

**FSA Code of Conduct  
on the Interaction with  
Patient Organisations**

**("FSA Code of Conduct Patient Organisations")**

Dated 13 June 2008

(announced in the German Federal Gazette of 23 July 2008, BAnz. No. 109, page 2684),

amended on 1 December 2011 (announced in in the German Federal Gazette of  
23 August 2012, BAnz. AT 23.08.2012 B5)

amended on 30 October 2018 (announced in in the German Federal Gazette of  
27 February 2019, BAnz. AT 27.02.2019 B7)

amended on 14 November 2019 (announced in the German Federal Gazette on 30 March  
2020,  
German Federal Gazette AT 30.03.2020)

## **Table of Contents**

### **Introduction**

### **Chapter 1: General Provisions**

- Section 1 Scope
- Section 2 Definitions
- Section 3 Responsibility for the conduct of third parties
- Section 4 General principles of interpretation
- Section 5 Guidelines by the FSA Board of Management

### **Chapter 2: General principles for interaction with patient self-help organisations**

- Section 6 Neutrality and independence
- Section 7 Separation
- Section 8 Transparency
- Section 9 Recommendation and promotion restrictions

### **Chapter 3: Special obligations in collaborating with patient organisations**

- Section 10 Observance of promotional restrictions
- Section 10a Gifts
- Section 11 Written documentation
- Section 12 Mutual business relationships
- Section 13 Use of logos and copyrighted materials
- Section 14 Prohibition of non-objective and editorial influence

Section 15 Informing the public

Section 16 Promotion of neutrality

Section 17 Events

Section 17a Donations to organisations of patient self-help organisations

**Chapter 4: Supervision and training**

Section 18 Supervision

Section 19 Commitment and training of  
employees and third-party contractors

Section 20 Updating the Code of Conduct

**Chapter 5: Effectiveness**

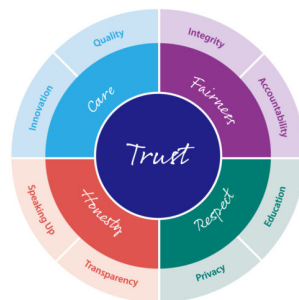
Section 21 Effectiveness

## **Introduction**

The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-Regulation for the Pharmaceutical Industry"), pursue to the objective of safeguarding and promoting health as mankind's most precious possession through research, development, production and distribution of medicinal products. The patients are at the centre of the industry's efforts to prevent, cure or relieve the consequences of diseases through effective medicinal products.

The task of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-Regulation for the Pharmaceutical Industry"), hereby consists of promoting fair competition in healthcare. In order to achieve this goal, in addition to self-evident adherence to existing provisions of the law (such as pharmaceutical and competition law, copyright law and industrial property rights, anti-corruption laws, as well as for the protection of personal health data), above all a dialogue based on respect and trust, as well as transparent cooperation with the patients who are members of patient organisations and their families is indispensable. The members of the association consider such interaction with these organisations to be an integral part of their work, in order to better understand the needs of those affected.

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



With the objective of structuring interaction with patient organisations in such a way that their neutrality and independence can be maintained and thus fair and objective interaction may be ensured in the interest of the patients, the general assembly of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-Regulation for the Pharmaceutical Industry") has passed the following

