

## **Code of Conduct of the Members of Arzneimittel und Kooperation im Gesundheitswesen e.V. (AKG e.V.) of 7 April 2008, amended on 22 April 2015**

Recognised by the Bundeskartellamt in its decision of 25 September 2014.

### **Introduction**

Health is a person's greatest asset. Drugs make a substantial contribution to our health and well-being. Research, development, the manufacturing and the distribution and sale of medicinal products place great demands on companies in the pharmaceutical industry. The patient is at the centre of efforts to use effective medicinal products to cure or prevent diseases or mitigate their consequences.

The trusting relationship between physician and patient is the basis of any therapy. Decisions regarding therapy are solely the responsibility of the medical profession. The pharmaceutical industry sees its mission as using scientific information about medicinal products to convey the knowledge that is required for the appropriate selection of medications. Beyond this, both research and the development of effective medicinal products would be unimaginable without close professional collaboration with physicians and other members of the health professions.

At the same time the members of the AKG believe in the principle that all measures used in the conveyance of information and in collaboration with physicians must be carried out within the limits of applicable laws. In Germany, interactions with health professionals have been clearly regulated by the Pharmaceutical Advertising Act (Heilmittelwerbegesetz – HWG) and the Medicinal Products Act (Arzneimittelgesetz – AMG) in Germany. Among other things, the Law on Combating Corruption (Gesetz zur Bekämpfung der Korruption) expanded and strengthened stipulations regarding the acceptance of bribes and corruption in the German Criminal Code (StGB).

The code of the Members of the German Association of Pharmaceutical Industries (BPI e. V.), which has been in existence since 1981, is amended and adapted to current statutory regulations by this version of the Code of Conduct of the Members of the AKG. The members of the AKG will be guided by and implement the approved code of conduct when undertaking any measures to convey information and promote collaboration with health professionals. The members of the AKG e.V. are aware that precise, fair and objective information about their medicinal products is required so that an objective therapeutic decision can be reached regarding their use.

With this intention, the AKG e.V. resolved to adopt the

### **AKG Code of Conduct.**

The AKG e. V. will advocate fair competition between pharmaceutical companies. The AKG Code of Conduct ensures that the pharmaceutical companies will truthfully and accurately convey scientific information about medicinal products, abstain from deceptive practices, avoid conflicts of interest with members of the health professions and act in accordance with the relevant laws and regulations.

The objective in this regard is the prevention of misleading information and corruption when dealing with medical professionals.

The AKG Code of Conduct ties into the general framework of regulations that implement voluntary control of the pharmaceutical industry under the principle of „prevention before sanction“ with the goal of promoting cooperation between the pharmaceutical industry and the health professions.

The member companies may impose their own additional rules and guidelines on themselves regarding cooperation with health care institutions and their employees as well as with physicians in private practice in accordance with the rules of fair competition. As a binding resolution of the minimum requirements, the AKG Code of Conduct will remain unaffected in these cases.

## **1. Section: Scope of Applicability**

### **§ 1 Scope of applicability**

- (1) The code applies to member companies as well as to companies affiliated with them, insofar as the affiliated companies have acknowledged the binding nature of the AKG Code of Conduct by signing a separate written agreement (“member companies” or “companies”).
- (2) The code applies
  1. to the product-related advertising regulated in section 3 of this code for medicinal products for human use within the meaning of § 2 of the Medicinal Products Act if
    - a) prescription-only medicinal products for human use are involved and
    - b) if the advertisement is directed toward the health professionsand

2. to the cooperation regulated in section 4 of this code of member companies with members of the health professions in the area of research, development and the manufacture and distribution and sale of prescription-only medicinal products for human use.
- (3) The Code does not apply to non-advertising information; within the meaning of this code, this includes in particular:
1. the labelling of a medicinal product as well as the package inserts;
  2. Correspondence and documents that do not serve an advertising purpose and that are required to answer a specific query regarding a specific medicinal product;
  3. technical information such as announcements of packaging changes, warnings about side effects as well as reference materials (e.g. product catalogues and price lists that do not contain product-specific statements);
  4. technical information related to diseases or human health;
  5. company-related information, e.g. to investors or current or prospective employees, including financial data, reports on research and development programmes as well as information about regulatory developments that affect the company and its products;
  6. company-related advertising without reference to specific medicinal products (image advertising).

