

6. Guideline pursuant to Section 6 Subsection 2 in association with Section 18 Subsection 3 Sentence 2 for interpretation of the term "marginal" (Section 18 Subsection 3 Sentence 1)

6.1 According to Section 18 Subsection 3 Sentence 1 of the Code the requirements spelled out in Section 18 Subsections 1 and 2 for contractual collaboration with healthcare professionals do not apply to the rendering of non-recurring, individual services in connec-

tion with market research activities (e.g. brief telephone interviews), as long as the remuneration provided in this case is “marginal”.

6.2 Remuneration is considered “marginal” as defined in Section 18 Subsection 3 Sentence 1 of the Code, to the extent that it does not exceed the amount of EUR 50.

7. Guideline pursuant to Section 6 Subsection 2 for interpreting the term “not be associated with promotional activities for medicinal products” (Section 19 Subsection 2 No. 12 Sentence 3)

7.1 According to Section 19 Subsection 2 No. 12 Sentence 3 of the Code the activities of medical sales representatives must not be associated with promotional activities for medicinal products.

7.2 When applying Section 19 Subsection 2 No. 12 Sentence 3 of the Code, care should be taken to preserve the main intent of the provision (that study-related activities shall not be associated with or abused for mere advertising purposes), and, in addition, that legitimate promotion of medicinal products by medical sales representatives shall not be called into question.

7.3 A prohibited association is made, for example, if in immediate time proximity or thematic context to study-related activities, promotional materials (such as product brochures of a promotional nature) are distributed for the medicinal product that is the subject of a non-interventional study. On the other hand, study-related activities do not preclude promotional activities for pharmaceutical products (other than those included in the study) by a medical sales representative, even if they occur in immediate time proximity to such study-related activities, as long as both activities are functionally separate from one another. A functional separation in this sense would be if the promotional activity simply took place on the occasion of a study-related activity without a thematic reference being made to that activity.

7.4 The following example is intended to illustrate the above-mentioned principles of interpretation:
The member company conducts an NIS for its medicinal product X. Within the scope of conducting the NIS the company deploys medical sales representative “P”, who visits doctors under supervision of the head of the company’s medical department, in order to explain the NIS, to include doctors in the NIS and to distribute and collect data survey sheets. In addition to medicinal product X, the company also markets medicinal product Y. As medical sales representative, it is P’s job to discuss both X and Y with doctors and providing promotional materials concerning them.

7.4.1 The following case constellations do not violate the provision in Section 19 Subsection 2 Sentence 3 of the Code, for example:

(a) P visits a doctor and only deals with the duties within the scope of the NIS.

(b) P visits a doctor. He seeks to enlist the doctor as a participant in the new NIS (on medicinal product X). He first discusses in detail the surveillance plan of the NIS and also leaves the doctor the SPC on X (which is the subject of the NIS).

(c) P visits a doctor and includes him in the NIS (on medicinal product X). Before or after the discussion of NIS-related aspects, P discusses medicinal product Y (which is not the subject of the NIS) in depth and leaves the doctor two new promotional brochures designated for distribution by the sales representatives.

(d) P visits a doctor on 26 May and exclusively discusses study-related questions with the doctor (concerning medicinal product X, which is the subject of the NIS). On 2 June, P visits the doctor again and discusses medicinal product X (the subject of the NIS) in depth (without mentioning the NIS currently in progress). During this visit, he also leaves two new promotional brochures about X, designated for distribution by the sales representatives.

(e) P visits a doctor on 26 May and exclusively discusses NIS-related questions with the doctor (concerning X, which is the subject of the NIS). On 2 June P visits the doctor again and discusses medicinal product Y (which is not the subject of the NIS) in detail. During his visit, he leaves two new promotional brochures about Y, designated for distribution by sales representatives.

7.4.2 The following case constellations, on the other hand, do violate the provision in Section 19

Subsection 2 Sentence 3, for example:

(a) P visits a doctor and includes him in the NIS (for medicinal product X). Before or after the discussion of NIS-related aspects, P discusses medicinal product X (which is the subject of the NIS) in detail and leaves two new promotional brochures about X, designated for distribution by the sales representatives, along with a plastic pen bearing the brand name X.

(b) P visits a doctor. He seeks to enlist the doctor as a participant in the new NIS (on medicinal product X). He first discusses the observation plan of the NIS. In order

to further convince the doctor of how meaningful it would be for him to participate, P leaves him two new promotional brochures concerning X (which is the subject of the NIS) designated for distribution by the sales representatives.

