FSA Code of Conduct on Transparency in Interactions with Healthcare Professionals and Healthcare Organisations ("FSA Transparency Code")

This is a translation provided by the FSA for service reasons.
Only the German version of the FSA Code is binding.

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Introduction

Companies in the pharmaceutical industry work closely with doctors, pharmacies and other healthcare professionals on a daily basis in a variety of ways. In these working relationships, the latter share their specialist knowledge and medical perspectives with the pharmaceutical industry and other specialist colleagues in order to continuously improve patient treatment through professional exchange. Medical independence and the independence of other healthcare professionals are a particular asset here. Working relationships between healthcare professionals and the pharmaceutical industry are only of great value for research and further development as well as the appropriate selection and use of medicinal products if there can be no doubt about the independence of the expertise and medical views they contribute.

The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." are also of the opinion that these activities must be adequately and fairly remunerated by the industry. At the same time, however, conflicts of interest that may arise from the cooperation between pharmaceutical companies and doctors and other healthcare professionals must be avoided. In order to avoid such conflicts of interest, the association "Frei-willige Selbstkontrolle für die Arzneimittelindustrie e.V." (Voluntary Self-Regulation of the Pharmaceutical Industry) has already adopted the Code of Conduct for the Cooperation of the Pharmaceutical Industry with Physicians, Pharmacists and other Healthcare Professionals ("FSA Code of Conduct for Healthcare Professionals") in the past, as well as guidelines for this purpose, with which this cooperation is aligned to high ethical standards. The industry's self-regulation has thus embarked on a very successful path, which must be further deepened in order to meet society's ever-increasing expectations regarding the transparency of cooperation. All measures to inform the public must be carried out in accordance with applicable data protection law, in particular the protection of personal health data.

The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." are guided by the following ethical guidelines:
[Graphic Ethos]

The association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." is therefore pursuing the goal of making the nature and scope of the cooperation between the member companies and the experts even more transparent. This is intended to avoid the appearance of conflicts of interest from the outset and further improve the general public's understanding of the high value and necessity of cooperation. To this end, the FSA General Assembly has adopted the following

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decided.

In order to take account of the increasing importance of digital health applications (DiGA) in the healthcare of patients, the members of the association have extended the scope of the Code beyond medicinal products to include DiGA.

Section 1: General provisions

§ 1
Area of application

(1) The Code applies to the disclosure of cooperation between member companies and their domestic subsidiaries and other affiliated companies with HCPs and HCOs, provided that the affiliated companies have recognized the binding nature of the Code by means of a separate written agreement. The attribution of violations by affiliated dependent companies that are neither members of the FSA nor have recognized the binding nature of the Code is governed by § 1 (3) of the FSA's Rules of Procedure. The member companies should work towards ensuring that all companies affiliated with them adhere to this Code when carrying out activities within the meaning of paragraph 2 in Germany or with HCPs working professionally in Germany, even if they have not expressly recognized it themselves and the Code is not otherwise binding for them.

(2) The Code is applicable to the recording and disclosure of monetary benefits provided by member companies in connection with prescription-only medicinal products for human use in accordance with § 48 of the German Medicinal Products Act (AMG) or DiGA and to which the FSA Code for Healthcare Professionals also applies as a minimum. This Code is not applicable in connection with the purchase and sale of medicinal products or DiGA within the meaning of § 33a SGB V.

(3) If a member company provides a HCP or an HCO based in a European country other than Germany with cash benefits, the publication of the cash benefit shall be the responsibility of a company operating in this country and affiliated with the member company. In this case, the member company is obliged to forward the information in accordance with §§ 7 and 8 of this Code and all other necessary information to the affiliated company so that this information is published in accordance with the respective National Code. The same applies mutatis mutandis if foreign affiliated companies in Europe provide benefits of monetary value to an HCP based in Germany and working here on a full-time basis. In such cases, the member company must ensure that the information provided to it by the foreign affiliated companies is disclosed in accordance with this Code. If no affiliated companies are available to the member company in the respective country, the member company must perform these tasks itself. In the case of the granting of non-cash benefits to an HCP working full-time in another European country or an HCO based there in connection with DiGA, the member company shall disclose these itself in accordance with this Code if and insofar as neither the statutory provisions of that country nor the respective National Code provide for a disclosure obligation.