## **§ 2 Definitions**

Health professionals within the meaning of this code are members of the health care professions or industry, institutions that serve human health, or other persons, to the extent they are authorised to engage in commerce with prescription-only medicinal products or use them while exercising their profession.

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

The responsibilities under this code apply to companies even if they commission others (e.g. advertising agencies, market research firms) to design or implement activities covered by this code.

## **2. Section: Principles**

### **§ 4 General principles**

- (1) When applying this Code not only must the wording of the individual regulations be observed, but also the spirit and intention of these regulations as well as the applicable laws, in particular the regulations of the AMG, the HWG, the law against unfair competition (Gesetz gegen den Unlauteren Wettbewerb - UWG), the German Criminal Code and the generally recognised principles of professional practice of members of the health professions.
- (2) The companies must allow themselves to be held to high ethical standards at all times. In particular, their conduct must not bring discredit to or lower trust in the pharmaceutical industry or be offensive. Furthermore, the special nature of medicinal products and the professional perception of the health professions addressed must be taken into consideration.
- (3) Pharmaceutical consultants must responsibly comply with their statutory obligations.

### **§ 5 Advertising**

When applying section 3 of this Code, the following general principles must be taken into account in particular:

1. Advertising should place the health professionals addressed in a position to form their own opinions of the therapeutic value of a medicinal product. It must therefore be accurate, balanced, fair, objective and complete. It should be based on a current evaluation of all relevant findings and clearly and plainly reflect these findings.
2. Advertising must promote the sensible use of medicinal products by presenting them objectively and without exaggerating their characteristics.

### **§ 6 Cooperation**

When section 4 of this Code is applied, the following general principles must be taken into account in particular:

1. Members of the health professions must not be dishonestly influenced in their therapeutic, prescribing and purchasing decisions. It is therefore prohibited to offer, promise or grant unfair advantages to them or a third party. In particular, the possible forms of cooperation described in detail in section 4 below may not be abused in a dishonest manner to influence the freedom of the members of the health professions in arriving at their therapeutic, prescribing and purchasing decisions.
2. Unfair advantages are in particular those that are granted in violation of the regulations of the HWG, the UWG, the German Criminal Code or the generally recognised principles of the professional practice of members of the health professions.

### **3. Section: Advertising**

#### **§ 7 Prohibition against misleading advertising**

- (1) Misleading advertising is prohibited.
- (2) Deception exists in particular
  1. if therapeutic effectiveness or effects are attributed to prescription-only medicinal products that these products do not possess,
  2. if the impression is falsely created that
    - a) success can be expected with certainty,
    - b) that no harmful effects will be experienced if the medicinal product is taken as directed or over a long period of time,
    - c) the advertisement is not being produced for purposes of competition,
  3. if untrue or misleading statements are made
    - a) with regard to the composition or characteristics of drugs, medicinal products, devices or other media or the manner of procedures or treatments or

- b) about the person, prior training, qualifications or successes of the manufacturer, inventor or the persons working for them or who have worked for them.
- (3) When determining whether withholding a fact is misleading, its suitability for influencing the prescribing decision of the health professionals addressed must particularly be taken into account.
- (4) Advertising must be sufficiently scientifically supported and may not contradict the specifications in the summaries of product characteristics. This applies especially to promotional messages that refer to certain advantages, qualities or characteristics of a medicinal product or active ingredients. Promotional messages about side effects must also reflect all available findings or be documented with clinical experience. Statements that have already been included in the approval of a medicinal product require no further scientific verification.

If members of the health professions so request, the appropriate scientific documentation must be made available to an appropriate extent.

