FSA Code of Conduct
on the Interaction with Healthcare Professionals
("FSA Code of Conduct Healthcare Professionals")

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Introduction

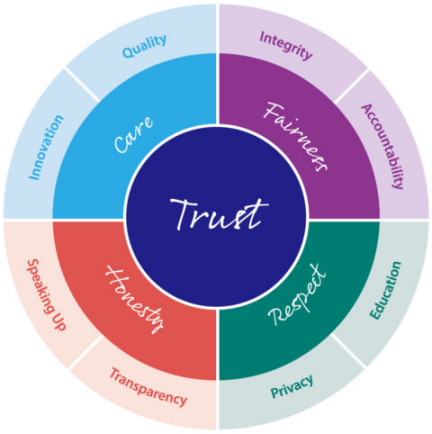
Health is mankind's most precious possession, and medicinal products make a key contribution to every individual's health and well-being. The research, development, production and distribution of medicinal products impose great demands on the companies within the pharmaceutical industry. The patients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

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 medicinal products by disseminating accurate and objective scientific information. Medicinal products are technically sophisticated and complex goods requiring comprehensive explanation. It is, therefore, an indispensable task of any medicinal product 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 medicinal products 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 medicinal products would be virtually impossible without close expert interaction with the medical profession, pharmacists and other healthcare professionals. Healthcare professionals support research and development of new drugs through their independent expertise. In doing so, they make a significant contribution to the pharmaceutical industry's ability to develop innovative medicines and thus improve the health and well-being of patients. At the same time, the trust relationship between physician and patient is the basis of every 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. All interaction by members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-Regulation for the Pharmaceutical Industry") with healthcare professionals are intended to meet the high standards of integrity that patients, government agencies and other interest groups, along with the public at large, are allowed to expect of the pharmaceutical industry.

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 medicinal products are to be adequately advertised, avoiding unfair practices and conflicts with healthcare professionals in relation to professional ethics. All measures in advertising and interacting with physicians and other healthcare professionals must remain within certain appropriate bounds and in accordance with the law (e.g. pharmaceutical and competition law, intellectual and industrial property rights, anti-corruption laws as well as data protection laws, in particular concerning the protection of personal data, including personal health data). 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 Interaction between Industry, Medical Facilities and their Employees in Reference to German Criminal Law) for the clinical sector also outline valuable reference points for the interaction of the pharmaceutical industry with office-based physicians and other healthcare professionals. The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-Regulation for the Pharmaceutical Industry") always strive to uphold the highest ethical standards.

In this, the members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-Regulation for the Pharmaceutical Industry") are guided by the following ethical guidelines:



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 interaction with physicians and other healthcare professionals, the general assembly of the FSA has passed the following

FSA Code of Conduct
on the Interaction with Healthcare Professionals

(FSA Code of Conduct Healthcare Professionals).

Chapter 1: Scope

Section 1: Scope

(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 Code of Conduct in a separate written agreement. The accountability for infringements of affiliated dependent companies, which are neither members of the FSA or have not acknowledged the binding nature of the Code of Conduct, is in accordance with Section 1 para. 3 of the FSA Code of Procedure. The member companies should work towards ensuring that all their affiliates comply with this Code of Conduct when carrying out activities in Germany within the meaning of paragraph 2 or with healthcare professionals working in Germany, even if they have not expressly acknowledged it themselves and they are otherwise not bound to the Code of Conduct.

(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 interaction of the member companies with healthcare professionals (HCPs) in the field of research, development, production and distribution of prescription-only medicines for human use as regulated in Chapter 4 of this Code of Conduct.