§ 2
Definitions

For the purposes of this Code:

1. "Healthcare professionals" (HCPs) are doctors and pharmacists resident or working full-time in Europe as well as all members of the medical, dental, pharmaceutical or other healthcare professions and all other persons who are authorized to prescribe, recommend or administer medicinal products for human use or DiGAs or to trade in them in a permitted manner as part of their professional activities. This also includes employees of public bodies or employees of payers who are responsible at this body for prescribing, procuring, supplying, administering or deciding on the reimbursability of medicinal products or DiGA, as well as employees of member companies who, in addition to their work for the company, work full-time as practicing doctors, pharmacists or other HCPs.

However, all other employees of a member company, wholesaler or other person dealing in medicinal products or DiGA are excluded.

2. "Reporting period" means the annual disclosure cycle under this Code and comprises a full calendar year.

2a. "Digital health applications" or "DiGA" are digital technologies that fall under the term "digital health applications" as defined in § 33a SGB V.

3. "Third parties" are natural or legal persons who represent member companies or who cooperate with other third parties on behalf of a member company or in connection with a medicinal product or a DiGA of the member company, such as distribution partners, wholesalers, consultants, contract research institutes, professional congress organizers, external sales representatives, market research companies, advertising agencies or providers of services in connection with events, public relations or the management of studies.

4. "EFPIA" is the "European Federation of Pharmaceutical Industries and Associations".

5. "EFPIA Code" means the EFPIA Code of Practice as amended on June 27, 2019, including the Annexes, which are expressly designated as binding and form part of this Code.

6. "Recipients" are those HCPs and HCOs to whom monetary benefits are provided that must be disclosed in accordance with this Code. Wholesalers, distributors or dealers of medicinal products or DiGA are not "recipients" within the meaning of this Code.

7. "Europe" refers to the countries in which National Codes of a Member Association are applicable. At the time of the last amendment of this Code, these are the following countries: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom.

8. "Financial support" is the granting of money or non-cash benefits to recipients, provided that this also pursues the company's own company-related objectives of image advertising or public relations work. This includes sponsoring, which also includes the rental of stand space and rooms as part of external training events.

9. "Continuing education events" are specialist and continuing education events as well as congresses, conferences, symposia and similar events on topics from the field of pharmaceutical and medical research and development, on specific clinical pictures and their therapy, on health policy topics or those that serve the professional exchange of experience of HCPs.

10. "FSA" is the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.".

11. "Monetary benefits" are payments (such as consultancy fees) and non-cash benefits (such as services provided by the member company or commissioned agencies). Monetary benefits can be provided directly or indirectly in favor of the recipient. Indirect provision of non-cash benefits occurs when these are not provided directly by the member company but via a third party (such as a contractual partner, an agency, affiliated companies or corporate foundations) for a member company for the benefit of the recipient.

12. "Healthcare organization (HCO)" means all medical or scientific institutions or associations based in Europe that are made up of healthcare professionals (e.g. medical-scientific societies) and / or provide medical services or conduct research through them (e.g. hospitals, university clinics or training and research institutions), regardless of their legal form of organization. This also includes institutions through which healthcare professionals provide services (such as consulting companies), regardless of the legal position or function of the healthcare professionals in these organizations. Organizations within the meaning of this Code do not include "patient self-help organizations" within the meaning of § 2 (21) of the FSA Code of Conduct for Patient Organizations. Independent contract research organizations that are not composed of prescribing healthcare professionals or affiliated with medical institutions (e.g. Clinical Research Organizations ("CRO") are only covered by the Code as HCOs if member companies provide services to recipients within the meaning of the Code via these monetary values (so-called "pass-through costs").

13. "Code" means the FSA Transparency Code.

14. "Expense Contribution" means support that may cover the costs of travel, accommodation (including hotel breakfast, if applicable) and/or registration to enable an individual HCP to participate in an event organized or created by a Member Company and/or a third party. Costs for hospitality are not covered by the cost contribution under this Code.

15. "Market research activities" are the systematic collection and evaluation of information using statistical and analytical methods as a basis for business decisions.

16. "Member companies" are the member companies within the meaning of the FSA Articles of Association as well as their domestic subsidiaries and other affiliated companies (all companies that are part of the same group company as the member company) that have recognized the binding nature of the Code by means of a separate written agreement.

17. "Member association" means an association which is a member of EFPIA and which represents pharmaceutical manufacturers at national level.

