

**Guidelines by the FSA Board of Management pursuant to Section 5 of the  
FSA Code of Conduct for Patient Organizations**

**1. Guideline pursuant to § 5 for the interpretation of § 2 Section 4**

- 1.1 The provision in § 2 Section 4 pertains to the definition of "events". "Events" are meetings or conferences involving patient self-help organizations, their members and/or other participants with the aim of disseminating information or exchanging information.
- 1.2 The term "disseminating information" in § 2 Section 4 is to be broadly interpreted. This includes the dissemination of the entire spectrum of knowledge and opinions, from the dissemination of specialized information to expressions of political opinions.

**2. Guideline pursuant to § 5 for the interpretation of § 2 Section 5**

- 2.1 In § 2 Section 5 defines the term "sponsoring". Accordingly, "sponsoring" is the provision of money, non-cash benefits, and donations in kind or significant non-financial benefits by companies for the support or patient self-help organizations, to the extent that the company is pursuing its own objective of image advertising or company public relations.
- 2.2 As opposed to "sponsoring" in which the sponsored party renders an image-enhancing or promotional service in return, the provision of a donation is always without the expectation of a service in return by the donation recipient and out of an altruistic motive. A donation is therefore the unilateral provision of money, non-cash benefits, and donations in kind or significant non-financial benefits by member companies, whereby these contributions do not represent a fee for a particular service. Moreover, donations as a subset of a unilateral contribution can only be made for charitable purposes and only to charitable organizations that are authorized to issue donation receipts as defined by fiscal statutes.
- 2.3 The provision of donations by member companies to patient self-help organizations is permitted under the conditions in No. 2.2 of the Code of Conduct. The fact that the Code of Conduct does not expressly mention "donations" does not mean that the provision of donations is impermissible.

**3. Guideline pursuant to § 5 for the interpretation of the term "high ethical standards"  
(§ 4 Section 2)**

- 3.1 According to § 4 Section 2 Subsection 1 member companies must at all times uphold high ethical standards.
- 3.2 "High ethical standards" as defined in the regulation also mean that member companies are not allowed to bring the image of patient self-help into discredit through their conduct.

**4. Guideline pursuant to § 5 for the interpretation of § 6 Section 2**

- 4.1 According to § 6 Section 2, the collaboration between member companies and patient self-help organizations must comply with and serve the statutory objectives and duties of these organizations.

Effective: 18 July 2012

- 4.2 This also means that the member companies ought to be prepared to take into consideration the special legal as well as fiscal requirements and status of patient self-help organizations in the course of their collaboration.
5. **Guideline pursuant to § 5 for the interpretation of the terms "non-material" and "financial" support (§ 6 Section 3 Subsection 2)**
- 5.1 According to § 6 Section 3 Subsection 1, patient self-help organizations must retain complete control over the content of their work and remain independent. According to § 6 Section 3 Subsection 2, this applies not only to "non-material" but also to "financial" support, along with all other types of collaboration.
- 5.2 "Financial" support as defined in § 6 Section 3 Subsection 2 is to be construed as all monetary and non-cash benefits that are contributed to a patient self-help organization by a member company, whether directly or indirectly via third parties (for instance, the assumption of costs for agencies etc.). "Non-material" support includes cases in which member companies do not provide monetary or non-cash benefits but rather support certain aims or objectives of patient self-help organizations in a "non-material" way (for instance, in that the member company becomes an advocate of the aims and objectives of the patient self-help organization towards political bodies).
6. **Guideline pursuant to § 5 for the interpretation of § 7 Section 3**
- Member companies shall avoid any action in association with the activities of their employees in or for patient self-help organizations that can lead to conflicts of interest between the member companies and the organizations. In particular, member companies are not permitted to issue orders or instructions to their employees that may lead to such conflicts of interest.
7. **Guideline pursuant to Section 5 in connection with Section 11 Subsection 2 for interpreting the term "fundamentals" (Section 11 Subsection 1)**
- 7.1 According to Section 11 Subsection 1 monetary contributions may be made by member companies to patient self-help organizations only based on a written agreement, which describes the fundamentals for collaboration. These fundamentals must stipulate the type and scope of payments or services expected of each partner, along with joint activities. This also applies to only indirect substantial monetary contributions or substantial third-party non-financial contributions.
- 7.2 Contributions to be made by member companies shall be specified and described in the greatest detail possible. The same applies to any services to be provided in return by the patient self-help organizations (such as: financial payments earmarked for particular purposes). Payments and services rendered in return shall thus be described in the most concrete and detailed terms possible, such as
- Type,
  - Subject,
  - Place and
  - Time.

Effective: 18 July 2012

The criteria for fulfilling a payment or service must be specified in writing in the most substantive terms possible. Fulfilment of a service simply based on the best judgment or sole discretion of a contract party or a third party is essentially insufficient. Additional benefits such as reimbursement of travel costs, in particular, are to be clearly spelled out in writing in advance. Additionally, it is to be contractually specified that payments are generally to be made to the previously-named account of the patient self-help organization only after the services have been rendered and an invoice has been submitted.

**8. Guideline pursuant to Section 5 in connection with Section 15 Subsection 2 for interpreting the obligation of transparency concerning benefits and payment of fees**

8.1 According to Section 15 Subsection 2 the member companies are obligated to report on the sum of monetary donations and benefits in kind per calendar year and patient organization is to be reported. In doing so, the subject of the payments or contractual services must be described in sufficient clarity.

