

**Guidelines by the FSA Board of Directors pursuant to Section 6 Subsection 2 of the FSA Code of Conduct for Interaction with Healthcare Professionals<sup>i</sup>**

(as of 12 December 2022)

**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 centralised 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 Directors 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 fulfilment 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 fulfil 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 Fulfilment 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 (hardcopy) or electronic form.
- 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 Directors 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 Directors 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 standardised 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 fulfilment 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 optimise 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 physician's 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 connection 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 internal 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 organisation 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 recognised 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 influence 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 fulfilment 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 organisational 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 kilometre rate for each kilometre 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.

**10a. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 2 Sentence 2 for interpretation of the term "necessary accommodation costs" for internal training events"**

- 10a.1 According to section 20 subsection 2 sentence 2 of the Code, only "necessary accommodation costs" may be covered for HCPs who are invited to internal training events. The following regulations apply to the assumption of accommodation costs for HCPs who participate in the internal training event without having an active role (e.g. speaker).

- 10a.2 In the case of a one-day internal training event, the reimbursement of accommodation costs is normally in line with the Code if

- the scientific programme of the training event complies with the requirements of section 20 sub-section 1 and sub-section 2 sentence 2, second half-sentence, and
- lasts a total of at least 6 hours and
- no more than the cost of one overnight stay by the HCP is covered.

Breaks and hospitality do not count as part of the scientific programme; in addition, the general requirements of the FSA Code must be observed for breaks and hospitality.

- 10a.3 In the case of an internal training event lasting several days, the assumption of accommodation costs is generally in accordance with the Code if

- the scientific programme complies with the requirements of section 20 sub-section 1 and sub-section 2 sentence 2, second half-sentence, and
- lasts at least 6 hours on average on each of the event days and
- no more than the costs for overnight stays of the HCP are covered in accordance with the number of days of the event.

Breaks and hospitality do not count as part of the scientific programme; in all other respects, the general provisions of the FSA Code must be observed for breaks and hospitality.

- 10a.4 In the case of an internal continuing education event which begins in the second half of the day on the first day of the event and continues in the first half of the day on the second day of the event, the assumption of overnight costs is generally in accordance with the Code if

- the scientific programme meets the requirements of section 20 sub-section 1 and sub-section 2 sentence 2, second half-sentence, and
- lasts a total of not less than 7 hours, of which not less than 2 hours may be spent on the first day and not less than 4 hours on the second day, and
- no more than the cost of the HCP's overnight stay between the two days of the event is covered.

Breaks and hospitality do not count as part of the scientific programme; in addition, the general requirements of the FSA Code must be observed for breaks and hospitality.

- 10a.5 In cases that lie outside the safe harbour described in sections 10a.2 to 10a.4, the question of the "necessity" of the assumption of accommodation costs is assessed in relation to the individual participating HCP and requires a critical examination.

Decisive criteria may be

- the time of departure,
- the time of return,
- travel duration and connections.

- 10a.6 The companies must document the existence of the requirements of sections 10a.2 to 10a.5.

**11. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 12 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. In the opinion of the FSA, an amount of up to approximately EUR 75.00 can currently still be considered socially adequate for hospitality in Germany taking into account the price increases that have occurred since the Code came into force in 2004 (as of September 2022).
- 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 location 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 fulfils 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 organisers 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 3 on the selection of the conference venue "solely on the basis of objective criteria"**

- 12.1 Company-organised events and the sponsoring of events, which in light of the conference venue, fulfil the following requirements, are generally regarded as being consistent with the Code of Conduct:
- The choice of conference venue is made solely on the basis of objective criteria.
  - In terms of the conference venue, to the extent that it is a hotel, a 4-star hotel or lower according to DEHOGA or of a comparable national or international standard. In terms of events that take place in foreign countries, hotels of higher categories may also be permissible, especially if this should be necessary due to the local security requirements.
  - The conference venue does not create an incentive effect that decisively influences its character. A decisive influential incentive effect can generally be ruled out if the conference venue
    - (i) is not known as an attraction or a recreational destination,
    - (ii) is not particularly lavish in its decor, and
    - (iii) does not offer any services that go beyond the typical standard of a 4-star business or conference hotel, convention center, etc. (e.g. extravagant wellness spa, golf course etc.).
- 12.2 In evaluating the aforementioned criteria, the viewpoint of third parties (i.e. the general public) is definitive, and not that of the healthcare professionals invited. In this, it makes no difference whether it is a one-day or multi-day event.
- 12a. Guideline pursuant to Section 6 Subsection 2 in association with Section 20 Subsection 3 on the selection of the conference location "solely on the basis of objective criteria"**
- 12a.1 Company-organised events and the sponsoring of events, which in light of the conference location, fulfil the following requirements, are generally regarded as being consistent with the Code of Conduct:
- The choice of conference location is made solely on the basis of objective criteria.

