

**Arzneimittel und Kooperation im Gesundheitswesen e.V. Code of Conduct
concerning Cooperation with Patient Organisations
("AKG Patient Organisation Codex")
of 6 November 2008, amended on 22 April 2015**

(Recognised by the Bundeskartellamt in its decision of 9 September 2014)

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Introduction

It is the task of the pharmaceutical industry to make a major contribution towards protecting, promoting and restoring human health by researching, developing, manufacturing and marketing pharmaceutical products.

The industry plays a key role in preventing and curing diseases and mitigating their effects.

The effective achievement of these objectives requires attentive and thorough support from persons whose lives are affected by the necessary, prolonged or permanent consumption of pharmaceutical products.

Thus, there is no alternative to the collection of direct experience from such affected persons. Anyone who intends to provide appropriate and sustainable assistance to the sick must be familiar with their needs.

The members of the association Arzneimittel und Kooperation im Gesundheitswesen – AKG e. V. [Medicinal Products and Cooperation in the Health Sector, Registered Association] have therefore decided to seek increasing consultation and cooperation with patient self-help organisations and to provide material and non-material support and aid for these organisations.

In this way, professional interest and taking socially responsible action are tied to one another.

To ensure that this cooperation is based on mutual respect and trust, and in particular to ensure transparent, fair and honest conduct on the part of the involved pharmaceutical companies at all times, the General Assembly of the association Arzneimittel und Kooperation im Gesundheitswesen – AKG e. V. has adopted the following AKG – Code concerning Cooperation with Patient Organisations.

Section 1: General Provisions

§ 1 Scope of Applicability

- (1) The code applies to the member companies (hereafter "companies"), their domestic subsidiaries and other associated companies, provided these associated companies have recognised the binding nature of the AKG Patient Organisation Code in the form of a specific written agreement.
- (2) The Code applies to cooperation between the companies and patient self-help organisations active in Europe and/or the EEA and/or Switzerland.

§ 2 Definitions

- (1) "Patient self-help organisations" are voluntary, non-profit groups of patients and/or their relatives and other carers whose activities involve jointly coping with diseases, the dissemination of information about diseases and possible therapies, representation of interests in the health and socio-political sector, the publication of media providing information and support for patients and/or the provision of counselling services.
- (2) The term "members" of patient self-help organisations also includes persons or institutions acting or presenting as representatives of these organisations.
- (3) "Cooperation" refers to the cooperation between the companies and patient self-help organisations or to the support provided for such organisations by companies.
- (4) "Events" are conferences or meetings between patient self-help organisations, their members and/or other invited participants (e.g. patients and/or their relatives and other carers) aimed at disseminating or exchanging information. Events are either organised or run by the patient self-help organisations themselves and supported by companies, or are organised, hosted, financed and/or run by the companies themselves or external organisers.
- (5) "Sponsoring" is the provision of financial funds, contributions in kind and/or services by companies in support of a patient self-help organisation in return for the granting of public relations rights to use the activities of the organisation on the basis of a written agreement.

§ 3 Responsibility for the Conduct of Third Parties

- (1) The obligations pursuant to this code also apply to companies even if they have authorised other parties (e.g. PR or event agencies) to organise and perform the activities covered by this code on their behalf.
- (2) Agencies or other authorised parties who contact patient self-help organisations on behalf of companies are obliged to clearly state that they are acting in an agent capacity.

§ 4 Principles of Interpretation

In the application of this code, not just the exact wording of the individual provisions shall be observed, but also the spirit and purpose of the code and relevant laws.

