

## **FSA Code of Conduct on the Interaction with Patient Organisations ("FSA Code of Conduct Patient Organisations")**

*This is a translation provided by the FSA for service reasons.  
Only the German version of the FSA Code is binding.*

dated 13.06.2008

(published in the German Federal Gazette on 23.07.2008, BAnz. No. 109, p. 2684),

amended on 01.12.2011

(published in the German Federal Gazette on 23.08.2012, BAnz. AT 23.08.2012 B5),

amended on 30.10.2018

(published in the German Federal Gazette on 27.02.2019, BAnz. AT 27.02.2019 B7),

amended on 14.11.2029

(published in the German Federal Gazette on 30.03.2020, BAnz. AT 30.03.2020 B6),

amended on 20.03.2024

(published in the German Federal Gazette on 11.12.2024, BAnz. AT 11.12.2024 B5)

## **Table of contents**

### **Introduction**

#### **Section 1**

##### **General provisions**

- § 1 Scope of application
- § 2 Definitions
- § 3 Responsibility for the conduct of third parties
- § 4 Principles of interpretation
- § 5 Guidelines of the FSA Executive Board

#### **Section 2**

##### **Principles for cooperation with patient self-help organizations**

- § 6 Neutrality and independence
- § 7 Separation
- § 8 Transparency
- § 9 Recommendation and advertising restrictions

#### **Section 3**

##### **Special obligations when cooperating with patient self-help organizations**

- § 10 Observance of advertising restrictions
- § 10a Gifts
- § 11 Written documentation
- § 12 Reciprocal service relationships
- § 13 Use of logos and copyright protected materials
- § 14 Prohibition of unobjective and editorial influencing measures
- § 15 Information of the public
- § 16 Promotion of neutrality
- § 17 Events
- § 17a Donations to organisations of the patient self-help

#### **Section 4**

##### **Monitoring and training**

- § 18 Supervision
- § 19 Obligation and training of employees and commissioned third parties
- § 20 Updating the Code

#### **Section 5**

##### **Entry into force**

- § 21 Entry into force

## **Introduction**

The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." pursue the goal of preserving and promoting health as the highest good of mankind through the research, development, manufacture and distribution of medicinal products. The patient is at the center of the efforts to prevent, cure or alleviate the consequences of diseases through effective pharmaceuticals.

The task of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." is to promote fair conduct in the healthcare sector. In order to achieve this goal, in addition to the self-evident consideration of existing legal regulations (such as pharmaceutical and competition law, copyright and industrial property rights, anti-corruption laws and data protection laws, in particular for the protection of personal health data), a respectful dialogue characterized by trust and transparent cooperation with the patients and their relatives who are members of patient self-help organizations are indispensable. The members of the association regard such cooperation with these organizations as an important part of their work in order to better understand the needs of those affected. Any cooperation of the members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." with patient self-help organizations or their members should meet the high standards of integrity that patients, government agencies and other interest groups as well as the public can expect from the pharmaceutical industry.

The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." are guided by the following ethical guidelines:

With the aim of shaping cooperation with patient self-help organizations in such a way that their neutrality and independence are safeguarded and in this way to ensure fair and objective cooperation in the interests of patients, the general meeting of the association, "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.", has adopted the following

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

decided.

In order to take account of the increasing importance of digital health applications (DiGA) in the healthcare of patients, the members of the association have extended the scope of the Code beyond medicinal products to include DiGA.