### **FSA Code of Conduct on the Interaction with Patient Organisations.**

## **Chapter 1: General Provisions**

### **Section 1**

#### **Scope**

- (1) The Code of Conduct is applicable to the member companies and their domestic subsidiaries and other affiliated companies, if these affiliated companies have acknowledged the binding nature of the Code of Conduct in a separate written agreement. The accountability for infringements of affiliated dependent companies, which are neither members of the FSA or have not acknowledged the binding nature of the Code of Conduct, is in accordance with Section 1 para. 3 of the FSA Code of Procedure. The member companies should work towards ensuring that all their affiliates comply with this Code of Conduct when carrying out activities in Germany within the meaning of paragraph 2 or with patient self-help organisations or their members who have their business address or their registered office in Germany, even if they have not expressly acknowledged it themselves and they are otherwise not bound to the Code of Conduct.
- (2) The Code of Conduct is applicable to the interaction of member companies with patient organisations and their members.
- (3) For activities according to paragraph 2 having international relevance, it is necessary to judge on a case-by-base basis which codes to apply (EFPIA Code of Conduct and/or a national code and/or several national codes). The following principles apply:
  1. To the extent that the Code of Conduct applies to any activity referred to in paragraph 2 that is carried out, sponsored or organised by or on behalf of a member company. If the activity takes place outside Germany, but in Europe, the national code of conduct of the member association in which the activity takes place shall also apply.
  2. In the case of an international event at which a member company supports the participation of a self-help organisation as described in Section 17, the Code of Conduct shall apply with respect to the rules concerning cost contribution if the member resides in Germany. To the extent the member of the self-help organisation lives outside of Germany, the national code of conduct of the member association of the country in which the member resides.
  3. If the provisions of the applicable codes are contradictory, the stricter provisions shall apply. This does not apply to the regulations that apply to the costs of hospitality for members of patient self-help organisations at foreign events in accordance with Section 17. For the assessment of the appropriateness and social adequacy of such services, only the code of conduct applicable at the conference venue shall apply (host country principle).

## **Section 2**

### **Definitions**

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

1. "Healthcare Professionals" or "HCPs" are European-based and full-time physicians and pharmacists, as well as any member of the medical, dental, pharmaceutical or other nursing professions who in the course of their professional activities are authorised to prescribe, recommend or use or lawfully trade in medicinal products for human use. This also includes employees of public authorities or employees of the funders responsible at that body for prescribing, procuring, supplying, administering or deciding on the reimbursement of medicines, as well as employees of the member companies who, in addition to working for the company, practise full-time as physicians, pharmacists or other HCPs. It excludes, however, all other employees of a member company, wholesaler or other person trading with medicinal products.
2. "Applicable code" means the EFPIA Code and/or the National Code or codes applicable under the provisions of this Code of Conduct, in particular Section 1 para. 3.
3. "Medicinal products" are medicinal products within the meaning of Section 2 German Drugs Act (AMG).
4. "Reporting period" means the annual disclosure cycle under this Code of Conduct and covers a full calendar year.
5. "Third parties" are natural or legal persons representing member companies or collaborating with other third parties on behalf of a member company or in connection with a pharmaceutical of the member company, e.g. distribution partners, wholesalers, consultants, contract research institutes, professional convention organisers, external field sales representatives, market research companies, advertising, press and event agencies or other providers of services in connection with events, public relations.
6. "EFPIA" is the European Federation of Pharmaceutical Industries and Associations.
7. "EFPIA Code" means the EFPIA Code of Practice as amended on 27 June 2019, including the Appendices, which are expressly referred to as binding and form part of the EFPIA Code.
8. "Recipients" are all organisations of patient self-help organisations and their members residing in Europe.
9. "Europe" refers to the countries where National Codes of a member association are applicable. At the time this Code of Conduct was last amended, these are the following countries: Belgium, Bosnia and Herzegovina, Bulgaria, Denmark, Germany, Estonia, Finland, France, Greece, Ireland, Iceland, Italy, Croatia,

Latvia, Lithuania, Malta, Netherlands, Northern Macedonia, Norway, Austria, Poland, Portugal, Romania, Russia, Switzerland, Serbia, Slovakia, Slovenia, Spain, Czech Republic, Turkey, United Kingdom, Ukraine.