(3) The Code of Conduct is not applicable to non-promotional information, including, within the meaning of this Code of Conduct, in particular:

1. the labelling of medicinal products and accompanying package leaflets;

2. correspondence and documents of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

3. factual information such as announcements relating to pack changes, adverse-reaction warnings as well as reference material (e.g. trade catalogues and price lists, provided they include no product claims);

4. factual information relating to diseases or human health;

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

(4) For activities according to paragraph 2 having international relevance, it is necessary to judge on a case-by-base basis which codes to apply (EFPIA Code of Conduct and/or a National Code and/or several National Codes). The following principles apply:

1. The Code of Conduct applies to any activity referred to in paragraph 2 that is carried out, financially supported (sponsoring) or organised by or on behalf of a member company. If the activity takes place outside Germany, the National Code of Conduct of the member association of the country in which the activity takes place shall also apply.

2. In the case of an international further training event at which a member company supports the participation of an HCP as described in Section 20, the rules concerning cost contribution as well as the provisions of the Code of Conduct shall apply, provided that the HCP carries out his primary occupation in Germany. To the extent the HCP practices his profession outside of Germany, the National Code of Conduct of the member association of the country in which the HCP has his primary occupation shall apply.

3. If the provisions of the applicable codes are contradictory, the stricter provisions shall apply. This does not apply to rules where the host country principle applies (hospitality).

Section 2: Definitions

The following definitions are within the context of the Code of Conduct:

1. "Healthcare Professionals" or "HCPs" are European-based and full-time physicians and pharmacists, as well as any member of the medical, dental, pharmaceutical or other nursing professions who in the course of their professional activities are authorised to prescribe, recommend or use or lawfully trade in medicinal products for human use. This also includes employees of public authorities or employees of the funders responsible at that body for prescribing, procuring, supplying, administering or deciding on the reimbursement of medicines, as well as employees of the member companies who, in addition to working for the company, practise full-time as physicians, pharmacists or other HCPs. It excludes, however, all other employees of a member company, wholesaler or other person trading with medicinal products.

2. "Applicable code" means the EFPIA Code and/or the national code or codes applicable under the provisions of this Code of Conduct, in particular Section 1 para. 4.

3. "Medicinal products" are medicinal products within the meaning of Section 2 German Drugs Act (AMG).

4. "Third parties" are natural or legal persons representing member companies or interacting with other third parties on behalf of a member company or in connection with a medicinal product of the member company, e.g. distribution partners,

wholesalers, consultants, contract research institutes, professional convention organisers, medical sales representatives, market research companies, advertising agencies or providers of services in connection with events, public relations or the management of studies.

5. "EFPIA" is the European Federation of Pharmaceutical Industries and Associations.

6. "EFPIA Code" means the EFPIA Code of Practice as amended on 27 June 2019, including the Appendices, which are expressly referred to as binding and form part of the EFPIA Code.

7. "Recipients" are all persons residing in Europe and working full-time as HCPs or HCOs.

8. "Europe" refers to the countries where National Codes of a member association are applicable. At the time this Code of Conduct was last amended, these are the following countries: Belgium, Bosnia and Herzegovina, Bulgaria, Denmark, Germany, Estonia, Finland, France, Greece, Ireland, Iceland, Italy, Croatia, Latvia, Lithuania, Malta, Netherlands, Northern Macedonia, Norway, Austria, Poland, Portugal, Romania, Russia, Sweden, Switzerland, Serbia, Slovakia, Slovenia, Spain, Czech Republic, Turkey, Hungary, Ukraine, United Kingdom, Cyprus.

9. "Financial support" means providing funds or transfers of value to recipients, provided that this also pursues the company's own image advertising or public relations objectives. This includes sponsoring, which also involves the rental of stand space and rooms for external events.

10. "Events" are professional and educational events, as well as congresses, conferences, symposia, and other similar events in the field of pharmaceutical and medical research and development, dedicated to specific clinical illnesses and their therapy, on health policy topics or such events that serve to promote the professional exchange of HCPs.

11. "FSA" is the Association of Voluntary Self-Regulation for the Pharmaceutical Industry ("Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.").

12. "Host country principle" refers to the financial limit for hospitality (meals and drinks) specified in a National Code.

