

**FSA Recommendations
on Collaboration of the Pharmaceutical Industry
with Partners in the Healthcare System and their Employees**

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Introduction

The health policy environment and the playing field for the development, sale and reimbursement of pharmaceuticals are in a state of upheaval. They increasingly require the involvement of widely diverse institutions in the healthcare system. This simultaneously results in new and/or more tightly-knit collaborative relationships between pharmaceutical companies and these institutions, including their employees.

In this, the member companies of FSA are in constant dialogue with numerous points of contact in the healthcare system. Along with ministries, public agencies and members of parliament, this additionally includes state institutions as well as joint self-administration in the healthcare system and their employees as representatives of these institutions. The collaboration and ongoing discourse between the pharmaceutical industry and partners in the healthcare system as well as their employees are something to be embraced and promoted.

Because this serves the purpose not only of vital information exchange but also better understanding of individual positions and thus upholds the common goal of all partners in the healthcare system to provide optimal patient care.

The association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." [The Association of Voluntary Self-Regulation for the Pharmaceutical Industry] seeks to promote this collaboration. In order to attain this goal, a dialogue of trust and transparency is indispensable, in addition to compliance with regulations, which of course goes without saying.

With the goal of guaranteeing ethical and objective collaboration, the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." [The Association of Voluntary Self-Regulation for the Pharmaceutical Industry] adopted the following

**"FSA Recommendations
on Collaboration of the Pharmaceutical Industry
with Partners in the Healthcare System and their Employees".**

Section 1: Area of Application and Principles

1. Area of Application

The following recommendations apply to the activities of the member companies in their collaboration with partners in the healthcare system, their employees and with members of parliament (hereafter referred to in abbreviated form as "*Cooperation Partners*"). The provisions of these recommendations should not be applied in the context of managed competition envisaged pursuant to the Social Security Code V [SGB V] (e.g. conclusion of discount and added-value contracts).

2. Definitions

- 2.1 "*Partners in the healthcare system*" are entities involved in the healthcare system or in healthcare policy such as ministries, public agencies and other public-law institutions as well as establishments for joint self-administration in the healthcare system. These also include European public authorities (e.g. the EU Commission and the EMA).
- 2.2 "*Employees*" of partners in the healthcare system are public employees, company employees, advisors and all other persons who play an active role on behalf of partners in the healthcare system.
- 2.3 "Members of Parliament" are member of the European Parliament, the German Bundestag or the state parliaments.

3. Responsibility for the Conduct of Third Parties

- 3.1 The recommendations should also apply to the companies if they appoint third parties (e.g. event or PR agencies etc.) to devise and carry out the activities that fall within the scope of these recommendations.

- 3.2 If agencies and or other contractors are to establish contact with cooperation partners on behalf of companies, their status as third-party contractors is to be made apparent, to the extent that this applies to the activities covered by these recommendations.

4. **Interpretation Principles**

- 4.1 The application of these recommendations should adhere not only to the letter of each provision but also to the spirit and purpose of the recommendations along with the definitive legal statutes.
- 4.2 The companies are to be held to high ethical standards at all times. In particular, their conduct must not discredit the pharmaceutical industry, diminish trust in it or be offensive.

5. **Principles for Collaboration**

- 5.1 Cooperation partners should not be *unfairly* influenced in their professional decisions. Therefore no benefits should be offered, promised or provided for the purpose of unfairly influencing these cooperation partners.
- 5.2 The collaboration of member companies with cooperation partners should occur *transparently* and *openly*. For employees of the partners of the healthcare system, this includes in particular the safeguarding of transparency by means of disclosure and obtaining permission from superiors.
- 5.3 In the interest of the greatest possible transparency, the collaboration should be adequately *documented* in writing.

Section 2: Hospitality

6. **Hospitality**

- 6.1 Hospitality is allowed within the setting of events and other professional occasions (e.g. working meals).
- 6.2 The hospitality costs should not exceed socially-acceptable bounds. Hospitality is considered socially acceptable when it is viewed overall as being customary, reasonable and conforming to the general principles of politeness.
- 6.3 Invitations of cooperation partners should generally be made in writing, unless they involve impromptu invitations.

Section 3: Events

7. **Invitations to Events**

- 7.1 The member companies are allowed to invite cooperation partners to events having the purpose of disseminating or exchanging information.

- 7.2 The choice of event venue and event meeting place should fit the occasion and be made entirely according to objective criteria (such as good accessibility for participants and speakers, adequate meeting rooms etc.). The choice of event venue and event meeting place must not be based on entertainment or recreational value.
- 7.3 In deviation from the provisions in No. 7.1 and 7.2 cooperation partners may be invited to special social occasions (e.g. receptions due to company anniversaries, laying of the foundation stone, inaugurations, plant tours), in order for them to participate in these events within the scope of their office, their official duty or in observance of the social obligations demanded by their individual official or political functions.
- 7.4 For events and invitations to social occasions, the member companies are allowed to cover socially-adequate costs for food and beverages in providing hospitality to the participants.
- 7.5 Invitations should be made in writing.
- 7.6 To the extent that the events involve further training sessions, at which participation is customarily subject to a fee, written permission should be obtained from the superior or employer prior to participation by members of partners in the healthcare system.
- 7.7 To the extent the cooperation partners give presentations or render other services to member companies, the recommendations in Section 4 should be observed.