- There is no decisive incentive effect on the character of the conference location.
    - (i) Generally, a decisive incentive effect can be ruled out if the conference location is a place
      - where there are conference venues and accommodation facilities that are typically also used to stage professional scientific events, and
      - whose infrastructure is not primarily tourism-oriented and
      - which has excellent connections to the public transport network.
    - (ii) By contrast, locations may also develop an incentive effect if the event takes place during or in close time proximity to a time frame in which the place has a decisive incentive effect due to special attractions, such as the Oktoberfest in Munich or Carnival in Cologne.
    - (iii) The incentive effect generally does not apply if the target group of participants at the event is drawn from the immediate vicinity of the location. This requirement is normally met if the one-way journey to the location for the participants does not exceed 50 kilometers.
- 12a.2 In evaluating the aforementioned criteria, the viewpoint of third parties (i.e. the general public) is definitive, and not that of the healthcare professionals invited. In this, it makes no difference whether it is a one-day or multi-day event.
- 13. 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)**
- 13.1 According to Section 20 Subsection 3 Sentence 4 of the Code, companies should avoid conference venues that are "known for their entertainment value".
- 13.2 Conference venues 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 venues 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.
- 14. Section 6 Subsection 2 in connection with Section 20 Subsection 11 for interpreting the term "extravagant" (Section 20 Subsection 3 Sentence 4)**
- 14.1 According to Section 20 Subsection 3 Sentence 4 of the Code, companies shall avoid conference venues that are known for their entertainment value or are considered "extravagant".
- 14.2 A conference venue 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 venue was chosen not for its conference options but because it is such an attraction. It is also typical of "extravagant" conference venues that they tend to be in the upper price range.

**15. 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)**

- 15.1 According to Section 20 Subsection 5 Sentence 1 of the Code, "financial support for organisers of external training events within a reasonable scope" is permitted.
- 15.2 In practice, financial support of external training events is generally provided to the organisers via donations or by concluding sponsoring agreements.
- 15.3 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. theatre, concert, and sport events etc.). Therefore, the organiser 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).

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

- 16.1 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 organiser'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.
- 16.2 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 organiser to name the company as a sponsor during the announcement and staging of the event.

**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 20 Subsection 5 Sentence 1 of the Code, "financial support for organisers of external training events within a reasonable scope" is permitted. In practice, financial support of external training events is generally provided to the organisers via donations or by concluding sponsoring agreements.
- 17.2 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 organiser. Because these entertainment programs are organised, 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.

17.3 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.

17.4 In order to comply with the rules under clause 17.3, it is therefore required for the organiser 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).

**18. Guideline pursuant to Section 6 Subsection 2 in connection with Section 20 Subsection 3 for interpretation of the term "reasonable hospitality" (Section 20 Subsection 1 Sentences 1)**

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

18.1.1 The "hospitality" is "appropriate" and does not exceed "reasonable bounds" if it is socially acceptable. The assessment of social adequacy is to be made by the member companies on their own responsibility based on the concrete circumstances of the respective individual case of hospitality. Any existing requirements of the medical institutions employing the recipients of the hospitality, which are known to the companies, must be taken into account.

18.1.2 From the point of view of risk minimisation, it is recommended that the hospitality of public officials be as transparent as possible, i.e. only with the approval of the employer or prior disclosure to the employer.

18.1.3 In the opinion of the FSA, an amount of up to approximately EUR 75.00 can currently still be considered socially adequate for hospitality in Germany taking into account the price increases that have occurred since the Code came into force in 2004 (as of September 2022).

18.2 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.

18.3 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.

- 18.3.1 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.
  - 18.3.2 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.
  - 18.3.3 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.
  - 18.3.4 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.
  - 18.3.5 The staffing of a convention stand with a bartender or a chef suggests extravagance.
- 18.4 For hospitality in foreign countries, clause 11.5 shall apply mutatis mutandis.

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<sup>i</sup> English translation of the „Leitlinien des Vorstands des FSA gemäß § 6 Abs. 2 FSA-Kodex Fachkreise (Stand: 12.12.2022)“.