## **Section 1: General provisions**

### **§ 1 Area of application**

- (1) The Code applies to member companies as well as their domestic subsidiaries and other affiliated companies, provided that the affiliated companies have recognized the binding nature of the Code in a separate written agreement. The attribution of violations by affiliated dependent companies that are neither members of the FSA nor have recognized the binding nature of the Code is governed by § 1 (3) of the FSA's Rules of Procedure. The member companies should work towards ensuring that all companies affiliated with them adhere to this Code when carrying out activities within the meaning of paragraph 2 in Germany or with patient self-help organizations or their members that have their business address or registered office in Germany, even if they have not expressly recognized it themselves and the Code is not otherwise binding on them.
- (2) The Code applies to the cooperation of member companies with patient self-help organizations or their members.
- (3) For activities pursuant to paragraph 2 with a cross-border dimension, the codes to be applied (EFPIA Code and/or a National Code and/or several National Codes) must be assessed on a case-by-case basis. The following principles shall apply:
  1. if an activity in accordance with paragraph 2 is carried out, sponsored or organized by a member company based in Germany or on its behalf, the Code shall apply. If the activity takes place outside Germany but in Europe, the National Code 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 members of a patient self-help organization as described in § 17, the rules of the Code shall apply with regard to the cost contribution if the member is resident in Germany. If the member of a patient self-help organization lives outside of Germany, the national code of the country in which the member resides shall apply.
  3. If the provisions of the Applicable Codes contradict each other, the more restrictive provisions shall apply. This does not apply to the regulations that apply to the costs of hospitality for members of patient self-help organizations at foreign events in accordance with § 17. For the assessment of the appropriateness and social adequacy of such benefits, only the code applicable at the respective event location shall apply (host country principle).

### **§ 2 Definitions**

For the purposes of this Code:

1. "Healthcare professionals" or "HCPs" are doctors and pharmacists working full-time in Europe as well as all members of the medical, dental, pharmaceutical or other healthcare professions and all other persons who are authorized to prescribe, recommend or administer medicinal products for human use or DiGAs or to trade in them in a permitted manner within the scope of their professional activity. This also includes employees of public bodies or employees of payers who are responsible at this body for prescribing, procuring, supplying, administering or deciding on the reimbursability of medicinal products or DiGA, as well as employees of member companies who, in addition to their work for the company, work full-time as practicing doctors, pharmacists or other HCPs. However, all other employees of a member

company, wholesaler or other person dealing in medicinal products or DiGA are excluded.

2. "Applicable Code" means the EFPIA Code and/or the National Code or National Codes applicable under the provisions of this Code, in particular § 1 para. 3.
3. "Medicinal products" are medicinal products within the meaning of § 2 AMG.
4. "Reporting period" means the annual disclosure cycle under this Code and comprises a full calendar year.
- 4a. "Digital health applications" or "DiGA" are digital technologies that fall under the term "digital health applications" as defined in § 33a SGB V.
5. "Third parties" are natural or legal persons who represent member companies or who cooperate with other third parties on behalf of a member company or in connection with a medicinal product or a DiGA of the member company, such as sales partners, wholesalers, consultants, contract research institutes, professional congress organizers, external sales representatives, market research companies, advertising, press and event agencies or other providers of services in connection with events and 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 June 27, 2019, including the Annexes, which are expressly designated as binding and form part of this Code.
8. "Recipients" are all patient self-help organizations based in Europe and their members.
9. "Europe" refers to the countries in which National Codes of a Member Association are applicable. At the time of the last amendment of this Code, these are the following countries: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom.
10. "FSA" is the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.".
11. "Host country principle" refers to the maximum financial limit for hospitality (meal and drinks) set out in a National Code.
12. "Monetary benefits" are payments (such as consultancy fees) and non-cash benefits (such as services provided by the member company or services provided by commissioned agencies). Monetary benefits can be provided directly or indirectly in favor of the recipient. Indirect provision of non-cash benefits exists if these are not provided directly by the member company but via a third party for a member company for the benefit of the recipient.
13. "International events" are events for which the company organizing, conducting or supporting the event or its participants is not based in the country of the event venue.

