FS Arzneimittelindustrie e.V.

Healthcare Professionals

Code

of Transparency for interaction with Healthcare Professionals and Healthcare Organisations

FSA Arzneimittel-industrie e.V.

To announce code infringements:
www.fs-arzneimittelindustrie.de

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Code of Transparency of the Association of Voluntary Self-Control of the Pharmaceutical Industry (Verein Freiwillige Selbstkontrolle für die Arzneimittelindustrie – FSA) for interaction with Healthcare Professionals and Healthcare Organisations

("FSA Transparency Code")

amended on 27 November 2013
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Introduction

Every day, companies from the pharmaceutical industry interact closely with physicians, pharmacies and other healthcare professionals in many different ways. In these working relationships, they share their expertise and medical insights with the pharmaceutical industry and other professionals with a view to constantly improving the treatment of patients through a process of professional exchange. In this context, medical independence as well as the independence of other healthcare professionals are a particularly valued asset. That is because the working relationships between healthcare professionals and the pharmaceutical industry are only of significant value for conducting research and promoting the development as well as objective selection and use of drugs if the independent nature of the expertise and medical insights they contribute are not in doubt.

The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (FSA) (Voluntary Self-regulation for the Pharmaceutical Industry) moreover believe that these activities must be adequately and fairly remunerated by the industry. At the same time, however, it is important to avoid conflicts of interest that may arise from the interaction of pharmaceutical companies with physicians and other healthcare professionals. To avoid such conflicts of interest, the FSA already in the past adopted a code for the collaboration of the pharmaceutical industry with doctors, pharmacists and other healthcare professionals as well as guidelines relating to such code in order to base such collaboration on high ethical standards. As a result of this, the self-regulation of the industry has achieved a high level of success which must be further promoted to ensure that the steadily rising expectations of society for transparency in such interaction can be met.

The FSA is therefore pursuing the aim of making the nature and scope of interaction amongst the member companies with healthcare professionals even more transparent. This is intended to prevent even the appearance of conflicts of interest and further raise awareness of the general public on just how valuable and necessary such interaction is. For this purpose, the General Assembly of the FSA has adopted the following

Code of Transparency of the Association for the Voluntary Self-regulation for the Pharmaceutical Industry (Verein Freiwillige Selbstkontrolle für die Arzneimittelindustrie – FSA) for interaction with healthcare professionals

("FSA Transparency Code").

Chapter 1: General provisions

§ 1 Area of application

(1) This Code shall govern the disclosure of interaction of the member companies, including their domestic subsidiaries and other affiliates, with healthcare professionals and organisations, provided that the affiliates have acknowledged the FSA Transparency Code ("Code") as binding by way of separate written agreement ("Member Companies" or "Companies"). The accountability for infringements of affiliated dependent companies, which are neither members of the association or have not acknowledged the binding nature of the Code of Conduct, is in accordance with § 1 para. 3 of the "FS-Arzneimittelindustrie" Code of Procedure.

(2) The Code shall be applicable to the recording and disclosure of Transfers of Value of the Member Companies in connection with medicinal products for human use pursuant to section 48 of the German Drugs Act (Arzneimittelgesetz – AMG). This Code shall not apply in connection with the purchase and sale of medicinal products.

§ 2 Definitions

(1) "Healthcare Professionals" shall mean physicians and pharmacists based in Europe and exercising their professional activities there on a full-time basis as well as any member of the medical, dental, pharmacy or other nursing professions or any other person who in the course of his or her professional activities may prescribe or apply or lawfully trade in medicinal products for human use.. These include employees of government agencies or employees of health insurance funds responsible at such agencies for prescribing, procuring, supplying or administering medicinal products or deciding on their eligibility for reimbursement, as well any employee of a Member Company who, besides their work for the Member Company, work on a full-time basis as practising physicians, pharmacists or other Healthcare Professionals, but not those physicians or other Healthcare Professionals who work on a full-time basis for Member Companies.

