

**Conduct Recommendations
for the Cooperation between
the Pharmaceutical Industry and Physicians (*)**

issued by

Bundesverband der Arzneimittel-Hersteller e.V. (BAH)
Bundesverband der Pharmazeutischen Industrie e.V. (BPI)
Verband Forschender Arzneimittelhersteller e.V. (VFA)

(* German version is applicable.)

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Introduction

Health is mankind's most precious possession, and pharmaceuticals make a key contribution to every individual's health and well-being. The research, development, production and distribution of pharmaceuticals impose great demands on the companies within the pharmaceutical industry. The patients are at the center of the industry's efforts to prevent, cure or relieve the consequences of diseases through effective pharmaceuticals.

The trust-based relationship between physician and patient is the foundation of each therapy. The therapy decision is the sole responsibility of the medical profession. The pharmaceutical industry has made a commitment to communicate the knowledge required for the appropriate selection of pharmaceuticals by disseminating scientific information. In addition, both the research and the development of effective pharmaceuticals would be virtually impossible without close expert collaboration with the medical profession.

For the pharmaceutical industry, the principle applies that all measures in communicating information and collaborating with physicians must remain within certain appropriate bounds and in accordance with the law. In this respect, the principles of separation, transparency, documentation and, for mutual services, the principle of equivalence as stipulated in the "Common Position" of the associations (Common Position of the Associations for assessing the Collaboration between Industry, Medical Facilities and their Employees in Reference to German Criminal Law) for the clinical sector also outline valuable reference points for the collaboration of the pharmaceutical industry with office-based physicians.

With the objective of promoting professional conduct in accordance with these principles and making a contribution to a fair competition in the collaboration with physicians, the German Association of Pharmaceutical Manufacturers (BAH), the German Association of the Pharmaceutical Industry (BPI) and the German Association of Research-based Pharmaceutical Companies (VFA) have published the following

Conduct Recommendations for the Cooperation between the Pharmaceutical Industry and Physicians.

By doing so, the participating associations intend to provide their member companies with specific information that will enable them to comply with the existing legal framework and that will promote fair collaboration.

Section 1: Area of Application and Publication

1. Area of application and publication

- 1.1 The conduct recommendations are applicable to the collaboration of companies of the pharmaceutical industry with physicians working in Germany in the field of research, development, production and distribution of pharmaceuticals.
- 1.2 The conduct recommendations will also be published on the Internet by the participating associations.

Section 2: Collaboration with Physicians

2. Principles

- 2.1 When collaborating with physicians, all applicable laws must be observed, especially the regulations of the German Drugs Act (AMG), the German Advertising in the Health Care System Act (HWG) and the German Penal Code (StGB), the generally recognized legal principles of the medical profession and the conduct recommendations of the participating associations of the pharmaceutical industry, which are based on these principles.
- 2.2 The company is responsible for the collaboration with physicians, even if it commissions others (e.g. advertising agencies or market research companies) to design or implement such a collaboration.

3. Prohibition of unfair advantages

- 3.1 Physicians must not be unfairly influenced in their decisions regarding therapy, prescriptions or procurement. Therefore, it is unlawful to offer, promise or grant them or any third party any unfair advantages. Especially the forms of collaboration described below must not be used in any unfair manner to influence the decision-making freedom of physicians regarding therapies, prescriptions or procurement.

- 3.2 Considered unfair are in particular those advantages that are granted in violation of the German Advertising in the Health Care System Act (HWG), the German Fair Trade Practices Act (UWG), the German Penal Code, or the generally recognized legal principles of the medical profession.

4. Contractual collaboration with physicians

- 4.1 Physicians may only render services for companies (e.g. lectures, consulting, clinical trials, drug monitoring projects) based on written agreements that clearly state both the nature of the service and the remuneration.
- 4.2 The contractually stipulated service to be rendered by the physician in question to the company must be scientific or medical in nature (prohibition of “fictitious contracts”).
- 4.3 The remuneration must be exclusively monetary and must be proportionate to the service rendered. When judging the appropriateness of the intended remuneration, the physician’s fee schedule may serve as a reference guide. To take into account the physician’s time expended, appropriate hourly rates may also be arranged.
- 4.4 In addition, physicians may be reimbursed for their out-of-pocket and travel expenses while rendering the contractual services.
- 4.5 Physicians or third parties must not be granted payment of any fees for their willingness to meet with pharmaceutical consultants or receive information from other members of the pharmaceutical company.
- 4.6 It is unlawful to offer, grant or promise physicians or any third party a fee or other monetary advantage for prescribing, applying or recommending a pharmaceutical to patients.

