Effective: 28 September 2015

Guidelines by the FSA Board of Management pursuant to

Section 6 Subsection 2 of the FSA Code of Conduct for Interaction with

Healthcare Professionals

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

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

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

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

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

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

3.1 Subject to 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 from.

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

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

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

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

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

4.2 Items of medical utility and samples may be provided if they serve a general educational function of facilitating the health professional gain a better understanding of the company's products and how to administer medicinal products sold by the company. Providing such materials is beneficial for patients if they serve the needs of patients undergoing treatment. In respect of the requirement that items of medical utility and samples have a modest or nominal value (i.e. be inexpensive), neither the Code nor these Guidelines explicitly stipulate fixed threshold amounts. Materials within the meaning of Section 15a Subsection 1 No. 2 of the Code are always deemed to be "inexpensive" if the provision of such materials is in accordance with healthcare law provisions (including but not limited to, Section 7 HWG), the professional regulations applicable to healthcare professionals, all other applicable statutory provisions, and also any other relevant regulations of the Code. This means that such materials are, for example, still considered "inexpensive" even where their value exceeds EUR 5.00, unless contrary to Section 7 HWG (e.g. because they do not pertain to product-related materials).

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

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

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

5. Guideline 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)

5.1 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".

5.2 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.

6. **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)**

6.1 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.

6.2 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.

6.3 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.

6.4 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.

6.4.1 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.

6.4.2 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.

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

7.1 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).

7.2 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.

8. **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 Sentence 1)**

8.1 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

8.2 "Reasonable travel expenses" are defined as train tickets (1st 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.

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

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9.1 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".

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

9.3 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.

9.3.1 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.

9.3.2 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.

9.3.3 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.

9.3.4 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.

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

9.4 For hospitality provided in such countries, in which, contrary to Section 20 Subsection 9 Sentence 5, 22 Subsection 2, there is no hospitality limit in the respective conference venue determined by the Code of Conduct, through which the EFPIA Code on the Promotion of Prescription only Medicines to, and Interactions with, Healthcare Professionals, the reasonable level shall continue to be determined by applicable tax-deductible blanket allowances that prevail for each country, as these reflect any higher price levels that may exist. The reasonable hospitality arrangement in foreign countries can thus be determined by comparing blanket allowances for other countries to the blanket allowances existing for Germany (FS I 2006.8-135). The benchmark mentioned above under clause 9.2 may thus increase by a particular percentage depending upon the price levels that prevail in other countries.

9.5 "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.

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

10. 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)

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

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

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

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

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

12. **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)**

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

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

12.3 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 organizer shall be obliged to declare in the subsequent agreement that the funds made available will not be used for the financing of entertainment programs or the invitation of companions of healthcare professionals, and will be used exclusively for the purpose of supporting the training event (see also FS I 2005.2-56).

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

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

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

14. **Guideline pursuant to Section 6 Subsection 2 in connection with Section 22 Subsection 2 for interpreting the term "reasonable" (Section 22 Subsection 1 Sentence 1)**

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

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

14.3 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.

14.3.1 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.

14.3.2 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.

14.3.3 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.

14.3.4 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.

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

14.4 For hospitality in foreign countries, clause 9.4 shall apply mutatis mutandis.