13. "Healthcare Organisation (HCO)" means any medical or scientific institution or association based in Europe, irrespective of its legal entity, comprising healthcare professionals (e.g. medical learned societies) and/or provides or conducts medical services or research through them (e.g. hospitals, university clinics or further training and research institutions). This also includes institutions through which HCPs render their services (such as consulting firms), regardless of the legal position or function the HCPs have in these organisations. Organisations within the meaning of this Code of Conduct do not include "Patient Organisations" within the meaning of Section 2 para. 1 FSA Code of Conduct Patient Organisations.

14. "Information and training materials" refer to inexpensive materials having direct relevance to the professional practice of HCPs and are directly related to patient care.

15. "International events" are events where the company organising, staging or supporting the event or its participants is not based in the country of the conference venue.

16. "Code of Conduct" refers to the FSA Code of Conduct Healthcare Professionals.

17. "Contribution to costs" is support that may encompass the costs of meals, travel, accommodation (including hotel breakfast, if applicable) and/or registration to enable participation of an individual HCP in an event organised by a member company and/or a third party.

18. "Items of medical utility and samples" refer to inexpensive items that are directly related to the further training of HCPs and thus improve the provision of medical services or patient care without replacing normal practice supplies.

19. "Employee of a member company" refers to employees or agents appointed by a member company to deal with any matter covered by this Code of Conduct. This also applies to employees or agents of third parties working on behalf of the company under a contract with third parties.

20. "Member companies" are the member companies as defined by the FSA charter and their domestic subsidiaries and the other affiliated companies (all companies that are part of the same corporate group as the member company) that have acknowledged the binding nature of the Code of Conduct in a separate written agreement.

21. "Member association" means an association which is a member of EFPIA and which represents pharmaceutical companies at the national level.

22. "Samples" are samples referred to in Article 96 of Directive 2001/83/EC.

23. "National Code" means the Code of Conduct of a member association implementing the relevant provisions of the EFPIA Code.

24. "Non-interventional studies" or "non-interventional trials", which also include surveillance studies, are prospective studies during the course of which knowledge is gained from the treatment of patients with medicinal products in accordance with the data specified in their approval for use (e.g. on the safety or efficacy of the medicinal product). The principle of non-intervention applies to all therapeutic and diagnostic measures.

25. "Personal health data" means any information pertaining to the physical or mental health or to the genetic characteristics inherited or acquired, of an identified or identifiable natural person, including the provision of health services, from which information concerning their state of health can be derived[1].

26. "Medical sales representatives" are persons within the meaning of Section 75 para. 1 German Drugs Act (AMG) who are hired by pharmaceutical companies to visit HCPs full-time in order to provide them with professional information on medicinal products and who possess the necessary expertise as defined by Section 75 para. 2 German Drugs Act (AMG).

27. "Donations and other benefits" relate to the provision of transfers of value to HCOs, made available voluntarily for the purposes of supporting healthcare, scientific research or further training, without the recipient's being obliged to provide a quid pro quo.

28. "Events" are all professional, promotional and scientific events, all congresses, conferences, symposia and similar events (including advisory board meetings, visits to research or production facilities, and planning, training or investigator meetings for clinical studies and non-interventional studies) that are organised by a member company or on its behalf or financially supported.

29. "Conference venue" refers to the geographical place where an event takes place (e.g. the city, place).

30. "Conference hotel" means the location where the event takes place (e.g. a hotel or convention centre).

31. "Prescription medicines" are medicines for human use which, according to Section 48 German Drugs Act (AMG), in connection with the ordinance allowing medicinal products to be dispensed to consumers only upon presentation of a medical or dental prescription.

32. "Advertising" includes all measures referred to in Article 86 of Directive 2001/83/EC undertaken by a member company or on its behalf. The measures covered include those using digital communication methods and channels, such as websites and social media.

[1] The definition is based on the definitions of 'personal data', 'genetic data' and 'health data' in Art. 4 para. 1, 13 and 15 of the General Data Protection Regulation.