- (5) Medicinal products may be designated as "safe" only when the corresponding scientific documentation is available.
- (6) Sweeping statements that a medicinal product has no side effects, toxic hazards or risk of addiction or dependency are prohibited. Statements that certain side effects, toxic hazards or risks involving addiction or dependency have not yet been identified are permissible only if they are supported with sufficient scientific documentation.
- (7) Drugs may be designated as "new" only within one year after they have been initially placed on the market; indications only within one year from when they are first advertised.

### **§ 8 Prohibition against covert advertising / transparency precept**

- (1) The promotional nature of advertising activities may not be concealed.
- (2) Advertisements that are paid for or released by a company must be designed so that they cannot be mistaken for independent journalistic statements.
- (3) With respect to publications by third parties about medicinal products and their use which are financed by a company in their entirety or in part, care must be

taken to ensure that these publications very clearly state that they are financed by the company.

### **§ 9 Prohibition against advertising non-approved medicinal products and non-approved indications**

Advertising medicinal products that require pharmaceutical approval is permissible only if they have been approved. An advertisement that refers to therapeutic applications or dosage forms which are not covered by the requirement for approval is prohibited.

### **§ 10 Mandatory specifications**

- (1) Each advertisement for medicinal products within the meaning of § 2 para. 1 or para. 2 no. 1 of the Medicinal Products Act must contain the following specifications:
  1. the name or the company and the place of domicile of the pharmaceutical entrepreneur,
  2. the name of the medicinal product,
  3. the composition of the medicinal product in accordance with § 11 para. 1 sentence 1 no. 6 (d) of the Medicinal Products Act
  4. the therapeutic indications,
  5. the contra-indications,
  6. the side effects,
  7. specific precautions for use to the extent they are required for labelling the containers and outer packaging,
  - 7a. for medicinal products that may only be prescribed by physicians or dentists, the marking "by prescription only",
- (2) According to para. 1 no. 2, with respect to medicinal products that contain only one pharmaceutically active ingredient, the specification must be followed by the description of this component with the note: "active ingredient"; this does not apply if a description of the active ingredient is included in the specification according to para. 1 no. 2.
- (3) The specifications mandated in paragraphs 1 and 2 must correspond with those that are mandated for package inserts under § 11 or § 12 of the AMG. If the specifications mandated in § 11 para. 1 sentence 1 no. 3 letters a and c and no. 5 of the AMG cannot be provided, they may be omitted.

- (4) The specifications mandated under paragraph 1 must be set apart and clearly distinguished from other promotional information and be clearly legible.
- (5) Paragraphs 1 and 2 do not apply to reminder advertisements for medicinal products. An advertisement is considered a reminder advertisement if it consists solely of the name of a medicinal product, and/or additionally the name, company or brand of the pharmaceutical entrepreneur or the note: "active ingredient".

### **§ 11 Reference to publications**

An advertisement is inadmissible if

1. Expert opinions or certificates are published or mentioned that have not been issued by persons who were designated to do so on the basis of scientific or technical knowledge and do not contain indications as to the name, profession and address of the person who issued the expert opinion or the certificate or the date of issuance of the expert opinion or certificate,
2. reference is made to scientific, technical or other publications without making clear in the advertisement whether the publication refers to the medicinal product, the process, the treatment, the device or other substance that is being advertised and without stating the name of the author, the date of publication or the source,
3. quotations, tables or other representations taken from the medical literature are not rendered verbatim.

### **§ 12 Comparative advertising**

- (1) Comparative advertising is any advertising that directly or indirectly identifies a competitor or the goods or services offered by a competitor.
- (2) Comparative advertising for medicinal products is inadmissible if the comparison
  - a) does not refer to medicinal products used for the same need or the same designated purpose;
  - b) is not objectively related to one or several essential, relevant, verifiable and typical characteristics or the price of this medicinal product;

- c) in commerce it leads to confusion between the advertiser and a competitor or between the medicinal products offered by the advertiser or the distinguishing marks used by them;
- d) unfairly takes of advantage or harms the reputation of a distinguishing mark used by a competitor;
- e) disparages or maligns the medicinal products, services, activities or personal or business relationships of a competitor or
- f) represents medicinal products as imitations of medicinal products sold under a protected trademark.