10. "FSA" is the Association of Voluntary Self-Regulation for the Pharmaceutical Industry ("Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.").
11. "Host country principle" refers to the financial limit for hospitality (meals and drinks) specified in a National Code.
12. "Monetary benefits" are payments (e.g. consulting fees) as well as non-monetary benefits (e.g. services of a member company or payments to contracted agencies). Monetary benefits can be rendered directly or indirectly in favour of the recipient. Indirect rendering of monetary benefits is where they are not made by the member company but rather are provided by a third party for a member company in favour of the recipient.
13. "International training events" are training events where the company organising, staging or supporting the event or its participants is not based in the country of the conference venue.
14. "Code of Conduct" refers to the FSA Code of Conduct Patient Organisations.
15. "Contribution of cost" is support that may encompass the costs of hospitality, travel, accommodation (including hotel breakfast, if applicable) and/or registration to enable participation of an individual member of a self-help organisation in an event organised by a member company and/or a third party.
16. "Employee of a member company" refers to employees or agents appointed by a member company to deal with any matter covered by this Code of Conduct. This also applies to employees or agents of third parties working on behalf of the company under a contract with third parties.
17. "Members" of patient organisations include their members, along with persons or institutions that act on their behalf or represent them as agents or representatives.
18. "Member companies" are the member companies as defined by the FSA charter and their domestic subsidiaries and the other affiliated companies that have acknowledged the binding nature of the Code of Conduct in a separate written agreement.
19. "Member association" means an association which is a member of EFPIA and which represents pharmaceutical companies at the national level.
20. "National Code" means the Code of Conduct of a member association implementing the relevant provisions of the EFPIA Code.
21. "Patient organisations" are voluntary, non-profit organisations of patients and/or their families, whose activities involve group support in coping with diseases, disseminating information about diseases and therapy options, lobbying in healthcare and social policy, publishing of media to inform and sup-

port patients and/or providing advisory services.

22. "Personal health data" means any information pertaining to the physical or mental health or to the genetic characteristics inherited or acquired, of an identified or identifiable natural person, including the provision of health services, from which information concerning their state of health can be derived<sup>1</sup>.
23. "Representatives of patient self-help organisations" are persons who, on behalf of a patient organisation, represent it and express their views on a specific therapeutic area or on a specific issue.
24. "Donation" is the one-sided granting of cash, monetary benefits, benefits in kind or substantial non-financial contributions by member companies to patient self-help organisations, whereby these contributions do not constitute remuneration for a specific service. Donations may only be made for charitable or comparable purposes (e.g. health care purposes such as research, teaching, education and training) and may only be made to charitable organisations.
25. "Sponsoring" is the provision of money, non-cash benefits, donations in kind or significant non-financial benefits by companies for the support of patient organisations, to the extent that the company is pursuing its own objectives of image advertising or company public relations.
26. "Events" are meetings or conferences involving patient organisations, their members and/or other invited participants (such as patients and/or their families) with the aim of disseminating information or exchanging information. The topics may range from the diagnosis, therapy and prevention of diseases, right down to healthcare policy or economic issues. Events are organised or staged by the patient organisations themselves and supported by member companies or organised, planned, financed, and/or staged by these member companies themselves or by third-party organisers.
27. "Conference venue" refers to the geographical place where an event takes place (e.g. the city, place).
28. "Conference hotel" means the location where the event takes place (e.g. a hotel or convention centre).
29. "Prescription medicines" are medicines for human use which, according to Section 48 German Drugs Act (AMG), in connection with the ordinance allowing medicinal products to be dispensed to consumers only upon presentation of a medical or dental prescription.
30. "Advertising" includes all measures referred to in Article 86 of Directive 2001/83/EC. The measures covered include those using digital communication methods and channels, such as websites and social media.

---

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



31. "Interaction" is the cooperation between member companies and patient organisations or their support by member companies.

### **Section 3**

#### **Responsibility for the conduct of third parties**

- (1) Companies shall comply with the obligations imposed hereunder even when they commission third parties to plan or implement on their behalf the activities covered by this Code of Conduct.
- (2) Companies must also take reasonable steps to ensure that other natural or legal persons with whom they cooperate (e.g. joint venture partners, licensees) also comply with the minimum standards laid down in the applicable codes.
- (3) If agencies or other contractors contact patient organisations on behalf of companies, their appointment shall be made clear.

### **Section 4**

#### **General principles of interpretation**

- (1) When applying the present Code of Conduct, not only the letter of the individual provisions, but also their spirit and intention as well as all applicable laws are to be observed, especially the rules of the German Advertising in the Health Care System Act outside the realm of healthcare professionals.
- (2) The companies must maintain high ethical standards at all times. In particular, their conduct must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry, patient self-help as whole or individual patient organisations, or to cause offence.