14. "Code" means the FSA Code of Conduct for Patient Organizations.
15. "Cost contribution" means support that may cover the costs of hospitality, travel, accommodation (including hotel breakfast, if applicable) and/or registration to enable an individual member of a patient self-help organization to participate in an event organized or created by a member company and/or a third party.
16. "Members" of patient self-help organizations are, in addition to their members, also persons or institutions that act or appear as their representatives or agents.
17. "Member association" means an association which is a member of EFPIA and which represents pharmaceutical manufacturers at national level.
18. "Member companies" are the member companies as defined in the FSA Articles of Association as well as their domestic subsidiaries and other affiliated companies that have recognized the binding nature of the Code by means of a separate written agreement.
19. "Employees of the member company" are employees or agents who are employed by a member company and who deal with all matters covered by this Code. Employees or agents of third parties who work for the company under a contract with a third party are treated in the same way.
20. "National Code" means the code of a member association that implements the relevant provisions of the EFPIA Code.
21. "Patient self-help organizations" or "patient organizations" are voluntary, non-profit associations of patients and/or their relatives whose activities include the joint management of diseases, the provision of information about diseases and their treatment options, the representation of interests in the health and socio-political field, the publication of media for the information and support of patients and/or the provision of advisory services.
- (22) 'personal health data' means any information relating to the physical or mental health or genetic characteristics, inherited or acquired, of an identified or identifiable natural person, including the provision of health care services, revealing information about his or her health status.
23. "Representatives of patient self-help organizations" are persons who represent a patient organization on its behalf and express its views on a specific therapeutic area or on a specific issue .
24. "Donation" is a unilateral granting of money, monetary benefits, benefits in kind or substantial non-financial benefits by member companies to patient self-help organizations, whereby these benefits do not constitute payment for a specific service. Donations can only be made for charitable or comparable purposes (such as for healthcare purposes such as research, teaching, training and further education) and only to charitable organizations.
25. "Sponsoring" is the granting of money, non-cash benefits, benefits in kind or substantial non-financial benefits by companies to promote patient self-help organizations, provided that the company's own company-related image advertising or public relations objectives are also pursued.
26. "Events" are meetings or encounters between patient self-help organizations, their members and/or other invited participants (such as patients and/or their

relatives) with the aim of providing or exchanging information. The topics can range from the diagnosis, treatment and prevention of illnesses to care-related, health policy or economic issues. Events are either organized or carried out by the patient self-help organizations themselves and supported by member companies or organized, hosted, financed and/or carried out by these member companies or third-party organizers.

27. "Venue" refers to the geographical place where an event takes place (e.g. the city, the town).
28. "Venue" means the place where the event is to take place (e.g. a hotel or convention center).
29. "Prescription-only medicinal products" are medicinal products for human use which, in accordance with § 48 of the German Medicinal Products Act (AMG) in conjunction with the Ordinance on the Prescription-only Supply of Medicinal Products, may only be supplied to consumers with a medical or dental prescription.
30. "Advertising" means all measures within the meaning of Art. 86 of Directive 2001/83/EC. This also applies accordingly to measures relating to DiGA. The measures covered also include those that use digital communication methods and channels, such as websites and social media.
31. "Cooperation" is the cooperation between member companies and patient self-help organizations or their promotion by member companies.

### **§ 3**

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

- (1) The obligations under this Code also apply to companies if they commission third parties to design and carry out the activities covered by this Code on their behalf.
- (2) Companies shall 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 set out in the Applicable Codes.
- (3) If agencies or other contractors come into contact with patient self-help organizations on behalf of companies, their commissioning must be made clear.

### **§ 4**

#### **Principles of interpretation**

- (1) When applying this Code, not only the wording of the individual provisions, but also their meaning and purpose as well as the applicable laws, in particular the provisions of the Therapeutic Products Advertising Act on the advertising of prescription-only medicinal products outside specialist circles, must be observed.
- (2) The companies must be measured against high ethical standards at all times. In particular, their conduct must not bring the pharmaceutical industry, patient self-help as such or individual patient self-help organizations into disrepute, reduce trust in them or be offensive.