18. "National Code" means the code of a member association that implements the relevant provisions of the EFPIA Code.

19 "Personal health data" means any information relating to the physical or mental health or genetic characteristics, inherited or acquired, of an identified or identifiable natural person, including the provision of health care services, from which information on his or her health status is derived[1].

[1] The definition is based on the definitions of "personal data", "genetic data" and "health data" in Art. 4 No. 1, 13 and 15 of the General Data Protection Regulation.

20. "Donations and other benefits" relate to the provision of monetary benefits to HCOs that are provided voluntarily for the purpose of supporting healthcare, scientific research or training, without the recipient being obliged to provide anything in return.

21. "Sponsoring" is the granting of money or non-cash benefits to recipients, provided that this also pursues the company's own company-related objectives of image advertising or public relations work. This also includes the rental of stand space and rooms as part of external training events.

§ 3
Principles of interpretation

When applying this Code, not only the wording of the individual provisions, but also their meaning and purpose as well as the statutory data protection provisions must be observed. When interpreting the Code, care must also be taken to ensure that the focus is on the recognizability of the provision of non-cash benefits to HCPs. In case of doubt, preference should be given to a disclosure of monetary benefits that relates to the allocation of such benefits to individual HCPs (rather than to HCOs).

§ 4
Guidelines of the FSA Executive Board

In addition to the individual cases prescribed in this Code, the FSA may issue binding guidelines on the interpretation of this Code by the Executive Board. The FSA publishes these guidelines on the Internet (www.fsa-pharma.de).

Section 2: Recognition and disclosure of monetary benefits

§ 5
Documentation and disclosure obligations

The member companies must document and publish all payments of monetary value in accordance with § 6 of this Code, which they make directly or indirectly for the benefit of the recipients, in accordance with the provisions of §§ 7-14 of this Code.

§ 6
Categories

The disclosure obligation relates exclusively to monetary benefits in connection with the following categories. Monetary benefits must be documented and disclosed in connection with

1. research and development of medicinal products in connection with the planning and implementation of non-clinical studies (in accordance with the OECD Principles on Good Laboratory Practice), clinical trials of phases I to IV (in accordance with Regulation 536/2014/EU), and non-interventional studies within the meaning of § 19 (1) and (2) of the FSA Code for healthcare professionals;

1a. research and development at DiGA in connection with the planning and conduct of clinical trials within the meaning of Art. 2 No. 45 MDR and other clinical trials within the meaning of § 3 No. 4 MPDG.

2. donations (in cash and in kind) and other contributions;
3. monetary benefits in connection with training events, in particular when supporting the participation of HCPs in training events within the meaning of § 20 of the FSA Code of Professional Conduct (conference or participation fees and assumption of travel and accommodation costs) and other events or in the direct or indirect promotion of HCOs in connection with the preparation, organization or implementation of such events (financial support);
4. service and consultancy fees or other payments by a member company for services provided by an HCP or an HCO on the basis of a contract between them, whereby the contractual services provided by the recipient to the member company may be of any kind, provided they do not already fall under categories 1-3 of this regulation. These fees include remuneration for services, consulting and other contractual services as well as expenses reimbursed in this context (such as travel expenses). Fees for market research activities constitute payments within the meaning of this No., provided that the member company

knows the name of the HCP who directly or indirectly performs these market research activities for the company.

§ 7
Individual and summarized information

(1) The publication must contain individual details for each recipient, stating the name of the recipient (§ 8 para. 1), on the total monetary benefits granted during the reporting period, provided that these benefits fall under the categories of § 6 No. 2 to 4 of this Code.

(2) The publication of the information pursuant to para. 1 shall be subdivided as follows:

1. monetary benefits to individual HCPs:
   a) Contribution to costs in connection with training events:
      (i) Conference or participation fees;
      (ii) Travel and accommodation costs.
   b) Fees for services, consultancy fees and other payments for contractual services provided by HCP, whereby a distinction must be made between remuneration and reimbursement of expenses.

2. monetary benefits to individual HCOs:
   a) Donations (in cash or in kind) and other contributions;
   b) Financial support in connection with training events:
      (i) Conference or participation fees;
      (ii) Financial support from HCO or third parties commissioned by HCO to organize the event;
      (iii) Travel and accommodation costs.
   c) Fees for services, consultancy fees and other payments for contractual services provided by HCO, whereby a distinction must be made between remuneration and reimbursement of expenses.