(2) "Organisations" shall mean, irrespective of their respective legal organisational form, all medical or scientific association or organisation having their seat in Europe which are made up of Healthcare Professionals (e.g. medical-scientific associations) and/or through the latter provide medical services or conduct research (e.g. hospitals, university hospitals or other teaching or research institutions). These also include institutions through which Healthcare Professionals perform services (such as consultancy services), irrespective of what position

or function the Healthcare Professionals assume in these Organisations. Organisations within the meaning of this Code do not include "Patient Organisations" within the meaning of § 2 para. 1 of the FSA-Kodex Patientenorganisationen (FSA Code of Conduct Patient Organisations). Independent contract research institutes which are not composed of prescribing Healthcare Professionals or are connected with medical facilities (e.g. clinical research facilities (CROs)), shall be covered by the Code only if Member Companies provide Transfers of Value to Recipients within the meaning of the Code through such institutions (referred to as "pass-through costs").

(3) "Europe" shall refer to the countries in which a national EFPIA Member Organisation exists. As at the effective date of this Code, EFPIA Member Organisations exist in the following countries: Belgium, Bulgaria, Denmark, Germany, Estonia, Finland, France, Greece, Ireland, Italy, Croatia, Latvia, Lithuania, Malta, the Netherlands, Norway, Austria, Poland, Portugal, Rumania, Russia, Sweden, Switzerland, Serbia, Slovakia, Slovenia, Spain, Czech Republic, Turkey, Ukraine, Hungary, the United Kingdom and Cyprus.

(4) "Recipients" shall mean those Healthcare Professionals and/or Organisations to which Transfers of Value to be disclosed subject to this Code are provided. Wholesalers, distributors or retailers of medicinal products are not "Recipients" within the meaning of this Code.

(5) "Transfers of Values (geldwerte Leistungen)" shall mean payments (such as consultancy fees) as well as benefits in kind (such as services of the Member Company or services of authorised agencies). Transfers of Value may be provided in favour of the Recipient directly or also indirectly. Transfers of Value are provided indirectly if provided not by the Member Company directly but through a third party (for example a contractual partner, agency, affiliates or also company trusts) on behalf of a Member Company in the Recipient's favour.

(6) "Training Events" shall mean events pursuant to § 20 of the FSA-Kodex Fachkreise (FSA Code of Conduct Healthcare Professionals).

(7) "Donations (monetary- or in kind) as well as other unilateral monetary or benefits in kind" shall mean unilateral benefits within the meaning of § 25 of the FSA Code of Conduct Healthcare Professionals.

(8) “Sponsoring” shall mean the grant of cash or benefits in kind to Recipients to the extent that a Company’s own aims of image promotion or public relations work are pursued thereby. This also includes the renting of booth space and premises as part of external Training Events.

(9) “Market Research Activities” shall mean the systematic collection and evaluation of information using statistical and analytical methods as a basis for entrepreneurial decisions.

§ 3 Interpretation principles

When applying the present Code, not only the letter of the individual provisions, but also their spirit and intention as well as the applicable data protection laws shall be observed. It shall moreover be ensured that in the interpretation of the Code paramount importance shall be given to recognisability of the grant of non-cash benefits to Healthcare Professionals. In cases of doubt, preference should be given to disclosure of Transfers of Value whose purpose is to attribute such benefits to individual Healthcare Professionals (instead of to Organisations).

§ 4 Guidelines of the FSA Board of Management

The FSA can also issue through its board of management binding guidelines for the interpretation of this Code, beyond the cases regulated in this Code. The association will publish such guidelines on the internet (www.fs-arzneimittelindustrie.de).

Chapter 2: Recording and disclosure of Transfers of Value

§ 5 Documentation and disclosure obligation

The Member Companies must document and publish, in accordance with the provisions of Sections 7-14 of this Code, all Transfers of Value pursuant to Section 6 of this Code which they provide either directly or indirectly to the Recipients in favour of such Recipients.