Section 4: Contractual Services

8. Rendering of fee-based services

- 8.1 The member companies should only engage employees of partners in the healthcare system (hereinafter referred to as "contractors") to render fee-based services (e.g. for giving presentations, carrying out advisory functions, acting as moderators, participating in sessions of advisory bodies, carrying out training events, or participating in market research activities) only under the following conditions:
- a) Prior to the services commencing, each contractor and member company should negotiate a written agreement specifying services to be rendered and remuneration to be paid for them.
 - b) Remuneration should only be made in the form of monetary compensation and be in reasonable proportion to the service to be rendered. In order to determine the reasonableness of the remuneration, factors such as the scope of negotiated services, the qualification of the contractor and the time requirement for the services shall be considered.
 - c) In the case of employees of partners in the healthcare system, the agreement should be approved by the employers and superiors respectively prior to the activity being performed and prior to remuneration being paid out.
 - d) The agreement can also specify that the member company assume reasonable travel expenses and necessary accommodation costs and envisage the provision of socially-adequate hospitality (see above under No. 6.2).
 - e) To the extent that the employee of the partner in the healthcare system is active in an official capacity for public bodies that may be relevant to the member company, and the company is aware of this, the agreement should also include an additional obligation on the part of the speaker to make this activity performed for the member company transparent towards these bodies.
- 8.2 To the extent that cooperation partners give presentations free of charge at events or engage in any other activities related to such events, an invitation to the event is sufficient. In this context, the provisions under Nos. 6 and 7 are to be observed.

9. Sponsoring

- 9.1 Sponsoring means that a member company supports the staging of an event through financial means and, in exchange, is allowed to develop image-enhancing promotional activities as part of the event.
- 9.2 A written sponsoring agreement should always be concluded. It should contain the remuneration to be paid to the organiser as well as what the member company is to be provided in exchange.
- 9.3 In drawing up the sponsor agreement, each contracting party's sponsoring guidelines – to the extent that they exist – are to be observed. To the extent that the sponsoring recipient involves a partner in the healthcare system who has no such guidelines, the tenets of the

agreement should adhere to the "General Administrative Rules for Sponsoring" from the Federal Ministry of the Interior.¹

- 9.4 For sponsoring offices of the Federal Administration, it should also be remembered that permission of the highest administrative offices must be obtained. For purposes of transparency, benefits made to the offices of the Federal Administration are also published in a biennial report to the Federal Ministry of the Interior, starting at an amount of EUR 5,000 per individual service rendered and disclosing the individual name of the sponsor and the sponsoring purpose.
- 9.5 In determining the level of remuneration, it should be ensured that there is no disproportion between the remuneration and the services rendered. The remuneration of the organiser should be made exclusively by monetary means. The remuneration should be made exclusively for the purpose of promoting the event.

Section 5: Donations and Gifts

10. Monetary and Material Donations

- 10.1 Monetary and material donations are only permitted to non-profit organisations, to the extent that these institutions are entitled to issue a confirmation of donation (donation receipt) as defined in fiscal statutes. Whereby the provision of donations should always occur for the public good and for a specific purpose, i.e. for the purpose of research and education, for improving health or patient care, for purposes of further training or for a charitable cause.
- 10.2 Donations to individual persons are not permitted.
- 10.3 To the extent that employees of partners in the healthcare system actively participate in the procurement of donations, upon provision of such a donation for reasons of transparency it is recommended that the employee's superior or employer of the employing organisation be informed, to the extent that the procurement of a donation is carried out on behalf of a third party.

11. Gifts

- 11.1 As a rule, personal gifts should generally be avoided, regardless of whether the recipient is a public official or not. It is recommended that personal gifts only be made in exceptional cases and on special occasions (when celebrating years of service or good-bye parties).

¹ Download at www.bmi.bund.de/cln_095/SharedDocs/Downloads/DE/Broschueren/DE/2006/Texte_zur_Korruptiospraevention2006.html

- 11.2 Gifts should be kept within socially-reasonable bounds. Gift-giving should observe the definitive rules of public agencies for accepting rewards or gifts.² For gifts to employees of the Federal Administration, the "Bulletin on the Prohibition on accepting Rewards and Gifts in the Federal Administration" from the Federal Ministry of the Interior should be observed.³ In case of doubt, employees of partners in the healthcare system should obtain prior permission from their superior and employer respectively.
- 11.3 The distribution of normal brochures and publications of the member companies and other information materials should occur within socially-acceptable bounds.

² See for example the administrative rule "Korruptionsbekämpfung in der öffentlichen Verwaltung des Freistaats Thüringen" ["Combating Corruption in Public Administration in the State of Thuringia"] dated 22 October 2002 (download at www.mi.brandenburg.de/sixcms/detail.php?gsid=lbm1.c.359443.de); Administrative rule on § 78 Niedersächsisches Beamtengesetz [Lower Saxony Public Employee Act] - "Annahme von Belohnungen und Geschenken" ["Acceptance of Rewards and Gifts"] dated 15 March 2000 (download at http://cdl.niedersachsen.de/blob/images/C1339819_L20.pdf).

³ Download at www.bmi.bund.de/SharedDocs/Downloads/DE/Themen/OED_Verwaltung/Korruption_Sponsoring/RS_Verbot_Annahme_Belohnungen.html.