5. Drug monitoring projects

- 5.1 Drug monitoring projects are scientific studies following the marketing authorization or registration of a pharmaceutical with the purpose of gaining new insights on the application of the pharmaceutical and its efficacy and tolerability in practice.
- 5.2 With regard to therapeutic and diagnostic measures, the principle of non-intervention applies to drug monitoring projects.

- 5.3 When planning, designing and implementing drug monitoring projects, the recommendations and guidelines published by the German Federal Institute for Drugs and Medical Devices (BfArM) should be observed. In particular, the completed surveillance sheets should be professionally evaluated and the execution of the drug monitoring project should be subjected to appropriate quality assurance measures.
- 5.4 In addition, the company should justify and document the planned number of patients and the amount remunerated for each surveillance sheet in the project file.
- 5.5 With regard to the amount remunerated for the implementation of a drug monitoring project, item 4.3 applies subject to the provision that said remuneration should be set in such a manner that it does not create an incentive to prescribe the pharmaceutical in question.

6. Invitation to job-related, science-oriented training events

- 6.1 Companies of the pharmaceutical industry may invite such physicians to their own, job-related training events, who are particularly concerned with said companies' research areas, pharmaceuticals and their therapeutic indications (in-house training events).
- 6.2 The company may only pay appropriate travel and accommodation costs for the invited physicians, if the job-related, scientific character of the in-house training event clearly takes center stage. During such training events, appropriate hospitality arrangements for the participants are also possible. However, the company must not pay for the participants' entertainment expenses (e.g. tickets for theater, concert or sports events). The actual participation of the invited physicians and the event program should be documented.
- 6.3 Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason.

- 6.4 The invitation of physicians to the job-related training events of any third party (external training events) may only include appropriate travel expenses, necessary accommodations and participation fees charged by said third party, if the scientific character of these events clearly takes center stage and if the company has a relevant interest in such a participation. The company may only assume the costs, if the event provides a link to the company's field of activities as well as a link to the expertise of the event participant.
- 6.5 Within appropriate limits, financial support for the organizers of external training events is permissible. However, entertainment programs must not be supported financially or in the form of donations. Companies supporting external training events should request that the financial support be officially disclosed by the organizer when the event is announced and when it takes place.
- 6.6 If the organizer is a member of the medical profession, the nature, content and presentation of the training event must be determined solely by said medical organizer.
- 6.7 The invitation and assumption of the costs for in-house and external training events must not include companions.
- 6.8 If physicians are commissioned by companies of the pharmaceutical industry to hold lectures at in-house or external training events or provide other services, Section 4 shall apply.

7. Gifts

- 7.1 For advertising gifts, the limits stated in Section 7 of the German Advertising in the Health Care System Act (HWG) must be observed.
- 7.2 In addition, gifts may be made for special occasions (e.g. for practice openings or anniversaries), as long as their value is within socially acceptable limits.

8. Hospitality

Hospitality is only permissible during scientific training events/conventions and work lunches/dinners to an appropriate and socially acceptable extent. The occasion for such a work lunch/dinner must be documented.

9. Sweepstakes for physicians

- 9.1 Sweepstakes, in which winning is solely due to chance, should also not be advertised to physicians.
- 9.2 Sweepstakes, in which the entry depends on a scientific or expert service of the participating physicians and for which the promised prize is appropriately proportionate to the scientific or expert service rendered by the entrants, are permissible.

10. Collaboration with physicians who are civil servants and/or employees of medical institutions

When collaborating with physicians who are civil servants and/or employees of medical institutions, the information and recommendations of the “Common Position” of the associations should also be observed.

Section 3: Pharmaceutical Safety

11. The “red hand” symbol

- 11.1 For advisories of newly identified, serious side effects, recall of defective batches or other information to be directly communicated to physicians and/or pharmacists to exclude risks for patients, a red-hand symbol and the text “Important information on a pharmaceutical” must be used on both the envelope and the letterhead. In particularly urgent cases, these advisories can also be disseminated orally, by fax or through public notices, e.g. via print media, radio and television.
- 11.2 Other scientific information, advertisements or direct marketing mail must never be sent out with the red-hand symbol or sent by priority mail, registered mail, telegram or fax and must not be labeled “Important Information.”

Section 4: Commitment and Training of Employees and Third-party Contractors

12. Commitment and training of employees and third-party contractors

- 12.1 Companies must commit their employees and third-party contractors collaborating with physicians to adhere to the conduct recommendations and ensure compliance through suitable organizational measures.
- 12.2 In addition, the employees must be informed of the most important principles of the professional regulations and obligations of the medical profession. Furthermore, they must be trained with regard to the content of these conduct recommendations.