**§ 5**  
**Guidelines of the FSA Executive Board**

In addition to the individual cases prescribed in this Code, the FSA may issue binding guidelines on the interpretation of this Code by the Executive Board. The FSA publishes these guidelines on the Internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)).

**Section 2: Principles for cooperation with patient self-help organizations**

**§ 6**  
**Neutrality and independence**

- (1) The FSA and its member companies recognize that patient self-help organizations focus their professional and political work exclusively on the needs and interests of people with disabilities, illnesses and those in need of care, as well as their relatives, in order to promote the self-determination of people with disabilities, illnesses and those in need of care.
- (2) The cooperation of member companies with patient self-help organizations must be consistent with and serve the respective statutory objectives and tasks of these organizations.
- (3) When member companies cooperate with patient self-help organizations, these organizations must retain full control over the content of their work and remain independent. This applies to both non-material and financial support as well as all other types of cooperation.
- (4) In the context of their cooperation with patient self-help organizations, member companies may not take any measures that damage the reputation of patient self-help.
- (5) The member companies must respect the neutrality and independence of the patient self-help organizations, particularly with regard to the events organized and carried out by them. If the member companies participate in the planning, this must be done in a balanced and objective manner. This excludes, for example, a one-sided presentation in favor of a company, a certain therapy or a certain product when organizing events and also includes a willingness to allow further presentations on the same topic in order to ensure that the event participants are informed as comprehensively as possible.
- (6) The member companies must also observe the neutrality and independence of the patient self-help organizations in the context of events they organize themselves. Here too, statements by member companies must be identified as such (e.g. by simply reproducing the company logo or by stating the author) and advertising for specific products, product groups or services must be excluded. In the case of presentations and lectures, the focus must be on the scientific and factually informative character.

**§ 7**  
**Separation**

- (1) Member companies may not establish patient self-help organizations. Representatives or employees of member companies may not exercise any functions in patient self-help organizations (in particular their bodies), unless they are scientific advisory boards of these organizations. The membership of employees of member companies in patient self-help organizations remains unaffected by this.



Sponsoring memberships of member companies in patient self-help organizations without voting rights in their membership meetings are permitted.

- (2) When cooperating with patient self-help organizations, member companies must ensure a clear separation between information or recommendations from this organization on the one hand and information from the company on the other.
- (3) If employees of member companies work in or advise patient self-help organizations, these employees must pay particular attention to possible conflicts of interest between the member companies and the organizations and avoid them.

## **§ 8 Transparency**

- (1) The cooperation of the member companies with patient self-help organizations and their promotion by the member companies must be transparent and open. The member companies shall reach agreement with the patient self-help organizations on the type and scope of the external presentation of the cooperation and promotion and record this in writing.
- (2) Member companies must ensure that patient self-help organizations indicate the authorship of the member companies if these organizations use publications or other representations of the member companies in their publications. If member companies support patient self-help organizations as part of a joint project, this must also be made clear to the outside world.

## **§ 9 Recommendation and advertising restrictions**

- (1) The cooperation of member companies with patient self-help organizations may not involve recommendations for individual prescription-only medicinal products or groups of medicinal products or DiGA. The appearance of representatives of the member companies at patient self-help organizations must not be aimed at establishing a promotional reference to prescription-only medicinal products or DiGA.
- (2) Member companies may only advertise that they support patient self-help organizations through donations on the basis of corresponding written agreements with these organizations. This does not affect the obligation of the member companies to agree in writing with patient self-help organizations that the total amount of donations made by the member companies to the respective patient self-help organization will be disclosed by the member companies once a year (§ 15 para. 1).
- (3) Member companies may agree with patient self-help organizations that these organizations refer to the support of the member company in their own advertising (including the respective homepage/website of such organizations). The scope and manner of such references must be set out in a written agreement.
- (4) In publications of patient self-help organizations that have been created with the support of a member company, reference must be made to this support. The logo or lettering of the company may also be used.
- (5) Member companies may only link to the respective homepage/website of patient self-help organizations on their websites with the consent of these organizations. A link to the download area of these organizations is only permitted on the basis of a written agreement, provided that this results in costs for these organizations. In the case of sponsoring agreements, the placement of active links from the websites of

these organizations to the websites of member companies is not permitted. Jointly operated websites are also not permitted.