### **§ 13 Unacceptably annoying advertising**

- (1) Advertising must not unreasonably annoy members of the health professions. An advertisement that is placed although it is obvious to the advertiser that the recipient does not wish to receive it would constitute an unacceptable annoyance.
- (2) Advertising using fax devices, autodialers or electronic mail is permissible only if the recipient has provided consent. When using electronic mail, consent may be presumed if the entrepreneur received the electronic mailing address from the recipient and if the recipient is clearly informed during each use that he may withdraw consent at any time.

### **§ 14 Red Hand Symbol**

- (1) For notifications of newly discovered, serious pharmaceutically related hazards or for other risk information that must reach the physician and/or pharmacist directly when action is required to exclude the endangerment of the patient if possible, the Red Hand symbol must be placed on both the envelopes and the correspondence itself with the inscription "Urgent notice regarding a medicinal product" ("Wichtige Mitteilung über ein Arzneimittel"). All available media may be used for sending a "Red Hand" letter and, depending on the requirements, a deliverability rate that covers as many bases as possible may be employed. In especially urgent cases it may also be necessary to disseminate these notices verbally, by fax, by e-mail or via public appeals, e.g. via the press, radio and television.

- (2) Neither as a whole nor in part may a "Red Hand" letter have the character of promotional mailings or contain promotional messages. Other scientific information, advertisements or promotional mailings may not have the „Red Hand“ symbol attached or identified as an "urgent notice".

### **§ 15 Samples**

- (1) The rules governing samples in § 47 para. 3 and 4 of the AMG constitute the standard.
- (2) The containers and outer packaging of the samples must be labelled with a clearly legible and permanently affixed imprint "sample, not for sale". This does not apply to containers holding less than ten millilitres or to ampoules containing only single-use units.
- (3) Since it is necessary to ensure that samples are only provided for the physician's information, it is prohibited to link the offer or the provision of samples with the offer or the provision of promotional gifts.
- (4) The samples must be accompanied by the technical information stipulated in § 11a of the Medicinal Products Act. This also applies to technical information that is voluntarily prepared.
- (5) Samples may not be provided at trade fairs that take place in connection with medical congresses or continuing education events, instead only requests from visitors may be accepted.

## **4. Section: Collaboration with members of the health professions**

### **§ 16 Prescriptions and recommendations**

It is prohibited to offer, grant or promise compensation or other monetary advantage to members of the health professions or third parties for the prescription and application of medicinal products or for the recommendation of a medicinal product to a patient.

### **§ 17 Contractual collaboration with physicians**

- (1) Services by physicians for companies (e.g. for lecturing, consulting, clinical studies, observational studies) may be provided only on the basis of a written contract in which the service to be performed and the compensation to be provided are clearly stipulated.
- (2) The contractual service to be provided by the respective physician must involve a scientific or technical activity for the company; this also includes activities for training and professional development purposes (prohibition against „fictitious contracts“). No collaboration may be secretly or deceptively misused for the purpose of influencing therapeutic or prescribing or purchasing decisions or for mere promotional purposes.
- (3) Compensation may consist only of money and must be appropriate to the service provided. When assessing appropriateness, the official scale of physicians' fees, among other factors, may provide guidance. Appropriate hourly rates may also be agreed upon to take time spent into account.
- (4) Physicians may also be compensated for reasonable expenditures and fees incurred while rendering services in fulfilment of their contractual obligations.
- (5) Physicians and third parties may not be granted compensation for their willingness to receive pharmaceutical consultants or to receive information from other company employees.

### **§ 18 Non-interventional studies of medicinal products**

- (1) Non-interventional studies, especially including but not limited to observational studies, are scientific studies that analyse findings obtained from the treatment of persons with medicinal products using epidemiological methods and in which the therapy, inclusive of diagnosis and monitoring, is not governed by a pre-defined test plan, but is determined solely by medical practice (§ 4 (23) Sentence 3 AMG).