§ 6 Categories

The publication requirement shall relate exclusively to Transfers of Value in connection with the categories as set out below. Transfers of Value must thus be documented and disclosed in connection with

1. *Research and development* in connection with the planning and performance of non-clinical studies (subject to the *OECD Principles on Good Laboratory Practice*), Phase I to Phase IV clinical trials (subject to *Directive 2001/20/EC*), and non-interventional studies within the meaning of § 19 of the FSA Code of Conduct Healthcare Professionals;

2. *Donations (monetary- or donations in kind) and other unilateral monetary or benefits in kind;*

3. *Transfers of Value in connection with Training Events*, in particular for supporting participation of Healthcare Professionals in Training Events within the meaning of § 20 of the FSA Code of Conduct Healthcare Professionals (registration fees as well as coverage of travel and accommodation expenses) and other events or for the direct or indirect support of organisations in connection with the preparation, organisation or holding of such events (Sponsoring);

4. *Fees for Service and Consultancy*, it being understood that services and consultancy services provided by the Recipients to the Member Companies may be of any kind, if they do not already fall under Categories 1-3 of this provision. These fees shall include both remuneration of services and consultancy services and the outlays reimbursed in this connection (such as travel expenses). Fees for Market Research Activities shall constitute services or consultancy services to the extent that the name of the Healthcare Professional who performs such Market Research Activities directly or indirectly for the Company is known to the Member Company.

§ 7 Individual and aggregate disclosure

(1) For each individual Recipient the disclosure must contain individual information, specifying the name of the Recipient (§ 8 para. 1), regarding the totality of Transfers of Value granted during the reporting period to the extent such benefits fall under the Categories of § 6 Nos. 2-4 of this Code.

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

1. Transfers of Value to a Healthcare Professional:

   a) Transfers of Value in connection with Training Events:
      (I) Registration fees;
      (II) Travel and accommodation expenses.

   b) Service and consultancy fees, with a distinction to be made between remuneration and reimbursement of outlays

2. Transfers of Value to an Organisation:

   a) Donations (monetary- or donations in kind) and other unilateral monetary or benefits in kind;

   b) Transfers of Value in connection with Training Events:
      (I) Registration fees;
      (II) Sponsoring agreements with Organisations or third parties authorised by the latter to perform the event;
      (III) Travel and accommodation expenses.

   c) Service and consultancy fees, with a distinction to be made between remuneration and reimbursement of outlays.

(3) Publication pursuant to paragraph 1 and paragraph 5 may be differentiated by the headings (i) payments, and (ii) non-financial benefits. The Member Companies shall also be free, for the purposes of the publication, to further subdivide the categories specified in paragraphs 2 and 3, notably by publishing the Transfers of Value for each individual contractual relationship or event.

(4) To the extent that Transfers of Value pursuant to § 7 para. 2 of this Code have been allocated through an Organisation indirectly to a Healthcare Professional, disclosure shall take place only once, where possible subject to § 7 para. 2 No. 1.

(5) The disclosure shall be made on an aggregated basis and without the individual Recipients being named if such benefits fall under the category "Research and development" (§ 6 No. 1). Reimbursement of outlays for participation in events in connection with research and development activities (such as travel and accommodation expenses for investigator meetings as part of clinical trials) shall also fall under this category.

(6) Moreover, those Transfers of Value which can be allocated to one of the Categories of § 6 No. 2-4 of this Code but for which a publication specifying the names of individual Recipients is not possible for legal reasons must be published in aggregated form. In such cases Transfers of Value must be allocated to the respective Categories under § 7 para. 2 No. 1 and published in aggregated form specifically disclosing the respective total number of Recipients as well as their percentage share in relation to all Recipients of Transfers of Value in such category, and the aggregated amounts accounted for by the respective category.