Section 3: Responsibility for the conduct of third parties

(1) Companies shall comply with the obligations imposed hereunder even when they commission third parties 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 other natural or legal persons, with whom they interact (e.g. joint venture partners, license holders), comply with the minimum standards laid down in the applicable codes.

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 recognised legal principles applicable to HCPs.

(2) The companies must maintain high ethical standards at all times. In particular, their conduct must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry or to cause offence. Additional regard must be paid to the special nature of medicines and the professional standing of the healthcare professionals addressed.

Section 5: Promotion

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

1. Promotion must enable the healthcare professionals addressed to form their own opinion of the therapeutic value of the medicinal product concerned. It must, therefore, be accurate, balanced, fair, objective and sufficiently complete to give a correct overall impression. It must also 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: Interaction

(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 (HCPs) must not be unfairly influenced in their decisions regarding therapy, prescriptions or procurement. Therefore, it is unlawful to offer, promise or grant them or any third party any unfair advantages. Especially the forms of interaction described in Chapter 4 below must not be used in any unfair manner to influence the decision-making freedom of HCPs 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 recognised legal principles applicable to HCPs.

(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 FSA 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 authorisation of the medicinal product do not require further scientific evidence. If so requested by HCPs, 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: Disguised promotion / Requirement of transparency

(1) Promotion must not be disguised. In particular, clinical evaluations, measures of drug surveillance measures and safety studies (including those of a retrospective nature) following the approval of a medicinal product are not allowed to constitute covert advertising.

(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 authorisation

(1) Medicinal products being subject to a marketing authorisation must not be promoted prior to the grant of such marketing authorisation. Any promotion going beyond the indications or medicinal product forms approved in the marketing authorisation is inadmissible.

(2) Unless otherwise specified by national laws or regulations, it is permissible to provide information on exhibition stands at an international training event concerning medicinal products (or their use) that are not approved or are not approved for that use in the country where the training event is being staged, or to provide information materials or otherwise communicate to participants. However, this only applies if each material is accompanied by a declaration indicating the countries in which the medicinal product is approved and also indicating that the medicinal product is not approved nationally or that the indication concerned is not covered. Furthermore, the information materials (indication, dosage form, etc.) must contain explanations demonstrating that the approval conditions vary internationally.

Section 10: Compulsory information

(1) All promotional material relating to medicinal products must include the following information clearly and legibly:

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

(2) For medicinal products that contain only one active ingredient, the information according to subsection (1) no. 2 must be followed by the name of such ingredient, including the indication "Wirkstoff" (active substance); this rule shall not apply if the information according to subsection (1) no. 2 contains the name of the active substance.

(3) The information according to subsections (1) and (2) above must be consistent with the information required by Section 11 of the German Drugs Act (AMG) for the package leaflet.

(4) Subsections 1 and 2 do not apply to reminder advertising. Reminder advertisement exists if the drug is promoted exclusively by the designation of the medicinal product or additionally with the name, the company or the brand of the pharmaceutical company or with the active substance along with the price and quantity information or information as to the package size.

(5) The medical sales representative must, when promoting individual medicinal products vis-à-vis HCPs, 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 HCPs 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 email address from the HCP 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 HCP has not objected to the use and the HCP 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 and e-mail address 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. Upon request by an HCP, the entry in an address list and other directories pertaining to him is to be removed.

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 medicinal product" must be used on both the envelope and the letterhead. In sending a "red hand" letter, it is possible to use all media available in accordance with the requirements of the largest possible degree of coverage in distribution. In particularly urgent cases, it may also be necessary to disseminate these advices orally, by fax or through public notices, e.g. via print media, radio and television.

(2) A "red hand" letter must not, either as a whole or in parts, have the character of promotional matter or contain advertising claims. Other scientific information, advertisements or direct marketing mail must never be sent out with the "red hand" symbol and must not be labelled "Important Information".

Section 15: Samples

(1) Pharmaceutical manufacturers may only supply samples of a medicinal product to healthcare professionals in the framework of Section 47 para. 3 and 4 as well as Section 10 para. 1 No. 11 AMG. The HCPs must be authorised to prescribe the product, in order to familiarise themselves with the product.