Non-interventional studies are not clinical studies within the meaning of § 4 (23) Sentence AMG and are therefore do not require approval. However, immediate notification must be submitted to the competent higher federal authority and, if observational studies are involved, also to the National Associations of Statutory Health Insurance Physicians [“Kassenärztliche Bundesvereinigungen”] and the National Association of Statutory Health Insurance Funds [Spitzenverband Bund

der Krankenkassen] (§§ 63 f. para. 1, 67 para. 6 AMG).

- (2) Any non-interventional study that is fully or partly funded by a pharmaceutical company must pursue a scientific objective. All non-interventional studies require a written contract between the company and the partner responsible for conducting the study (clinical institution, physician in private practice). The contract must clearly specify the examinations that are to be performed, the compensation payable and the medical-pharmaceutical benefits of the test results for the funding company.
- (3) § 17 para. 3 applies to the nature and level of compensation payable for non-interventional testing. The compensation must be set so as to not create an incentive to prescribe a certain medicinal product and so that it is not otherwise suitable for influencing decisions relating to therapy, prescribing and/or purchasing.
- (4) The planning, design and implementation of non-interventional studies shall comply with the relevant statutory regulations and, if they constitute observational studies, shall be guided by the recommendations and guidelines of the Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (PEI) as amended from time to time. These recommendations and guidelines are to be understood as binding regulations.
- (5) The principle of non-intervention applies to the entire non-interventional study. This means that the therapy, including diagnosis and monitoring, shall be carried out in accordance with customary medical therapy practice.
- (6) The non-interventional study is not based on an interventional study plan, but on an observation plan that is to be drawn up prior to commencement of the study. The observation plan must be based on routine procedures and enable structured, systematic observation.
- (7) A medicinal product may not be prescribed for the purpose of including a patient in a non-interventional study. The prescription of a medicinal product and inclusion of the patient in a non-interventional test must be kept separate. A patient may therefore not be selected for participation in a non-interventional test until after the therapy has been decided.

### **§ 19 Invitation to professional scientific continuing education events**

- (1) The member companies may invite members of the health professions to their own professional continuing education events, which deal in particular with their research fields, medicinal products and the indications thereof (internal continuing education events).
- (2) Invitees may be remunerated for commensurate travel and accommodation expenses (including a hotel breakfast) as long as the professional scientific nature of the internal continuing education event is the primary objective. Offering reasonable hospitality to participants for such continuing education events is also possible. Entertainment programmes (e.g. theatre, concert, sporting events) for the participants may not be financed or organised. The presence of the participants as well as the programme of the event conducted must be documented.
- (3) Accommodation and hospitality may not exceed an appropriate limit and in particular must be subordinate in importance to the professional scientific purpose of the internal event. The selection of the event location (city or region) and the event venue for internal continuing education events as well as the invitation of members of the health professions to the event must be conducted in accordance with objective standards. For example, the recreational value of the city in which the event will be held is not an objective reason.
- (4) Invitations of members of the health professions to professional continuing education events held by third parties (external continuing education events) may only cover reasonable travel and accommodation expenses (including a hotel breakfast) as well as the enrolment fees charged by the third party if the scientific nature of these events is the primary objective and the company has an objective interest in participating.

Assumption of expenses is permissible only if there is a relationship between the event and both the field of activity of the member company as well as the technical specialty of the event participant.

- (5) Financial support provided to the organisers of external continuing education events for such events is permissible within reasonable limits. Entertainment programmes, however, may not be organised or supported financially or via donations. The member companies that financially support external continuing education events must see to it that the organiser discloses this support both when the event is announced and when it is conducted.