### **Section 5**

#### **Guidelines by the FSA Board of Management**

The FSA can also issue through its board of management binding guidelines for the interpretation of this Code of Conduct, beyond the cases regulated in this Code. The FSA will publish such guidelines on the internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)).

## **Chapter 2: General principles for interaction with patient self-help organisations**

### **Section 6 Neutrality and Independence**

- (1) The FSA and its member companies acknowledge the fact that the professional and political work of patient organisations is guided solely by the needs and interests of persons with disabilities, diseases and in need of care, along with their families, in order to thus promote the self-determination of persons with disabilities, diseases and in need of care.
- (2) The interaction of member companies with patient organisations must be in line with and uphold the respective statutory aims and tasks of these organisations.
- (3) When member companies collaborate with patient organisations, these organisations must retain complete control over the content of their work and remain independent. This applies not only to non-material but also financial support, along with all other types of interaction.
- (4) The member companies must not undertake any measures within the scope of their interaction with patient organisations that would damage the reputation of patient self-help.
- (5) The member companies must respect the neutrality and independence of the patient organisations, in particular with regard to the events organised and staged by the latter. To the extent that member companies are involved in determining planning, this is to be done in a balanced and objective way. When staging events, this for example precludes a one-sided presentation in favour of a company, or particular therapy or a particular product, and it includes a willingness to allow additional presentations on the same topic, in order to guarantee that event participants will receive information that is as comprehensive as possible.
- (6) The member companies are to also respect the neutrality and independence of the patient organisations within the scope of events organised by the companies themselves. Here as well, remarks by the member companies are to be clearly identified as such (for example by simply including the company logo or via an appropriate reference to the author) and the promotion of specific products, product groups or services is to be excluded. The primary purpose of presentations and lectures must be the dissemination of scientific and objective information.

## **Section 7 Separation**

- (1) The member companies may not establish any patient organisations. Representatives or employees of member companies may not act in any capacity for patient organisations (in particular, their executive bodies), unless it involves the scientific advisory boards of these organisations. The membership of member company employees in patient organisations shall remain unaffected by this provision. It is permissible for member companies to be sustaining members of the patient organisations without voting rights at their general assemblies.
- (2) In their interaction with patient organisations, member companies are to adhere to a strict separation between information of a particular organisation on the one hand and information from the company on the other hand.
- (3) To the extent that member company employees should become involved in or advise patient organisations, these employees are to be especially mindful of possible conflicts of interest between the member companies and the organisations and to avoid these.

## **Section 8 Transparency**

- (1) The interaction of member companies and patient organisations as well as their support by member companies are to proceed in a transparent and open manner. The member companies shall reach an agreement with each patient organisation concerning the nature and scope of how the interaction and support is portrayed externally and shall document this in writing.
- (2) The member companies must undertake to ensure that patient organisations make reference to the authorship of member companies, to the extent that these organisations use published material or other presentations from the member companies in their publications. If member companies support patient organisations within the scope of a joint project, this shall be made clear in external communications.

**Section 9**  
**Recommendation and promotion restrictions**

- (1) The interaction of member companies with patient organisations must not involve recommendations for individual prescription-only medicinal products or groups of medicinal products. The appearance of member company representatives at patient organisations must not be aimed at making promotional references to prescription-only medicinal products.
- (2) On the basis of appropriate written agreements with patient organisations, member companies may advertise the fact that they support these organisations with donations, This does not affect the obligation of member companies to agree in writing with patient organisations that the benefits donated by the member companies to the organisation shall be published as a lump sum once each year by the member companies (Section 15 para. 1).
- (3) Member companies may agree with patient organisations that these organisations shall make reference to the support by the member companies in their own promotional materials (including each homepage/website of such organisations). Hereby the scope as well as the manner of each reference shall be documented in a written agreement.
- (4) Publications of patient organisations, which originated from the assistance of a member company, must make a reference to this support. The logo or name of the company may be used.
- (5) On their websites, member companies are allowed to include a link to the given homepage/website of patient organisations only with the permission of that organisation. A link to the download section of this organisation is only permissible based on a written agreement, to the extent that costs are incurred by these organisations. In sponsoring agreements it is impermissible to create active links from web pages of these organisations to the website of member companies. Jointly-operated internet websites are not permissible either.
- (6) The granting of advertising rights within the meaning of para. 2 to 5 by patient organisations may not be used by member companies either directly nor indirectly for the purpose of advertising products or product groups.