- (6) The granting of advertising rights within the meaning of paragraphs 2 to 5 by patient self-help organizations may not be used by the member companies either directly or indirectly to advertise products or product groups.

### **Section 3: Special obligations in cooperation with patient self-help organizations**

#### **§ 10**

#### **Observance of advertising restrictions**

The member companies must observe the applicable general restrictions under competition law and drug advertising law for the advertising of prescription drugs (in particular § 10 HWG) and for the advertising of DiGA.

#### **§ 10a**

#### **Gifts**

- (1) It is generally not permitted to promise, offer or grant gifts to representatives of patient self-help organizations.
- (2) The prohibition described in paragraph 1 shall not apply if the corresponding benefits are otherwise permissible under this Code or if an exception regulated in § 7 (1) sentence 1 Nos. 2 to 5 HWG applies.

#### **§ 11**

#### **Written documentation**

- (1) Cooperation between a member company and patient self-help organizations or members of patient self-help organizations, insofar as financial benefits are granted by member companies to these organizations or their members as part of this cooperation, may only take place on the basis of a written contract that describes the key points of the cooperation. These key points include, in particular, the type and scope of the respective services and joint activities. The contracts must also list the indirect benefits to be granted (such as the provision of services free of charge by the member company) or other non-financial benefits (such as training, agency services, setting up websites) if these benefits or support services are significant. The obligation to conclude a written contract also exists if only significant indirect benefits or other significant non-financial benefits are granted as part of the cooperation.
- (2) For the interpretation of the term "key points" within the meaning of this provision, the Executive Board of the Association shall issue a binding guideline in accordance with § 5.

#### **§ 12**

#### **Mutual service relationships**

- (1) Contracts under which patient self-help organizations and members of patient self-help organizations ("contractual partners") provide paid services to member companies are only permissible if the contractual services serve healthcare purposes. The contractual relationship must also meet the following criteria:

1. the contractual partner and the company must agree on a written contract that meets the requirements of § 11 before commencing the services.
  2. Prior to the conclusion of the contract, the member company must have clearly established and documented a justified need for the services to be provided and for the conclusion of the contract with the contractual partner.
  3. the selection and number of commissioned contractors and the scope of the services to be provided by them must not exceed what is reasonably necessary to fulfill the intended tasks.
  4. The company must document the contractual relationship and the services provided. The essential documents must be kept for a period of at least 1 year after termination of the contractual relationship. The company must also use the services provided in an appropriate manner.
  5. The remuneration may only be in cash and must be in reasonable proportion to the service provided.
  6. the contractual partners may also be reimbursed for reasonable expenses and out-of-pocket expenses incurred in the fulfillment of their contractual obligations in accordance with paragraph 4.
  7. The conclusion of the contract may not involve any obligation on the part of the contracting parties to recommend certain medicinal products or DIPs or to promote their sale in any other way. Contracts with the aim of unfairly influencing the contractual partners are not permitted (prohibition of "sham contracts").
- (2) Companies must oblige their contractual partners to refer to their activities for the company in the context of oral or written public statements, provided that the public statement relates to the subject matter of the contract or to the company in general.
  - (3) The requirements for contractual cooperation set out in paragraph 1 sentence 2 and paragraph 2 shall not apply to the provision of non-recurring, isolated services by patient self-help organizations and members of patient self-help organizations in connection with market research activities (e.g. short telephone interviews), provided that the remuneration for these is insignificant. For the interpretation of the term "minor" within the meaning of this provision, the Executive Board of the Association shall issue binding guidelines in accordance with § 5.
  - (4) If a contractual partner participates in events as part of his contractual activity for the company, the provisions of § 17 shall apply accordingly (e.g. for the selection of the conference venue and/or the conference location, for the reimbursement of the cost contribution and the prohibition of entertainment and leisure programs).
  - (5) If the contractual partners are HCPs, the FSA Code for Professionals must be observed in addition to this Code.
  - (6) The contractual partners may not receive remuneration solely for their participation in events within the meaning of § 17.