(2) The supplying of samples is limited to a period of two years after the initial request by each HCP. The period specified in Sentence 1 starts over in all instances of a new approval according to Section 29 para. 3 AMG, a major change of Type II pursuant to Annex II No. 2 letter a) or an approval extension pursuant to Annex 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 medicinal products that were placed on the market prior to 31 December 2011, the initial sample request by each HCP 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 Section 6 para. 1 no. 2 of this Code, and Section 7 German Advertising in the Health Care System Act (HWG), member companies may only provide HCPs with

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

2. items of medical utility and samples, aimed directly at the education of HCPs 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 Section 6 para. 2 for the interpretation of the term "inexpensive" in the meaning of this clause.

(3) The provision of information and training materials, as well as items of medical utility and samples shall not circumvent the prohibition of gifts pursuant to Section 21 and also shall not constitute an incentive to prescribe, purchase, supply, recommend or administer a particular medicinal product.

(4) The information and training materials, as well as items of medical utility and samples, may be marked with the name of the member company. They are only allowed to refer to the name of the medicinal product if this is indispensable for the proper use of the material or item by the patient.

Section 16: 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: Interaction with HCPs and HCOs

Section 17: Prescriptions and recommendations

It is unlawful to offer, grant or promise HCPs or any third party a fee or other transfer of value for prescribing, applying or recommending a medicinal product to patients.

Section 18: Contractual interaction with HCPs and HCOs

(1) Member companies are only allowed to commission HCPs or HCOs ("Contractual Partners") for paid services (e.g. for lectures, consulting, clinical studies, non-interventional studies, including surveillance studies, e.g. participation in meetings of advisory bodies, the organisation of training events or for participation in market research activities), if the agreed services are provided for the purpose of supporting healthcare, research or further training. The contractual relationship must also meet the following criteria:

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. Prior to concluding of the contract, the member company is required to clearly determine and document a legitimate need for the services to be rendered, as well as for the conclusion of contract. 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. The employee responsible for the selection is required to have the necessary professional competence to make a proper assessment.

4. The number of contractual partners and the scope of the services to be rendered by them are not allowed to exceed the anticipated tasks 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 studies and drug monitoring projects, as well as all other studies or data collection (including retrospective examinations).

(2) The companies must obligate their contractual partners to refer to their services rendered to the company in their publications, lectures and other public statements, if the subject matter of the public statement is at the same time the subject matter of the contractual relationship or any other subject matter affecting the company. This also applies to physicians employed by the company in as far as they continue to practise their profession outside their activities for the company (as private practitioner or clinic physicians).

(3) The requirements for contractual interaction specified in nos. 1 and 5 of para. 1 as well as in para. 2 and the documentation duties specified in no. 2 of para. 1 are not applicable to the rendering of non-recurring, occasional services by HCPs in connection with market research activities (e.g. short telephone interviews) if the payment is inexpensive. Under these prerequisites, Section 24 is not applicable either. The board of management of the association is issuing binding guidelines according to Section 6 para. 2 for the interpretation of the term "inexpensive" in the meaning of this clause.

(4) If a contractual partner participates in an internal or external (training) event within the framework of providing services for the company, rules laid down in Section 20 apply accordingly (e.g. the selection of the conference venue and/or the conference hotel, for payment of the cost contribution as well as the prohibition of entertainment and leisure programmes). The same applies to the participation of contractual partners in events (e.g. at advisory board meetings or participation in investigator meetings for clinical or non-interventional studies).

(5) The contractual partners or third parties must not be granted payment of any fees or any other transfer of value for their willingness to meet with pharmaceutical consultants or receive information from other members of the pharmaceutical company. The contractual parties are not allowed to receive remuneration solely for participating in events as defined by Section 20.