### **Chapter 3: Special obligations in collaborating with patient organisations**

#### **Section 10 Observance of promotional restrictions**

Member companies must observe all applicable legal restrictions concerning the promotion of prescription-only medicinal products (in particular Section 10 of the German Advertising in the Health Care System Act (HWG)).

#### **Section 10a Gifts**

- (1) It is prohibited to promise, offer or grant gifts to representatives of patient self-help organisations.
- (2) The prohibition of paragraph 1 does not apply if the benefits are allowed under this Code or an exclusion under Section 7 para. 1 sentence 1 no. 2 – 5 HWG is applicable.

#### **Section 11 Written documentation**

- (1) To the extent that the scope of interaction provides for financial payments by member companies to these organisations, interaction between member companies and patient organisations may only proceed on the basis of a written agreement that spells out the basic elements of the interaction. These basic elements include in particular the type and scope of the respective payments and joint activities. The agreements must also list indirect benefits in kind (such as the member company's providing services free of charge) or any other non-financial benefits in kind (such as training sessions, agency services, the setting up of web sites), to the extent these benefits or support services are significant. The obligation to conclude a written agreement is also in effect if the scope of interaction only involves the provision of significant indirect benefits or other significant non-financial benefits.
- (2) For interpreting the term "basic elements" within the definition of this provision, the management board of the association may issue a binding guideline pursuant to Section 5.

## **Section 12**

### **Mutual Business Relationships**

- (1) Contracts under which patient organisations render services to member companies in exchange for payment are only permissible to the extent that the contracted services are related to healthcare. The contractual relationship is also required to fulfil the following criteria:
  1. The contractual partner and the company must agree on a written contract that meets the requirements of Section 11 before commencing with services.
  2. Prior to concluding an agreement, the member company is required to clearly determine and document a legitimate need for the services to be rendered, as well as for the conclusion of contract.
  3. The selection and the number of contractual partners, and the scope of the services to be rendered by them are not allowed to exceed the anticipated tasks in a reasonable manner.
  4. The company must document the contractual relationship and the services provided. Material documents must be retained for a period of at least 1 year after the contractual relationship has ended. The company must also use the services provided in an appropriate manner.
  5. The remuneration may only consist of money and must be in reasonable proportion to the service rendered.
  6. In addition, the contracting parties may be reimbursed for reasonable expenses and out-of-pocket expenses incurred in the performance of the contractual services they are required to provide in accordance with para. 4.
  7. The conclusion of the contract is not allowed to be associated with any obligation of the contracting parties to recommend certain medicinal products or to promote their sale in any other way. Contracts aimed at unethically influencing the contracting parties are not permissible (prohibition of "sham contracts").
- (2) The companies must oblige their contractual partners to make reference to their activity on behalf of the company when making verbal or written public statements, to the extent the public statement relates to the subject of the contract or to the company in general.
- (3) The requirements for contractual interaction specified in para. 1 sentence 2 and para. 2 are not applicable to the rendering of non-recurring, individual services of patient self-help organisations and members of patient self-help organisations

in connection with market research activities (e.g. brief telephone interviews), to the extent that the remuneration here is minor. For the interpretation of the term "minor" within the meaning of this provision, the Board of Management of the Association issues binding guidelines in accordance with Section 5.