Section 2: Principles of Cooperation with Patient Self-Help Organisations

§ 5 Neutrality and Independence

- (1) The association Arzneimittel und Kooperation im Gesundheitswesen e.V. and its member companies pursuant to § 1 (1) assume that the technical and political activities of the patient self-help organisations are geared solely to the needs and interests of disabled or sick persons and/or persons in need of care , so as to promote their self-determination.
- (2) Cooperation between the companies and patient self-help organisations shall be guided by the written objectives and tasks of these organisations.
- (3) Within the scope of cooperation between the companies and patient self-help organisations, the latter organisations must always retain full control over the contents of their work and remain independent.
- (4) Within the scope of cooperation, the companies are obliged not to take any measures which would damage the reputation of self-help.
- (5) The companies shall respect the neutrality and independence of the patient self-help organisations, especially in connection with events organised and run by these organisations. Insofar as the companies contribute to the stipulation of subject matter or the choice of speakers at such an event, this must be done in a balanced and objective manner.
- (6) The companies shall also respect the neutrality and independence of the patient self-help organisations in connection with events run by the companies themselves. Any statements made by the companies must be clearly indicated as such. The provision of scientific and objective information must always be the defining feature of all presentations and lectures.

§ 6 Separation of Interests

- (1) The companies are not permitted to establish any patient self-help organisations themselves. Representatives or employees of the member companies shall not hold office in patient self-help organisations (in particular on their governing bodies), with the exception of the scientific advisory boards of patient self-help organisations. This shall not affect the rights of employees of the companies to be members of patient self-help organisations. Companies are entitled to be passive supporting members of patient self-help organisations.
- (2) Within the scope of the cooperation between the companies and patient self-help organisations, the companies shall ensure clear a distinction between information and/or recommendations provided by the organisations on the one hand and information provided by the companies on the other.
- (3) If employees of the member companies become active in or advise patient self-help organisations, the companies shall take steps to ensure that the employees avoid any conflicts of interest between the company and the organisation.

§ 7 Transparency

- (1) Cooperation between the companies and patient self-help organisations must be open and transparent. The companies shall reach mutual agreement with the patient self-help organisation concerned regarding the nature and scope of how the cooperation and support is to be represented to third parties and shall record that agreement in writing.
- (2) The companies shall take steps to ensure that patient self-help organisations disclose the authorship of the companies if the organisations use any articles or other presentations by the companies in their own publications. Any support provided by the companies for patient self-help organisations in the course of a joint project must also be clearly indicated.
- (3) The companies are entitled to advertise the fact that they support patient self-help organisations only on the basis of a corresponding written agreement with the patient self-help organisation in question.
- (4) Companies can reach agreements with patient self-help organisations under which these organisations refer to the support provided by the company in their own PR activities (including the home page/website of the organisation). In that case, the extent and manner of such references must be recorded in a written agreement.
- (5) Any publications by patient self-help organisations which are produced with support from a company must reference that support.
- (6) The companies are entitled to offer links from their websites to the home page or website of a patient self-help organisation only with the organisation's consent. Any link to the download portion of such an organisation which could entail expenses for the organisation is permissible only on the basis of a written agreement. In the case of sponsoring agreements, no active links may be provided from the organisation's website to the website of the company. Patient self-help organisations and companies are not permitted to host joint websites.
- (7) Companies are not entitled to use the advertising rights granted to them pursuant to the above (3) and (4) to promote products or product groups either directly or indirectly.

Section 3: Special Obligations concerning Cooperation with Patient Self-Help Organisations

§ 8 Compliance with Advertising Bans

The companies are obliged to comply with the general bans and restrictions on the promotion of prescription drugs pursuant to the laws on competition and medicinal products as amended from time to time (in particular Section 10 of the German Pharmaceutical Advertising Act ["HWG"]).

§ 9 Written Agreements

Any cooperation between a company and a patient self-help organisation in the course of which the company grants cash or in-kind benefits to the organisation must be based on a written agreement that outlines the key items of the cooperation.