(3) The publication pursuant to para. 1 and para. 5 can be differentiated according to the categories (i) payments and (ii) non-financial benefits. Member companies are also free to further subdivide the categories mentioned in paragraphs 2 and 3 for the purposes of publication, in particular by publishing the monetary benefits for each individual contractual relationship or event.

(4) If monetary benefits pursuant to § 7 (2) of this Code have been indirectly allocated to an HCP via an HCO, disclosure should only be made once and, if possible, in accordance with § 7 (2) No. 1.

(5) The publication must be summarized (aggregated) and without naming the individual recipients if these benefits fall under the category "research and development" (§ 6 No. 1 or No. 1a). This also includes the reimbursement of expenses for participation in events in connection with research and development activities (such as travel and accommodation costs for investigator meetings in the context of clinical studies).

(6) In addition, those monetary benefits must be published in aggregated form which can be assigned to one of the categories of § 6 nos. 2-4 of this Code, but for which publication by naming individual recipients is not possible for legal reasons. In such cases, monetary benefits must be allocated to the respective categories under § 7 (2) No. 1 and published in aggregated form, whereby the respective total number of recipients as well as their percentage share in relation to all recipients of monetary benefits in this category and the aggregated amounts attributable to the respective category must be stated in detail.

(7) Benefits to independent contract research organizations that are not composed of prescribing HCPs or affiliated with medical institutions (e.g. CROs) only constitute benefits to be disclosed under this Code if member companies provide benefits to other recipients within the meaning of this Code via these monetary values (so-called "pass-through costs").

§ 8
Information about the recipients

(1) When disclosing the information pursuant to § 7 (1) (individual information), the respective recipients must be described in such a way that they can be clearly identified. In particular
1. the full name;
2. the exact practice or business address and
3. the lifelong medical number of the recipient (if available) is disclosed.

(2) Disclosures must be made using the model attached to this Code as Annex 1.

§ 9
Reporting period

(1) The reporting period is the calendar year.

(2) The first reporting period shall cover the 2019 calendar year.

§ 10
Time of disclosure

(1) Disclosure of the information shall be made once a year.

(2) The information must be disclosed no later than 6 months after the end of the reporting period. The report should be published between June 20 and June 30 of the following year. If a member company aims for earlier publication, the disclosure obligations under the FSA Code of Conduct for Patient Organizations must be fulfilled at the same time.

§ 11
Place and duration of disclosure

(1) Disclosure of the information must be made on a publicly accessible website under the responsibility of the member company. The information may also be published on a Europe-wide website of affiliated companies, provided that the information for the member company can be accessed separately there.

(2) By way of derogation from para. 1, the information may also be published via a central external platform provided by a third party.

(3) The information shall be disclosed for a period of at least 3 years after the initial disclosure, unless (i) national regulations or provisions stipulate a shorter period or (ii) the corresponding legal basis under data protection law for the disclosure (e.g. legitimate interest, legal obligation or consent) is no longer applicable or can no longer justify the data storage and / or the disclosure of the data.

§ 12
Language

Disclosure of the information must be made in German. This also applies if a Europe-wide platform is chosen for the disclosure. It is recommended that the disclosures are also made in English.

§ 13
Methodological notes

(1) The member company shall prepare summary notes on the methodology, recording and publication of its disclosures and publish these notes in accordance with § 11 of this Code, whereby the relevant notes shall be published for each reporting period and updated as necessary.

(2) The notes should explain in an easily understandable way how the information is recorded and disclosed. They should show the underlying methodology as well as specific points that are important for the timing and valuation of grants, in particular the treatment of multi-year contracts, VAT and currency issues.

(3) The member companies shall determine the methodology for the collection and publication of the information in accordance with § 3 of the Code at their own discretion.

§ 14
Retention obligations

(1) The member company must document the monetary benefits provided, insofar as they are to be published. The documentation may also be in electronic form.

(2) The documentation shall be kept for at least 5 years after the end of the respective reporting period, unless a shorter period is mandatory for legal reasons.

Section 3: Entry into force

§ 15
Entry into force

The version of the Code adopted by the General Meeting on 20.03.2024 shall enter into force on the same day, but not before it has been acknowledged as competition rules by the Federal Cartel Office in accordance with § 24 (3) GWB.

The Federal Cartel Office acknowledged the Code in the present version as competition rules in its decision of 05.11.2024.