- (6) If the event organiser is a member of the health professions, the type, content and presentation of the continuing education event must be determined solely by this organiser.
- (7) For internal and external continuing education events, an invitation or the assumption of expenses may not be extended to accompanying persons. This also applies to hospitality.
- (8) This code applies to the organisation, implementation and/or support of international events as well as to the invitation and support by companies of participation of members of the health professions in these events.
- (9) The organisation, implementation and/or support for continuing education events outside the EEA (EU and Norway, Liechtenstein, Iceland) and Switzerland or the assumption of expenses for their participants is permissible only if
  1. the majority of participants come from a country other than the country where the member company has its place of domicile
  2. the necessary resources or expertise are available at the location of the event (e.g. recognised medical congresses with international lecturers)and in view of which there are logistical reasons for the selection of a different country for location of the event.
- (10) To the extent members of the health professions hold lectures or provide other services at internal or external continuing education events on behalf of member companies, § 17 shall apply.

## **§ 20 Online information**

Professional information for members of the health professions is in principle also permissible via the Internet as individual online communication (eDetailing).

The precondition is that the modules offered fulfil the characteristics of imparting technical, scientific information and are related to the company's products and their uses or to the research fields of the company. In addition, in individual cases, a prior determination of the willingness of the person addressed to participate is required.

### **§ 21 Gifts**

- (1) In product-related advertising, the limits established in § 7 HWG are to be observed with respect to promotional gifts. To the extent that no other provision is made in § 7 HWG, these gifts must be of "minor value". Promotional statements on promotional gifts other than the name of the company, the company logo or the brand of the company and/or the name of the medicinal product or the designation of its active ingredient are permissible only if they satisfy the mandatory specifications pursuant to § 10.
- (2) Furthermore, within the scope of non-product related advertising, gifts for special occasions (e.g. opening a medical practice, anniversaries) may be granted if they are kept within reasonable limits. No special occasion is required provided the gift is of minor value.

### **§ 22 Donations**

- 1) Donations (monetary or donations in kind) may be made to institutions, organisations or associations of members of the health professions (e.g. hospitals, university hospitals, medical science associations) that provide medical services or conduct research, teach and/or provide continuing education, only if
  - the donations are made within the scope of recognized non-profit purposes and
  - the donations cannot be regarded as influencing therapy, prescribing or purchasing decisions, based on an objective assessment of the circumstances under which they are made, and
  - due and proper documentation of the donations is kept for a minimum of 5 years as from the date on which the donation was made.
- 2) The companies should publish a list of all donations granted to the recipients stated in the above 1) once per annum (no later than 31 March of the following year) if donations made to any one recipient exceed the sum of € 10,000.00 per annum.
- 3) Donations to individual members of the health professions are not permitted.

### **§ 23 Hospitality**

Hospitality is permissible only in conjunction with internal continuing education events, as well as dinners, and within reasonable limits. The occasion of a dinner must be documented. Providing hospitality to accompanying persons is not permitted.

### **§ 24 Contests and prize drawings for members of the health professions**

- (1) Product-related advertising to members of the health professions using contests in which winning is based solely on luck is also not permitted.
- (2) Prize drawings in which participation depends on scientific or technical services or performance by the participating members of the health professions and in which the prospective prize is reasonably proportionate to the scientific or technical performance to be provided by the participants are permissible.

### **§ 25 Collaboration with members of the health professions as officers and/or employees of medical institutions**

When collaborating with members of the health professions who are officers and/or employees of medical institutions, the advisory opinions and recommendations of the "joint position" of the associations must also be taken into account. In service relationships with medical institutions and their employees, the following general principles should be complied with in particular:

1. Service relationships with medical institutions or their employees may not be abused for the purpose of influencing purchasing decisions.
2. Depending on the object of the service relationships and the employment regulations, the contract must be entered into with the medical institution itself or with its employees. If the contract is entered into with the medical institution itself, it establishes the principles of the cooperation via a standing operating procedure. If the contract is entered into with the physician/ employee, the respective company must insist on written confirmation from the medical party to the contract that this person has comprehensively informed his/her principal/employer and the consent from the employer that is normally required has been provided. The information is considered comprehensive only if it discloses those facts that are significant with respect to the relationship between the employee and the company. For documentation reasons, the company may also require the other party to the contract to submit the corresponding written consent of the employer. In the latter case, the provision of the written consent to the company, if so requested, should not be refused.
3. The contractual provisions must be based on legitimate interests of the parties to the contract. In no case may price reductions, discounts etc. be granted through the indirect means of entering into cooperation agreements

in place of commercial transactions. When selecting a contractual party, his/her professional qualifications alone may be used as a determining factor.