8. Guideline pursuant to Section 6 Subsection 2 in association with Section 20 Subsection 1 for interpretation of the staging of external training events (Section 20 Subsection 1)

8.1 Pursuant to Section 20 Subsection 1, member companies may invite healthcare professionals to their own industry-related training events specifically related to their fields of research, pharmaceuticals and their therapeutic indications (in-house training events).

8.2 The subject of such training events may partly or exclusively involve providing health policy information related to the company and its products. An example of this is information about the reimbursement status of a drug and the related consequences for the prescribing physicians.

9. Guideline pursuant to Section 6 Subsection 2 in association with Section 20 for the invitation to third-party job-related science-oriented further training events (selection criteria and organization measures)

9.1 Third-party job-related further training events (external further training events, such as conventions and symposiums) generally make a substantial contribution towards promoting scientific advancement, professional exchange of experience, the presentation of evidence-based therapy guidelines and for the development of new therapies and treatment opportunities.

9.2 The support of participation of members of the medical profession in such job-related external further training events is recognized in terms of professional and pharmaceutical marketing law (Section 32 Subsection 2 Model Code of Conduct for Physicians working in Germany (MBO-Ä), Section 7 Subsection 2 HWG). Because the support of participation in further training events by companies represents a unilateral payment to healthcare professionals, a criminal liability may arise for the companies and healthcare professionals involved (Sections 331 et seq., 299, 299 a/b German Criminal Code (StGB)), to the extent that it is abused to influence the therapy, prescription and procurement decisions or such an impression already arises.

9.3 In order for essentially desirable support of further training to be non-objectionable and without any impression of unethical granting of advantages, the Code of Conduct already provides a series of regulations. Accordingly, first of all, the separation principle, along

with definitive regulations concerning professional conduct, pharmaceutical marketing law and criminal law are to be strictly observed (Section 6 Subsections 1 and 2). For further specification of these rules, Section 20 Subsection 4, among others, provides that the scientific character should be the major focus of the events, the events should bear relevance both to the member company's field of activity and to the event participant's field of specialty, and there must be an objective interest of the company in the participation of the relevant healthcare professional.

9.4 The objective of this guideline is to provide FSA member companies criteria under which in an individual case, an objective interest of the company in the participation of healthcare professionals and their support can be affirmed.

9.5 This guideline does not provide information on questions concerning the reasonableness of locations, hospitality, travel and accommodation options.

Type of further training event

9.6 Only external further training events may be considered for support in which the scientific character is clearly the main focus and which have the effect of further developing the medical basis of knowledge, the therapeutic or diagnostic capabilities or research activity for the participant.

Criteria for the selection of a participant

9.7 The participant is required to be active in a field bearing material and substantive relevance to the scientific further training event. This relevance is provided, for example, in case of identical indication.

9.8 The further training event should provide the participant knowledge or ability that he can use in his professional work for impart to other healthcare professionals.

9.9 In addition, the FSA member companies are to ensure the highest possible degree of transparency, as well as documenting the essential criteria for the selection of the participant and the underlying communication.

Special conditions for the support of a participant

9.10 In supporting healthcare professionals, the member companies pledge to encourage healthcare professionals, who through their duties in committees (e.g. in pharmaceutical commissions or the plenum of the Joint Federal Committee (G-BA), can exercise influ-

ence on the sponsoring company's sales of pharmaceuticals, to at least disclose their activities to these bodies as well, in addition to obtaining employer permission in the case of public officials/notifying the employer.

9.11 Support of healthcare professionals is precluded, particularly if

(a) they have been promised by employees in the sales and marketing department of the company that costs would be assumed, without prior involvement in the decision by the medical department of the company or by the company department otherwise responsible (see below clauses 9.13 and 9.14);

(b) in association with cost assumption by the company, they have referred directly or indirectly to their therapy, prescription or sourcing decisions or have promised them as a quid pro quo for these decisions, and/or have not ensured that the selection of the participants is not made based on sales-related parameters (e.g. relationship between volume of prescription/patient numbers);

(c) they have not submitted the required written documents, e.g. employer approval for hospital physicians, a declaration of consent or proof that the administration or employer or fulfilled the conditions of the employer or institutions for acceptance of support prior to the beginning of the further training event as planned.