### **§ 13**

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

- (1) Member companies may only use the logo or copyrighted materials of patient self-help organizations (such as the right to use an organization's logo in publications, product information, on the Internet, in advertising or at events) on the basis of a written agreement with these organizations. In particular, the regulations in § 9 para. 6 and § 10 must be observed.
- (2) Contracts pursuant to para. 1 must clearly indicate the intended purpose and the type of use of the logo or copyrighted materials.

- (3) The use of logos or copyrighted materials shall not constitute unlawful advertising within the meaning of this Code or applicable laws and regulations.
- (4) Paragraphs 2 and 3 apply accordingly to contracts in which member companies grant patient self-help organizations the right to use the logo of the member company in publications, on the Internet or at events. Patient self-help organizations may not be obliged by the company to directly or indirectly advertise products, product groups or services for the diagnosis and treatment of illnesses or disabilities.

#### **§ 14**

#### **Prohibition of unobjective and editorial influence**

Member companies may not influence the editorial work of the publications of patient self-help organizations they support without a justifiable objective reason (e.g. from a scientific perspective or to correct inaccuracies in content). Mere economic interests do not constitute a justifiable objective reason within the meaning of sentence 1.

#### **§ 15**

#### **Informing the public**

- (1) Member companies must provide the public with a list of those patient self-help organizations to which they grant financial contributions or significant indirect or non-financial contributions (such as services provided by the member company or services provided by commissioned agencies, etc.) on a national or Europe-wide basis. This obligation also applies to contracts in accordance with § 12 for the provision of significant paid services.
- (2) The member companies undertake to report on the sum of monetary and non-cash benefits and the significant management fees paid per calendar year and patient organization. This also includes the value of non-financial benefits if these can be assigned a monetary value. The object of the benefits or contractual services must be described clearly enough for the average reader to understand the nature of the benefits or agreement. However, confidential information does not have to be made public. The description of significant indirect or non-financial benefits to which a financial value cannot be assigned must show their benefit for the patient self-help organization. The report must be submitted no later than 6 months after the end of the relevant reporting period and must be publicly available 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 June 20 and June 30 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. Disclosure of the information must be made on a publicly accessible website under the responsibility of the member company. The information may also be published on a Europe-wide website of affiliated companies, provided that the information can be accessed separately there for the member company. The member company may use the template in Annex 1 of the Code for the disclosure.
- (3) Member companies must work to ensure that their support of patient self-help organizations is made known to the public from the outset.
- (4) The contracts of the member companies with patient self-help organizations must each contain a provision in which the respective patient self-help organization

declares its consent to the member company publishing the annual, cumulative cash and non-cash benefits or the annual service fee paid by the member company.

- (5) For the interpretation of the term "significant" within the meaning of paragraphs 1 and 2, the Executive Board of the Association shall issue a binding guideline in accordance with § 5.
- (6) Member companies shall publish summarized information on the methodology they used to identify the relevant grants and to prepare the report.

## **§ 16 Promotion of neutrality**

Member companies welcome the receipt of donations, sponsorship or other contributions from various sources by patient organizations. The member companies may therefore not demand from patient organizations that these organizations grant the respective company exclusivity with regard to the support of such an organization or its activities (including its events) and may not allow such exclusivity to be granted unsolicited.