(7) In the event a Member Company grants Transfers of Value to a Healthcare Professional or Organisation not based in Germany but in another European country and exercising its professional activity there on a full-time basis, publication of the Transfers of Value shall be made under the responsibility of a company operating in such country and affiliated with the Member Company. In this case the Member Company shall be required to forward to the company affiliated with it the information pursuant to § 7 and 8 of this Code as well as all other required information so that such information is published subject to the transposing in the respective European country of the EFPIA HCP/HCO Disclosure Code[1]. The same shall apply *mutatis mutandis* in the event that foreign affiliated companies in Europe should grant Transfers of Value to a Healthcare Professional based in Germany and exercising their professional activity here on a full-time basis. In such cases the Member Company is required to ensure that the information disclosed to it by the affiliated foreign company is disclosed in accordance with this Code. If no affiliated companies are available to the Member Company in the respective country, the Member Company shall perform such duties itself.

[1] EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations as of 24 June 2013.

§ 8 Information regarding the Recipients

(1) When disclosing the information pursuant to § 7 para. 1 (Individual information), a description of the respective Recipients ensuring their clear identifiability must be given. In this regard the following information in particular must be disclosed:

1. the full name;

2. the exact practice or business address, and

3. the Recipient's lifelong physician ID (if available).

(2) In a guideline, the board of management of the FSA shall announce standardised models for proper recording of the data to be published. This guideline shall be based on the Schedule 2 model of the EFPIA HCP/HCO Disclosure Code.

§ 9 Reporting period

(1) The reporting period is the calendar year.

(2) The first reporting period shall be calendar year 2015.

§ 10 Time of disclosure

(1) Disclosure of the information shall take place once a year.

(2) Disclosure of the information must take place no later than 6 months from the end of the reporting period.

§ 11 Place and duration of disclosure

(1) Disclosure of the information shall be made on a publicly accessible website under the responsibility of the Member Company. The information may also be published on a pan-European website of affiliated companies if the information relating to the Member Company can be accessed there separately.

(2) In derogation to paragraph 1, a publication of the information may also take place through a centralised external platform made available by a third party

(3) Disclosure of the information must take place for a period of at least 3 years from first-time disclosure unless a shorter period is required on imperative legal grounds.

§ 12 Language

Disclosure of the information shall be made in German. This shall also apply if a pan- European platform is chosen for the disclosure. Disclosure of the information additionally in English is recommended.

§ 13 Methodology

(1) Each Member Company shall prepare a notices summarising the methodology used by it in recording and publishing the disclosures and shall publish such notices subject to Section 11 of this Code. Such notices shall be published and, where applicable, updated for each reporting period.

(2) The notices shall explain in easily comprehensible form how the information is recorded and disclosed. They shall reveal the underlying methodology as well as specific items of significance for the timing and a valuation of the benefits, in particular the treatment of multi-year contracts, VAT and currency aspects.

(3) The Member Companies shall prepare the methodology for recording and publication of the information according to their duly exercised discretion giving due regard to § 3 of the Code.

§ 14 Retention requirements

(1) The Member Company shall document the granted Transfers of Value to the extent these are subject to the disclosure obligation. Documentation may also be made in electronic form.

(2) The documentation shall be retained for a period of at least 5 years from the end of the respective reporting period unless a shorter period is required on imperative legal grounds.

Chapter 3: Effectiveness

§ 15 Effectiveness

The FSA Transparency Code in its version adopted by the general assembly on 27 November 2013 shall take effect on 1 January 2014, but not before being recognised as competition rules by the Federal Cartel Office pursuant to Section 24 (3) of the German Restraints of Competition Act (Gesetz gegen Wettbewerbsbeschränkungen – GWB).

The Federal Cartel Office has acknowledged the FSA Transparency Code in the present version as competitive regulations with decision of 22 May 2014, received on 26 May 2014.

Passed by
FSA members' meeting
on 27 November 2013

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