9.12 Residual risks can be minimized, for example, through

(a) support of further training events limited per healthcare professional for a certain period and to a particular number;

(b) a maximum amount for support of a healthcare professional per year, which, if exceeded, either precludes the support of participation or only allows it under the condition of cost participation of the healthcare professional;

(c) having healthcare professionals participate in overall costs (registration fee, travel, and/or accommodation costs), e.g. (i) by way of a percentage cost participation in overall costs or (ii) through assumption of a specific portion (such as the registration fee and/or travel costs);

(d) an overall budget for support of further training events, from which the support of healthcare professionals is paid countrywide, instead of regional budgets. In doing so, the budget responsibility lies in the medical department and not with sales and marketing;

(e) the companies' entrusting independent bodies with the selection of suitable further training events, as well as possible participants for a particular further training event.

Requirements for the organization of internal company work flow and processes

9.13 In addition to fulfillment of the specified substantive requirements for supporting further training events and observance of criteria for the selection of participants, it is advisable towards further minimizing risks to safeguard compliance with the separation principle through the establishment of a suitable in-company organizational work flow and appropriate processes. Analogous to the regulations for non-interventional studies in Section 19 Subsection 2 Nos. 12 and 13 of the Code of Conduct, it is advisable for pharmaceutical sales representatives not to make the selection decision with respect to suitable participants. Rather, the decision should be made with the involvement of the company's medical department, or in another department capable of making the necessary substantive decisions and not directly integrated into the sales or marketing department. Also analogous to the regulations for non-interventional studies, pharmaceutical sales representatives or other employees in direct sales contact with healthcare professionals may be involved in administrative work flows (a right to make suggestions remains unaffected by this).

9.14 It is furthermore recommended to more clearly specify the principles and the process flows to be hereby observed for the selection, planning and implementation of "Standard Operating Procedures". The same applies both with respect to the further design of substantive requirements for the type of further training event, as well as the selection and exclusion criteria. Finally, it should be ensured in the company that the selection decisions are adequately written down and, in doing so, that there is sufficient documentation of the underlying subject matter and decisive considerations.

10. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 11 for interpretation of the term "reasonable travel costs" (Section 20 Subsection 2 Sentence 1 and Subsection 4 Section 1)

10.1 According to Section 20 Subsection 2 Sentence 1 and Subsection 4 Sentence 1 of the Code only "reasonable travel expenses" along with necessary costs for accommodation may be paid for participants invited to in-house and external training events.

10.2 "Reasonable travel expenses" are defined as train tickets (first class) as well as private vehicle expenses in the amount of the tax-deductible kilometer rate for each kilometer driven for business travel, and the reimbursement for miscellaneous travel costs (public transportation, taxis).

For air travel, the payment of expenses in economy class for inner-European flights, as well as business class for intercontinental flights, is considered reasonable. Reimbursement of first class flights, on the other hand, is considered unreasonable.

11. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 11 for interpretation of the terms "reasonable hospitality arrangements" (Section 20 Subsection 2 Sentence 2) and "reasonable bounds for accommodation and hospitality" (Section 20 Subsection 3 Sentence 1)

11.1 According to Section 20 Subsection 2 Sentence 2 of the Code, a "reasonable hospitality arrangement" may be provided to participants of in-house training events. Moreover, pursuant to Section 20 Subsection 3 Sentence 1, "accommodation and hospitality" may not exceed "reasonable bounds".

11.2 The "hospitality arrangement" is "reasonable" and does not exceed "reasonable bounds" as long as it is socially acceptable. An amount of roughly EUR 60.00 is a benchmark for what is still considered a reasonable hospitality arrangement in Germany, under consideration of price increases and the value-added tax increase since the Code of Conduct took effect in 2004 (effective: July 2008).

11.3 For catering performed by a catering company, the amount specified under clause 11.2 only applies to food and drinks, but not for other miscellaneous costs of catering.

11.4 According to Section 20 Subsection 2 Sentence 2 of the Code a "reasonable hospitality arrangement" may be provided to participants of in-house training events. Within the bounds specified below, this also applies to the hospitality at conference stands of external training events.

11.4.1 As the main purpose of the convention stand is to provide information on the company's products, indications and areas of research, hospitality should clearly play a secondary role and should not constitute an independent incentive to visit the stand.

11.4.2 Appropriate refreshments are typically hot beverages such as various types of coffee, tea, cocoa, as well as non-alcoholic beverages such as soft drinks and water. An additional selection of drinks such as non-alcoholic beer, freshly pressed fruit juices, fruit juice cocktails, etc. exceeds these bounds.

11.4.3 Cookies, sweets, small muffins, mini sheet cakes, pieces of cut fruit, or basic sandwiches or open-faced rolls served with cold cuts are deemed appropriate.