## **§ 17 events**

- (1) Member companies may only organize or support events if the selection of the conference venue and the conference location is based solely on objective considerations. Such a reason is not, for example, the recreational value of the conference venue. Conference venues that are known for their entertainment value or are considered extravagant are to be avoided.
- (2) In the context of events, appropriate hospitality for members of patient self-help organizations or other participants is also possible, regardless of whether the event is organized by a patient self-help organization or a member company.
- (3) Member companies may reimburse members of patient self-help organizations or other participants who attend such events for an appropriate contribution to the costs with regard to the main purpose of the event. Entertainment and leisure programmes (e.g. theater, concerts, sporting events) for participants may neither be financed nor organized. If the members or other participants referred to in sentence 1 are HCPs, the FSA Code for Professional Groups must be observed in addition to this Code. The invitation or the assumption of costs for events may not relate to accompanying persons of members of patient self-help organizations or other participants, unless the member concerned or the other participant is absolutely dependent on the support of accompanying persons due to an illness or disability.
- (4) The organization, implementation and/or support of international events or the payment of cost contributions for their participants is only permitted if
  1. the majority of participants come from a country other than the country in which the member company is based, or
  2. The necessary resources or expertise are available at the event location, and in view of this, there are logistical reasons for choosing a venue in another country.
- (5) If speakers give lectures on behalf of member companies, paragraphs 2 and 3 shall apply accordingly, whereby an appropriate fee may also be paid. No remuneration may be paid to members of patient self-help organizations for mere participation in an event.

- (6) For the interpretation of the terms "appropriate", "known for their entertainment value" and "extravagant" within the meaning of this provision, the Executive Board of the FSA shall issue binding guidelines in accordance with § 5.

#### **§ 17a**

#### **Donations to patient self-help organizations**

- (1) In addition to compliance with the relevant legal requirements, donations to patient self-help organizations require that such donations are properly documented, whereby this documentation must be kept for a period of at least 5 years after termination of the contractual relationship.
- (2) Donations to individual members of patient self-help organizations are not permitted unless they are otherwise permissible under this Code or relate to an exception regulated in § 7 (1) sentence 1 No. 2 to 5 HWG.
- (3) The support of members of patient self-help organizations to participate in events is the subject of § 17.

### **Section 4: Monitoring and training**

#### **§ 18**

#### **Monitoring**

Member companies must take suitable organizational precautions to ensure compliance with the Code. This also includes the establishment of a suitable approval process for the conclusion of contracts with patient self-help organizations.

#### **§ 19**

#### **Obligation and training of employees and authorized third parties**

- (1) Employees of the member company must be familiar with the obligations of the companies under this Code and all applicable legal requirements. The companies are responsible for ensuring that their employees comply with these requirements.
- (2) Third parties who support the member companies in activities within the framework of this Code must be familiar with the requirements of the applicable regulations and relevant laws and provisions. The member companies must oblige their employees and commissioned third parties who are active in the area of cooperation with patient self-help organizations to comply with this Code.
- (3) Employees must also be trained on the content of this Code.
- (4) The Association will support the member companies through training and advisory measures to expand their knowledge of this Code and its interpretation and to avoid violations of the Code.

#### **§ 20**

#### **Updating the Code**

The FSA association will regularly exchange information with the Bundesarbeitsgemeinschaft Selbsthilfe von Menschen mit Behinderung und chronischer Erkrankungen und ihren Angehörigen e.V. (BAG SELBSTHILFE) as the relevant umbrella organization of patient self-help organizations in Germany with the aim of further developing the regulations of this Code and their enforcement in the sense of a trusting cooperation between the member companies and patient self-help organizations.

## **Section 5: Entry into force**

### **§ 21 Entry into force**

The version of the Code adopted by the General Meeting on March 20, 2024 shall enter into force on the same day, but not before it has been acknowledged as competition rules by the Federal Cartel Office in accordance with § 24 (3) GWB.

The Federal Cartel Office acknowledged the Code in the present version as competition rules in its decision of 05.11.2024.