Section 18a: Transparency for clinical studies

For reasons of transparency concerning the results of clinical studies, the companies must comply with the requirements of Section 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

(1) The involvement and treatment, including the inclusion and treatment, including the diagnosis and monitoring, of patients in non-interventional studies, do not follow a pre-defined test plan, but exclusively medical practice. The decision to involve a patient in a non-interventional trial must be clearly separated from the decision to prescribe the medicinal product. The evaluation of the data collected is to be carried out using 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 have a scientific purpose and is not allowed to represent a disguised advertising measure.

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 (Section 27 para. 6). This also includes responsibility for the budget.

3. The implementation (e.g. the selection of study centres and addresses of physicians or other HCPs 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 HCPs 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 is to observe its disclosure and documentation duties according to the German Drugs Act (AMG).

7. The remuneration agreed must be in an appropriate relationship to the services rendered. With regard to the amount remunerated, Section 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 medicinal product in question. The performance of the study is not allowed to be misused to influence therapy-, prescription or procurement decisions.

8. To the extent that the competent ethics committee offers consultation prior to carrying out the study, this must be obtained by scientist head of the study.

9. The participation in a study is conditional on a prior written informed patient consent, if this is necessary for data protection reasons. Moreover, a prior written confirmed information and consent is recommended (on the involvement of the

study centre and the physician or other HCPs, the intended role of the patient and the planned use of the data).

10. Within 21 days of starting to recruit patients information on the planned study must be entered in a publicly accessible register (title of study, aims, name of the study leader, planned number of study centres and the number of cases involved), in accordance with the joint declaration of the IFPMA, EFPIA, JPMA and PhRMA on the registering of clinical studies, comp. Section 18a.

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

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 (Section 27 para. 6). The participation of medical sales representatives in the study is not to be associated with advertising activities for medicinal products.

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 Section 26 are applicable to this study.

Section 20: Invitation to job-related, science-oriented (training) events

(1) The member companies may invite HCPs to their own job-related (training) events who are particularly concerned with said companies' research areas, medicinal products and their therapeutic indications (internal (training) events).

(2) A reasonable cost contribution may be paid to the invitees. In doing so, travel and accommodation costs can only be covered to the extent that the job-related scientific character of the internal (training) event clearly takes centre stage. During such training events, reasonable hospitality arrangements for the participants are also possible. However, the company must neither finance nor organise any entertainment- and leisure

time programs of the participants (e.g. theatre, concert or sports events). The actual participation of the invited persons and the event program must be documented.

(3) The cost contribution is not allowed to exceed a reasonable limit, and must be of secondary importance, particularly with regard to the professional scientific purpose of the internal event. The selection of the conference location and conference venue as well as the invitation of HCPs 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 HCPs to the job-related events of any third party (external (training) events) may only include a reasonable cost contribution; it is prohibited to assume the costs of the hospitality of participants. In addition, the scientific character of the events must clearly take centre stage, and the company is required to have a relevant interest in such a participation. The company may only make a cost contribution 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 HCPs.

(5) Within appropriate limits, financial support for the organisers of external (training) events is permissible. In this, entertainment programs may not be financially supported or otherwise supported (e.g. through donations). Member companies providing financial support for external (training) events must ensure that the support is disclosed by the organiser both when the event is announced and when it is held. Moreover, when providing financial support to external (training) events, for the selection of the conference location and conference venue and for hospitality, the provisions concerning internal events shall apply mutatis mutandis. ["and conference venue" valid from 1 January 2021]

(6) If the organiser is a member of the medical profession, the nature, content and presentation of the training event must be determined solely by said medical organiser.

(7) The invitation, the contribution to costs or financial support are not allowed to include companions for internal and external events unless the HCP in question is absolutely dependent on assistance from accompanying persons due to an illness or disability.

(8) No member company may organise, hold and/or sponsor international events or pay cost contributions for their 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 recognised medical congresses with international lecturers),

and, in view of these factors, it makes greater logistical sense to hold the event in another country. With external international events logistical reasons could speak for an event location abroad, if it concerns an established further training event of a recognised national or international medical scientific association or a consortium of such associations at a suitable location for the holding of such events in the country of the headquarters of one of the associations (e.g. joint traditional events of recognised German speaking association from Germany, Austria or Switzerland in suitable event locations in Austria and Switzerland).

