

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

("FSA Code of Conduct Patient Organisations")

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Table of Contents	Page
Introduction	4
Chapter 1: General Provisions	4
Section 1 Area of Application	4
Section 2 Definitions	5
Section 3 Responsibility for the conduct of third parties	6
Section 4 General principles of interpretation	6
Section 5 Guidelines by the FSA Board of Management	7
Chapter 2: General principles for collaboration with patient self-help organisations	7
Section 6 Neutrality and Independence	7
Section 7 Separation	8
Section 8 Transparency	8
Section 9 Recommendation and promotion restrictions	9
Chapter 3: Special obligations in collaborating with patient self-help organisations	10
Section 10 Observance of promotional restrictions	10
Section 11 Written agreements	10
Section 12 Use of logos and copyrighted materials	11
Section 13 Prohibition of non-objective and editorial influence	11
Section 14 Informing the Public	11

	Section 15	No exclusivity	12
	Section 16	Events	12
Chapter 4:	Supervision and Training		13
	Section 17	Supervision	13
	Section 18	Commitment and training of employees and third-party contractors	14
	Section 19	Updating the Code of Conduct	14
Chapter 5:	Effectiveness		14
	Section 20	Effectiveness	14

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 pharmaceuticals. The patients are at the centre of the industry's efforts to prevent, cure or relieve the consequences of diseases through effective pharmaceuticals.

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. Essential elements for achieving this goal, in addition to self-evident adherence to existing provisions of the law (such as the German Advertising in the Health Care System Act (HWG)), is 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. The members of the association consider such collaboration with these organisations to be an integral part of their work, in order to better understand the needs of those affected.

With the objective of structuring collaboration with patient organisations in such a way that their neutrality and independence can be maintained and thus fair and objective collaboration 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 Collaboration with Patient Organisations.

Chapter 1: General Provisions

Section 1 Area of Application

- (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 "FSA Code of Conduct Patient Organisations" in a separate written agreement ("member companies" or "companies"). The accountability for infringements of affiliated dependent companies, which are neither members of the association or have not

acknowledged the binding nature of the Code of Conduct, is in accordance with § 1 para. 3 of the "FS-Arzneimittelindustrie" Code of Procedure.

- (2) The Code of Conduct is applicable to the collaboration of member companies with patient organisations. To the extent that collaboration with patient self-help organisations takes place in Germany or certain related activities take place outside of Germany in other European countries, the valid code of conduct in that country shall be applicable alongside this FSA Code of Conduct Patient Organisations. To the extent that collaboration or certain related activities take place with patient organisations located in other European countries, the code shall be applicable of the European country in which the patient organisation is domiciled, alongside this FSA Code of Conduct Patient Organisations. "Code" within the meaning of sentences 2 and 3 is the code of conduct through which the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations is implemented in a given country. In the event of a conflict, the more restrictive rule shall apply.

Section 2 Definitions

- (1) "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 support patients and/or providing advisory services.
- (2) "Members" of patient organisations include their members, along with persons or institutions that act on their behalf or represent them as agents or representatives.
- (3) "Collaboration" is the cooperation between member companies and patient organisations or their support by member companies.
- (4) "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.

- (5) "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.

Section 3

Responsibility for the conduct of third parties

- (1) Companies shall comply with the obligations imposed hereunder even when they commission others (e.g. press and event agencies) to plan or implement on their behalf the activities covered by this Code of Conduct.
- (2) 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 must be observed, especially the restrictions for the promotion of prescription-only pharmaceuticals 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 or to cause offence.

Section 5

Guidelines by the FSA Board of Management

The association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-regulation for the Pharmaceutical Industry") can also issue through its board of management binding guidelines for the interpretation of this Code, beyond the cases regulated in this Code. The association will publish these guidelines on the internet (www.fs-arzneimittelindustrie.de).

Chapter 2: General principles for collaboration with patient self-help organisations

Section 6

Neutrality and Independence

- (1) The association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-regulation for the Pharmaceutical Industry") 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 collaboration 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 collaboration.
- (4) The member companies must not undertake any measures within the scope of their collaboration 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 organized and staged by the latter. To the extent that member companies are involved in determining the content or choosing the speakers at an event, 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 pres-

entations 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 organized 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 collaboration with patient organisations, member companies are to adhere to a strict separation between information of a particular organization 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 collaboration 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 com-

panies shall reach an agreement with each patient organisation concerning the nature and scope of how the collaboration 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 collaboration of member companies with patient organisations must not involve recommendations for individual prescription-only pharmaceuticals or groups of pharmaceuticals.
- (2) The appearance of member company representatives at patient organisations must not be aimed at making promotional references to prescription-only pharmaceuticals.
- (3) 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 14 para. 1).
- (4) 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.
- (5) 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.
- (6) 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.

- (7) The granting of advertising rights within the meaning of para. 3 to 6 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 pharmaceuticals (in particular Section 10 of the German Advertising in the Health Care System Act (HWG)).

Section 11

Written agreements

- (1) To the extent that the scope of collaboration provides for financial payments by member companies to these organisations, collaboration between member companies and patient organisations may only proceed on the basis of a written agreement that spells out the basic elements of the collaboration. 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 collaboration 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

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 7 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 from patient organisations.
- (3) Para. 2 applies 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 13

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 14

Informing the Public

- (1) The member companies must make available to the public a list of patient organisations 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.). Member companies oblige to report on the total amount of

monetary benefits and/or donations in kind per calendar year and patient organisation. Member companies must for the first time provide such information by 31 March 2009 on collaboration with patient organisations for the period from 1 July 2008 to 31 December 2008. The list is to be updated at least once annually (by 31 March at the latest for the previous calendar year).

- (2) Member companies must undertake to ensure that their support of patient organisations is disclosed to the public by these organisations from the beginning.
- (3) The agreements of member companies with patient organisations are to include a provision by which each patient organisation is to grant permission to the member company to publish the annual cumulative monetary donations or donations in kind by the member company.
- (4) For interpretation of the term "significant" as defined para 1, the management board of the association may issue a binding guideline pursuant to Section 5.

Section 15

No exclusivity

Member companies may not require of patient organisations that these organisations grant exclusivity to the given company with regard to support of said organisation or its activities (including its events), nor may they not allow such exclusivity to be granted unsolicited.

Section 16

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 organized by a patient organisation or by a member company.

- (3) Member companies may reimburse members of patient organisations or other participants visiting such events for any reasonable travel costs, necessary accommodation costs as well as any applicable participation fees charged. In the event that the members or other participants referred to in sentence 1 are members of the healthcare profession, the "FS Pharmaceutical Industry" Code of Conduct is to be adhered to, along with this Code.
- (4) It is only permissible for a member company to pay for the costs of participants in events which take place outside the country where the member company is domiciled 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.
- (6) For interpretation of the terms "reasonable", "known for its entertainment value" and "extravagant", the management board of the association may issue a binding guideline pursuant to Section 5.

Chapter 4: Supervision and Training

Section 17

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 18

Commitment and training of employees and third-party contractors

- (1) Member companies must commit their employees and third-party contractors being concerned with collaboration with patient organisations to adhere to this Code of Conduct.
- (2) Furthermore, employees must be trained with regard to the content of this Code of Conduct.
- (3) 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 19

Updating the Code of Conduct

The association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-regulation for the Pharmaceutical Industry") 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 20

Effectiveness

The Code of Conduct in the version passed on 13 June 2008 by the member companies will become effective on 1 July 2008, 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 FSA Code of Conduct Patient Organisations in the present version as competitive regulations with decision of 13 October 2008, received on 15 October 2008.]