Warm meals such as waffles, tarte flambee, spring rolls, pastry finger foods, popcorn, wieners, small schnitzel or desserts such as ice cream, red fruit pudding, exceed these bounds.

11.4.4 Not appropriate is “extravagant” hospitality that, due to the decoration and set-up, creates the impression that the experience character is intended to take precedence over an opportunity to engage in a professional discussion.

11.4.5 The staffing of a convention stand with a bartender or a chef suggests extravagance.

11.5 For hospitality provided in such countries, in which, contrary to Section 20 Subsection 9 Sentence 5, 22 Subsection 2, there is no hospitality limit in the respective conference venue determined by the Code of Conduct, through which the EFPIA Code on the Promotion of Prescription only Medicines to, and Interactions with, Healthcare Professionals, the reasonable level shall continue to be determined by applicable tax-deductible blanket allowances that prevail for each country, as these reflect any higher price levels that may exist. The reasonable hospitality arrangement in foreign countries can thus be determined by comparing blanket allowances for other countries to the blanket allowances existing for Germany (FS I 2006.8-135). The benchmark mentioned above under clause 11.2 may thus increase by a particular percentage depending upon the price levels that prevail in other countries.

11.6 “Accommodation” does not exceed “reasonable bounds”, to the extent that

- the hotel fulfills the criteria of a business conference hotel with respect to its infrastructure, technical equipment and facilities;
- it does not have any extraordinary wellness areas or features; and
- it is not known as an attraction or a recreational destination.

In weighing the reasonableness of accommodation, it should also be taken into account whether, given due to how the hotel is perceived by the invited healthcare professionals, the mere stay in the hotel in and of itself creates an attraction that would tend to unduly influence these healthcare professionals in their freedom of therapy and prescription.

Hotels that fall within the 5-star category are not immediately eliminated as “unreasonable”, provided that the business character of the establishment is the main focus and the hotel is not especially renowned for its luxury features.

11.7 The reasonableness of the financial support provided to the organizers of external training by way of sponsoring shall also be measured in terms of the promotional presence accorded to the sponsor (marketing and advertising effect) (see also FS I 2005.2-56).

12. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 11 for interpretation of the term "known for their entertainment value" (Section 20 Subsection 3 Sentence 4)

12.1 According to Section 20 Subsection 3 Sentence 4 of the Code, companies should avoid conference hotels that are "known for their entertainment value".

12.2 Conference hotels are "known for their entertainment value" if they are the sites for events such as shows, variety acts, concerts and movies, amusement-park attractions or gambling events. For this reason, conference hotels shall not be considered if, although they have adequate conference facilities, they are located on the grounds of an amusement park, for example, and open up the opportunity to visit it.

13. Section 6 Subsection 2 in connection with Section 20 Subsection 11 for interpreting the term "extravagant" (Section 20 Subsection 3 Sentence 4)

13.1 According to Section 20 Subsection 3 Sentence 4 of the Code, companies shall avoid conference hotels that are known for their entertainment value or are considered "extravagant".

13.2 A conference hotel is considered "extravagant" if it is not primarily known as a typical business or conference hotel but rather prominently features particularly luxurious or unusual decor. Conference venues are considered "extravagant", even if they are adequately equipped for conferences, if at the same time their overall attractiveness on the basis of their decor and featured facilities must create the impression that the conference hotel was chosen not for its conference options but because it is such an attraction. It is also typical of "extravagant" conference hotels that they tend to be in the upper price range.

14. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 11 for interpretation of the term "reasonable scope of financial support of external training events" (Section 20 Subsection 5 Sentence 1)

14.1 According to Section 20 Subsection 5 Sentence 1 of the Code, "financial support for organizers of external training events within a reasonable scope" is permitted.

14.2 In practice, financial support of external training events is generally provided to the organizers via donations or by concluding sponsoring agreements.

14.3 Such financial support is not reasonable if used to finance entertainment programs (Section 20 Subsection 5 Sentence 2 of the Code). The intent of this rule is to try to prevent circumvention of the prohibition of assuming the costs for ancillary and companion programs (e.g. theater, concert, sport events etc.). Therefore, the organizer shall be obliged to declare in the subsequent agreement that the funds made available will not be used for the financing of entertainment programs or the invitation of companions of healthcare professionals, and will be used exclusively for the purpose of supporting the training event (see also FS I 2005.2-56).

15. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 5 Sentence 3 for interpretation of the term "working towards"

15.1 According to Section 20 Subsection 5 Sentence 3 of the Code of Conduct, the member companies financially supporting external training events must work towards the organizer's disclosure of the fact that support is being provided, during both the announcement and staging of the event. This obligation applies also to the support of training events staged by commercial providers.

15.2 Based on Section 18 Subsection 1 Sentence 1 No. 1, it is already evident prior to performance of services, the contractors and the companies must negotiate a written agreement specifying services to be rendered and remuneration to be paid for them. For sponsoring, the naming of the company as a sponsor of the event during the announcement and staging of the event is generally part of the commercial quid pro quo's for which the companies obtain a contractual guarantee. In this case, the due diligence obligation as defined in § 20 Section 5 Sentence 3 is met. Should the sponsoring agreements contain no such provision, the company is required to provide a written instruction to the organizer to name the company as a sponsor during the announcement and staging of the event.

16. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 11 for interpretation of the term "reasonable scope of financial support of external training events" (Section 20 Subsection 5 Sentences 1 and 2)

16.1 According to Section 20 Subsection 5 Sentence 1 of the Code, "financial support for organizers of external training events within a reasonable scope" is permitted. In practice, financial support of external training events is generally provided to the organizers via donations or by concluding sponsoring agreements.

16.2 On the occasion of external further training events, in practice many separate entertainment programs (including hospitality) take place, which are not financed by the member companies but rather through other sources (e.g. through the collection of admission fees by the participating physicians for such entertainment programs). This may involve the festive opening event of a convention with live music or opera visits, museum tours, disco nights, etc. staged by the organizer. Because these entertainment programs are organized, financed and carried out totally independently from the member companies (any financial support of these entertainment programs would also be prohibited), nothing would generally preclude sponsoring of such events by the member companies.

16.3 Such financial support is not reasonable and is thus prohibited, however, if used to finance entertainment programs (Section 20 Subsection 5 Sentence 2 of the Code). The intent of this rule is to try to prevent circumvention of the prohibition of assuming the costs for ancillary and companion programs.

16.4 In order to comply with the rules under clause 16.3, it is therefore required for the organizer to be obliged by a member company in an agreement that the funds made available will not be used for the financing of entertainment programs or the invitation of companions of healthcare professionals, and will be used exclusively for the purpose of supporting the training event (see also FS I 2005.2-56).

17. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 11 for interpretation of the term "reasonable scope of financial support of external training events" (Section 20 Subsection 5 Sentences 1 and 2)

17.1 According to Section 22 Subsection 1 Sentence 1 of the Code of Conduct, payment for hospitality is permissible only within "reasonable" and socially-acceptable bounds.

17.2 A payment for hospitality is "reasonable" and does not exceed "reasonable bounds" if it is socially acceptable. An amount of roughly EUR 60.00 is a benchmark for what is still considered a reasonable hospitality arrangement in Germany, under consideration of price increases and the value-added tax increase since the Code of Conduct took effect in 2004 (effective: July 2008).

17.3 For catering carried out by a catering company, the amount specified under clause 11.3 applies only to food and drinks, but not to other miscellaneous costs of catering.

17.4 According to Section 20 Subsection 2 Sentence 2 of the Code a "reasonable hospitality arrangement" may be provided to participants of in-house training events. Within the

bounds specified below, this also applies to the hospitality at conference stands of external training events.

17.4.1 As the main purpose of the convention stand is to provide information on the company's products, indications and areas of research, hospitality should clearly play a secondary role and should not constitute an independent incentive to visit the stand.

17.4.2 Appropriate refreshments are typically hot beverages such as various types of coffee, tea, cocoa, as well as non-alcoholic beverages such as soft drinks and water. An additional selection of drinks such as non-alcoholic beer, freshly pressed fruit juices, fruit juice cocktails, etc. exceeds these bounds.

17.4.3 Cookies, sweets, small muffins, mini sheet cakes, pieces of cut fruit, or basic sandwiches or open-faced rolls served with cold cuts are deemed appropriate. Warm meals such as waffles, tarte flambee, spring rolls, pastry finger foods, popcorn, wieners, small schnitzel or desserts such as ice cream, red fruit pudding, exceed these bounds.

17.4.4 Not appropriate is "extravagant" hospitality that, due to the decoration and set-up, creates the impression that the experience character is intended to take precedence over an opportunity to engage in a professional discussion.

17.4.5 The staffing of a convention stand with a bartender or a chef suggests extravagance.

17.5 For hospitality in foreign countries, clause 11.5 shall apply mutatis mutandis.

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