§ 10 Use of Logos and Copyright Materials

- (1) The companies are entitled to use the logo or copyright materials of patient self-help organisations (for instance the right to use the organisation's logo in publications, product information leaflets, on the internet, in advertising materials or at events) only with the written consent of the organisation concerned.
- (2) The written consent pursuant to (1) shall stipulate restrictions on the purpose and manner of use of the logo or copyrighted materials.
- (3) The above (2) shall likewise apply to consent by a company that grants a patient self-help organisation the right to use the company's logo in publications, on the internet or at events. The company is not entitled to oblige patient self-help organisations to promote products, product groups, diagnostic or therapeutic services for diseases or disabilities either directly or indirectly.

§ 11 Ban on Unjustified and Editorial Influence

The companies shall not exercise any influence on the editorial work of a publication produced by a patient self-help organisation and promoted by the company unless they have a legitimate, objective reason for doing so (e.g. scientific aspects or to rectify inaccuracies in the contents). Purely commercial interests do not constitute a legitimate, objective reason in the sense of the above sentence 1.

§ 12 Informing the Public

- (1) The companies are obliged to provide the general public with a list of those patient self-help organisations to which they grant substantial financial payments and/or in-kind benefits. As a rule, any individual benefit with a value of € 60 is deemed substantial. A list of the total sum of financial payments and/or in-kind benefits is to be drawn up per patient organisation and per annum and must be updated no later than 31 March of the following year.
- (2) The companies shall take steps to ensure that their support for patient self-help organisations is disclosed to the general public by the organisations from the beginning of such support.
- (3) Companies shall reach a written agreement with the patient self-help organisations concerning the manner and way in which the obligations pursuant to the above (1) are to be satisfied.

§ 13 Non-Exclusiveness

The companies shall not demand that the patient self-help organisations grant the company exclusive rights regarding the support of such an organisation or its activities (including the organisation's events) and shall not accept such exclusive rights, even if they are provided without a request from the company.

§ 14 Events

- (1) The companies are only permitted to organise or support events if the choice of venue (city and location) is based solely on objective criteria.
- (2) Reasonable hospitality may be provided for the members of patient self-help organisations, their relatives and carers in the course of events, irrespective of whether the event is organised by a patient self-help organisation or by a company.
- (3) The companies are entitled to reimburse any members of patient self-help organisations, relatives and/or carers attending such an event for reasonable travel expenses, necessary accommodation expenses and, where applicable, any admission fees charged.
- (4) The organisation or support or assumption of expenses for persons attending events outside the EEA (EU and Norway, Liechtenstein and Iceland) and Switzerland is permissible only if
 1. the majority of persons attending come from a country other than the country in which the member company has its place of domicile, or
 2. needed resources or specialist knowledge are available at the event venueand therefore logistical reasons exist that support the choice of venue in a different country.
- (5) The above (2) and (3) shall likewise apply if speakers give presentations on behalf of companies, in which case a reasonable fee may also be paid over and above the reimbursement of expenses.

Section 4: Monitoring and Instruction

§ 15 Monitoring

The companies shall take suitable organisational measures to ensure compliance with this Code.

§ 16 Obligations and Training of Employees and Authorised Third Parties

- (1) The companies shall oblige their employees and any authorised third parties working in cooperation with patient self-help organisations to comply with this code.
- (2) The companies shall furthermore provide training to their employees in the content of this code.

§ 17 Ongoing Development of the Code

The association Arzneimittel und Kooperation im Gesundheitswesen e.V. shall regularly exchange information with the Federal German working party "SELBSTHILFE von Menschen mit Behinderung und chronischer Erkrankungen und ihren Angehörigen e.V. (BAG SELBSTHILFE – SELF-HELP for people with disabilities and chronic diseases and their relatives), as the competent umbrella association of patient self-help organisations in Germany, with the goal of promoting the ongoing development of the provisions of this Code and its enforcement in the interests of promoting trust-based cooperation between the companies and patient self-help organisations.

Section 5: Effective Date

§ 18 Effective Date

The AKG Code of Conduct concerning Cooperation with Patient Organisations enters into force upon recognition of competition rules by the Bundeskartellamt under § 24 Para. 3 GWB.