8.2 In the communication and description, it is recommended that the benefits and contractual payment of fees be clearly separated (for instance, by using separate categories) from cases in which a company, in the form of an expense allowance (as defined by Section 17 Subsection 3) merely covers the reasonable expenses and accommodation costs of the representative of a patient organization. Examples would include allowing the participation of patient representatives in an discussion event organized by the company on health policy topics or the collaboration of a patient representative free of charge in an advisory body of a company.

**9. Guideline pursuant to Section 5 in connection with Section 15 Subsection 5 for interpreting the term "considerable" (Section 15 Subsection 1)**

9.1 Member companies must make available to the public a list of patient self-help organizations to whom they provide financial support or considerable indirect or non-financial contributions.

9.2 Indirect contributions are characterized by services in kind rendered by third parties (such as contracted agencies) (Example: Support of a patient self-help organization in preparing an event through an agency, whereby the costs of the agency are assumed directly by the company). Non-financial contributions are those by which member companies themselves render services in kind (Example: Support of a patient self-help organization in preparing an event through an (internal) department of the company).

9.3 Financial contributions – regardless of their value – must be included in the list. Financial contributions also include sponsoring memberships of member companies. It is only necessary to list all indirect or non-financial contributions to the extent that these are considered "material".

9.4 The "materiality" principle expresses the fact that it must involve a "payment in kind" exceeding a certain threshold. This includes services which in the course of normal business dealings are only rendered in exchange for a fee and the value of which, when viewed objectively, could influence the behaviour of patient self-help organizations. This is to be differentiated from pure

Effective: 18 July 2012

favours or benefits that may be classified as being of a trivial nature, as is generally customary in normal business dealings and the rendering of which is considered socially adequate, even if there is no financial *quid pro quo*. The value of the materiality threshold is at around EUR 60.00 for an individual service.

10. **Guideline pursuant to Section 5 for interpreting the term "known for their entertainment value" (Section 17 Subsection 1 in connection with Section 17 Subsection 6)**
  - 10.1 According to Section 17 Subsection 1 the choice of a conference venue and conference hotel for events organized or supported by member companies must be made solely according to objective criteria. Conference hotels known for their entertainment value are to be avoided.
  - 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 venues shall not be considered if, although they have adequate conference facilities, they are located on the grounds of an amusement park, for example. To this extent, the interpretation of the term corresponds to the interpretation of the identical term in the FSA Code for Healthcare Professionals (Section 20 Subsection 3 Sentence 4).
11. **Guideline pursuant to Section 5 in connection with Section 17 Subsection 6 for interpreting the term "extravagant" (Section 17 Subsection 1)**
  - 11.1 According to Section 17 Subsection 1 Sentence 1 the choice of a conference venue and hotel must be made solely according to objective criteria. Pursuant to Section 17 Subsection 1 Sentence 2 conference hotels that are considered extravagant are to be avoided.
  - 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 venue was chosen not for its conference options but because of its attractions. It is also typical of "extravagant" conference hotels that they tend to be in the upper price range. To this extent, the interpretation of the term corresponds to the interpretation of the identical term in the FSA Code for Healthcare Professionals (Section 20 Subsection 3 Sentence 4).
12. **Guideline pursuant to Section 5 in connection with Section 17 Subsection 6 for interpreting the term "reasonable entertainment" (Section 17 Subsection 2)**
  - 12.1 Reasonable entertainment of members of patient self-help organizations at events is permissible.
  - 12.2 Entertainment 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 reasonable entertainment costs in Germany (effective: July 2008).
  - 12.3 For entertainment outside Germany, whether entertainment is reasonable shall be determined by the tax-deductible blanket entertainment allowances that prevail in other countries, as these reflect any higher price levels that may exist. The reasonableness of entertainment in foreign

Effective: 18 July 2012

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 No. 12.2 may thus increase by a particular percentage depending upon the price levels that prevail in other countries.

13. **Guideline pursuant to Section 5 in connection with Section 17 Subsection 6 for interpreting the term "reasonable travel costs" (Section 17 Subsection 4)**

13.1 Member companies may reimburse members of patient self-help groups or other participants within the scope of events for "reasonable travel costs".

13.2 "Reasonable travel costs" 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 assumption of costs in the 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.

In determining what is reasonable, guidance may be obtained from the "Guidelines for Self-Help Institutions in Collaborating with Private and Public Entities, Organizations and Companies, especially in the Healthcare Field".

14. **Guideline pursuant to Section 5 in connection with Section 17 Subsection 6 for interpreting the term "reasonable remuneration" (Section 17 Subsection 5)**

14.1 Member companies may assume the cost of additional "reasonable remuneration" of speakers who give lectures at events.

14.2 According to the equivalency principle, services rendered and remuneration received must be in reasonable proportion to one another. The reasonableness is to be judged in terms of whether the remuneration for the speaking engagement can be considered "typical market value". To this extent, there are no other criteria than those for general collaboration with healthcare professionals, so it depends upon each individual case.

Effective: 18 July 2012

Here are some of the major considerations

- Type and scope of the speaking engagement (including the time and effort for preparation, delivery of the presentation, and follow-up activities such as publications, for example, etc.)
- Meaning and complexity of the subject matter to be addressed,
- The professional qualification and reputation of the speaker among his professional peers at large,
- any rights of use provision for the materials and results created.

For calculating the level of remuneration, it cannot make any difference whether the speaker is procuring the company's products or has influence on the procurement of products.

Effective: 18 July 2012

In determining what is reasonable, guidance may be obtained from the "Guidelines for Self-Help Institutions in Collaborating with Private and Public Entities, Organizations and Companies, especially in the Healthcare Field".