4. Performance and compensation must be reasonably proportionate to one another. This aspect should be examined prior to entering into a contract and should be comprehensively documented. The same applies to contract fulfilment and the corresponding work results.
5. Contracts must be entered into in writing. The accounts (including account holders) through which the financing is to be managed are to be specified.
6. Payment of the contractually agreed compensation may be made only if the services due have been properly rendered. It is possible to render payments in advance, for the purpose of an advance payment at the beginning of a research project, for example, if this advance payment is properly offset against the total compensation owed after the conclusion of the project. Payment of the contractually agreed compensation should be in the form of non-cash payments to the bank account stipulated in the respective contract.
7. If the medical institutions or their sponsors are contracting parties and they have issued internal guidelines for collaboration with companies, these must be complied with. If the companies have issued their own guidelines, they must also be complied with.

## 5. **Section: Tasks and training of employees and appointed third parties**

### **§ 26 Qualifications and tasks of the employees**

- (1) The companies must ensure that their pharmaceutical consultants, including the persons involved via contracts with third parties, as well as other representatives of the company, who approach are members of the health professions, hospitals or other institutions of the health industry in connection with advertising for medicinal products are appropriately trained and competent so that they can provide accurate and sufficiently complete information about the medicinal products they present.
- (2) Pharmaceutical consultants must be familiar with the obligations that the companies enter under this code as well as with all applicable statutory regulations. The companies are responsible for ensuring that the pharmaceutical consultants comply with these requirements.

- (3) Other employees of the companies as well as others involved via contracts with third parties, who are involved in the preparation or approval of promotional materials or activities should be familiar with the requirements of the applicable regulations and relevant laws and regulations.
- (4) The pharmaceutical consultants shall forward to their company's science office all information that they receive in connection with the use of this company's medicinal products, in particular reports of side effects.
- (5) Pharmaceutical consultants must ensure that the frequency, length and the manner of their visits to members of the health professions do not unreasonably disrupt practice operations.

#### **§ 27 Tasks and training of employees and appointed third parties**

- (1) The member companies must commit their employees and appointed third parties who are engaged in advertising medicinal products or work with members of the health professions to comply with this code and to ensure compliance with it through suitable organisational measures. This may also include the establishment of the function of "Compliance Officer" for one or several employees.
- (2) The persons named in paragraph 1 must also be informed of the essential principles of the professional code and professional obligations of the members of the health professions. They must also receive training in the content of this code.

### **6. Section: Transparency**

#### **§ 28 Transparency**

Transparency is an indication of fair business practice.

As from 2016, all cash-equivalent benefits in connection with continuing education events pursuant to § 19, any other unilateral benefits and any benefits granted to members of the health professions or health organisations on the basis of reciprocal agreements are to be published in an annual list which is available to the general public, beginning with the data for calendar year 2015. Publication shall comply with the statutory data protection regulations as amended from time to time.

The list is to be broken down into the categories (a) Research and development, (b) Donations and other unilateral cash or non-cash benefits, (c) Cash-equivalent benefits in connection with continuing education events and (d) Service and consultancy fees.

Publication in the research and development category is to be in the form of an aggregated list. Publication in the other categories should generally enable allocation of the entry to individuals. In case of any legal grounds or grounds relating to the individual company which preclude individual publication, publication shall be in the form of an aggregated list.

The list can be published on the company's website and can also take the form of a reference to other publications.

The member companies are entitled to make exceptions for minor benefits. Further details are stated in the "Transparency" guidelines issued by the Board.

§ 22 Para. 2 is unaffected by this section.

## **7. Section: Effective date**

### **§ 29 Effective date**

The code of the members of the AKG enters into force upon its recognition as rules of competition by the Bundeskartellamt under § 24 para. 3 GWB.