- (4) If a contractual partner participates in events within the framework of providing services for the company, rules laid down in Section 17 apply accordingly (e.g. the selection of the conference venue and/or the conference hotel, for payment of the cost contribution as well as the prohibition of entertainment and leisure programmes).
- (5) If the contracting parties are HCPs, the FSA Code of Conduct Healthcare Professionals shall be observed in addition to this Code of Conduct.
- (6) The contractual parties are not allowed to receive remuneration only for participating in events as defined by Section 17.

### **Section 13**

#### **Use of logos and copyrighted materials**

- (1) Member companies are allowed to use the logo or copyrighted materials from patient organisations (such as the right to use the logo of an organisation in publications, production brochures, on the internet, in advertising or at events) only on the basis of a written agreement with these organisations. The provisions in Section 9 para. 6 and Section 10 are hereby to be observed in particular.
- (2) Agreements according to para. 1 must clearly spell out the intended purpose as well as type of use of the logo or copyrighted material.
- (3) The use of logos or copyrighted materials is not allowed to constitute impermissible advertising in the meaning of this Code of Conduct or applicable laws and regulations.

- (4) Para. 2 and 3 apply accordingly for agreements by which member companies grant patient organisations the right to use the member company's logo in publications, on the internet or at events. Patient organisations may not be contracted to directly or indirectly promote products, product groups or services for diagnostics and therapy of diseases or disabilities.

#### **Section 14**

##### **Prohibition of non-objective and editorial influence**

The member companies may not exercise influence on the editorial work of patient organisation publications supported by them without reasonable justification (e.g. on scientific grounds or in order to correct inaccuracies in content). Mere commercial interests do not constitute reasonable justification within the meaning of sentence 1.

#### **Section 15**

##### **Informing the Public**

- (1) The member companies must make available to the public a list of all patient organisation that they support financially in Germany and throughout Europe or that receive significant indirect or non-financial benefits (such as services in kind by a member company or services rendered by a hired agency etc.). This obligation also applies to contracts according to Section 12 involving the rendering of significant services for fees.
- (2) Member companies oblige to report on the total amount of monetary benefits and donations in kind per calendar year and patient organisation. This also includes the value of non-financial benefits, if a monetary value can be attributed to them. The subject of the grant or contractual benefits should be described clearly enough to enable the average reader to understand the nature of the grants or agreement. It is not necessary for confidential information to be made public, however. The description of significant indirect or non-financial benefits to which a financial value cannot be attributed must show their benefit for the patient self-help organisation.



The report must be submitted at the latest 6 months after the end of the relevant reporting period and must be publicly accessible for a period of at least 3 years after its initial disclosure, unless (i) national rules or regulations require a shorter period or (ii) the relevant legal basis for publication under data protection law (e.g. legitimate interest, legal obligation or consent) is no longer applicable or can no longer justify the storage and/or publication of the data. The report should be published between 20 and 30 June of the following year. If a member company seeks earlier publication, the disclosure obligations under the FSA Transparency Code must be fulfilled at the same time. The disclosure of the information must be made on a publicly accessible website for which the member company is responsible. The information may also be published on a Europe-wide website of affiliated companies, provided that the information for the member company can be accessed separately there. The member company may use the template in Appendix 1 of the Code of Conduct for disclosure.

- (3) Member companies must undertake to ensure that their support of patient organisations is disclosed to the public by these organisations from the beginning.
- (4) The agreements of member companies with patient self-help organisations are to include a provision by which each patient organisation is to grant its permission to the member company to publish the annual cumulative monetary donations or donations in kind or the annual compensation by the member company for services rendered.
- (5) For interpretation of the term "significant" as defined in para. 1 and 2, the management board of the association may issue a binding guideline pursuant to Section 5.
- (6) Member companies shall publish summary information on the methodology they have used in identifying the relevant grants and preparing the report.

### **Section 16** **Promotion of Neutrality**

The member companies welcome patient organisations receiving donations or other benefits from various sources. Therefore, member companies are not allowed to demand of patient self-help organisations that these organisations grant the respective company exclusivity in terms of support of such an organisation or its activities (including its events) and also do not allow such exclusivity to be granted without being asked.