(9) At international events organised, staged or supported by a member company, the company is required, where possible, to provide an affiliate based in the country of the conference venue, prior notification of its activities, or seek appropriate advice for the proper implementation of these activities. If an affiliate pays a cost contribution for the participation of an HCP in an international further training event, it must also give prior notice of the payment of the fee to an affiliated company based in the country where the HCP is professionally active, where available, or obtain appropriate advice for the proper implementation of these activities.

(10) For other events, the aforementioned paragraphs apply accordingly.

(11) If HCPs are commissioned by member companies to hold lectures at internal or external events or provide other services, Section 18 shall apply.

(12) The board of management of the FSA may also issue binding guidelines according to Section 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 HCPs or employees, members, workers or representatives of HCOs. This applies irrespective to product-related or non-product-related advertising.

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

Section 22: Hospitality

(1) Hospitality is only permissible during internal 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 to the extent they are not absolutely necessary for the support of an HCP (comp. Section 20 para. 7).

(2) The assessment of what is reasonable and socially acceptable when providing hospitality in foreign countries shall be subject exclusively to the code valid at the particular conference venue (host country principle).

(3) The board of management of the FSA may also issue binding guidelines according to Section 6 para. 2 on the interpretation of the term "reasonable".

Section 23: Sweepstakes for HCPs

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

(2) Sweepstakes are only permissible, if entry depends on a scientific or expert service of the participating HCPs and the promised prize is appropriately proportionate to the scientific or expert service rendered by the entrants.

Section 24: Interaction with HCPs in their function as civil servants and/or employees of medical institutions

When interacting with HCPs 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 HCOs

(1) In addition to compliance with the relevant legal requirements, donations and grants to HCOs require that such grants

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 and grants to individual HCPs are not permissible.

(3) The supporting of HCPs in continued professional development events is the subject matter of Section 20.

Section 25a:
Use of logos and copyrighted materials

(1) The member companies may use the logo or copyrighted materials of HCOs (e.g. the right to use the logo in publications, product information, on the internet, in advertising or at events) only on the basis of a written agreement with them.

(2) Agreements referred to in paragraph 1 shall clearly state the intended purpose and the manner of use of the logo or copyrighted material.

Section 26:
Promotion of neutrality

The member companies welcome HCO's receiving donations or other grants from various sides. Therefore, member companies are not allowed to demand from HCOs that they grant the respective company exclusivity in terms of support and also do not allow such exclusivity to be granted without being asked. This applies accordingly to financial support.

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 HCPs, hospitals or other HCOs 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) The employees of the member company, in particular medical sales representatives must be familiar with the companies' obligations hereunder and all applicable laws and regulations. Companies are responsible for ensuring that their employees, in particular medical sales representatives, comply with these requirements.

(3) Third parties who support the member companies during activities within the scope of this Code of Conduct must also be familiar with the requirements of the applicable rules and relevant laws and regulations.

(4) The persons responsible for the selection of contractual partners in the meaning of Section 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 Section 75 (2) of the German Drugs Act (AMG). The companies are free to decide how they best set up and organise the scientific service with the existing resources and organisation structure and to which operational department they issue individually or jointly the following tasks. The scientific service is in particular responsible, that

1. the medicinal products are not given a misleading designation, information or packaging, and

2. the labelling, 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 or other employees of the member company and third party contractors on the requirements Section 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 HCPs, 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 bein concerned with in the advertising of medicinal products or interacting with HCPs to adhere to this Code of Conduct and ensure compliance through suitable organisational 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 HCPs. 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 Code of Conduct in the version passed by the general assembly on 14 November 2019 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 new version of Section 20 para. 5 comes into force on 1 January 2021.

The Federal Cartel Office has acknowledged the Code of Conduct in the present version as competitive regulations with decision of 9 March 2020, received on 09.03.2020.