**Section 17**  
**Events**

- (1) Member companies may only organise or support events provided that the choice of conference venue and conference hotel has been made solely according to objective criteria. Conference hotels known for their entertainment value or considered extravagant are to be avoided.
- (2) It is possible within the scope of events for member companies to provide reasonable hospitality for members of patient organisations, independent of whether the event was organised by a patient organisation or by a member company.
- (3) Member companies may only organise or support events to the extent that the selection of the conference venue and conference hotel is made solely according to objective criteria. Entertainment and leisure activities (e.g. theatre, concerts, sport events) of the participants may be neither financed nor organised by companies. In case that the members or other participants referred to in sentence 1 are HCPs, the FSA Code of Conduct Healthcare Professionals is to be adhered to, along with this Code. Invitation or the assumption of costs at events may not extend to companions of members of patient organisations or the other participants, unless the member involved or the other participant is dependent upon the support of accompanying persons due to an illness or a physical disability.
- (4) The organisation, staging and/or support of international events or the payment of cost contributions for their participants are only permissible if
  1. the majority of participants are from a country different from where the member company is domiciled, or
  2. the required resource or expertise is available at that conference venueand in view of these factors, it makes greater logistical sense to hold the event in another country.
- (5) To the extent that speakers give speeches on behalf of member companies, para. 2 and 3 shall apply accordingly, whereby an additional reasonable fee may be paid. No remuneration may be paid to members of patient self-help organisations for mere participation in an event.
- (6) For interpretation of the terms "reasonable", "known for its entertainment value" and "extravagant", the management board of the FSA may issue a binding guideline pursuant to Section 5.

## **Section 17a**

### **Donations to Organisations of Patient Self-Help Organisations**

- (1) In addition to compliance with the relevant legal requirements, donations to patient self-help organisations require, that such donations are properly documented, whereby this documentation is to be retained for a period of at least 5 years after the contractual relationship ends.
- (2) Donations to individual members of patient self-help organisations are not permissible unless they are otherwise permitted under this Code of Conduct or relate to an exception regulated in Section 7 (1) sentence 1 no. 2-5 German Drugs Act (AMG).
- (3) The support of members of patient self-help organisations for participation in events is the subject of Section 17.

## **Chapter 4: Supervision and Training**

### **Section 18 Supervision**

Member companies are to take appropriate organisational precautions to safeguard compliance with this Code of Conduct. This also entails the adoption of an appropriate approval process for the conclusion of agreements with patient organisations.

### **Section 19 Commitment and training of employees and third-party contractors**

- (1) Member companies must commit their employees and third-party contractors being concerned with interaction with patient self-help organisations to adhere to this Code of Conduct. The companies are responsible for ensuring that their employees comply with these requirements.
- (2) Third parties supported by the member companies in case of activities within the scope of this Code of Conduct must be knowledgeable about the requirements of the applicable regulations and relevant laws and rules. The member companies are to oblige their members and contracted third parties active in the area of cooperation with self-help organisations to comply with this Code of Conduct.

- (3) Furthermore, employees must be trained with regard to the content of this Code of Conduct.
- (4) The association will support the member companies with training and advisory measures in order to increase expert knowledge of this Code of Conduct and its interpretation, and to avoid infringements of it.

## **Section 20 Updating the Code of Conduct**

The FSA will confer regularly with the German self-help working group for people with disabilities, chronic diseases and their families (BAG SELBSTHILFE) as the leading umbrella organisation of patient organisations in Germany with the aim of updating this Code of Conduct and its enforcement in the spirit of trust-based cooperation of the member companies with patient organisations.

## **Chapter 5: Effectiveness**

### **Section 21 Effectiveness**

The Code of Conduct in the version passed on 14 November 2019 by the member companies will become effective on the same day, however not before it has been acknowledged as competitive regulations by the Federal Cartel Office pursuant to Section 24 para. 3 of the German Restraints of Competition Act (GWB).

The Federal Cartel Office has acknowledged the Code of Conduct in the present version as competitive regulations with decision of 09 March 2020, received on 09.03.2020.

