

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")

Dated on 27 November 2013 (announced in the German Federal Gazette on 18 June 2014, German Federal Gazette AT 18 June 2014 B2),

amended on 4 December 2014 (announced in the German Federal Gazette on 27 May 2015, German Federal Gazette AT 15 June 2015 B4,

amended on 30 October 2018 (announced in the German Federal Gazette on 27 February 2019, German Federal Gazette AT 27 February 2019 B7,

[amended on 14 November 2019 (announced in the German Federal Gazette on 30 March 2020, German Federal Gazette AT 30.03.2020)]

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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, is 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 association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (FSA) (Voluntary Self-Regulation for the Pharmaceutical Industry)" already in the past adopted a code for the interaction of the pharmaceutical industry with doctors, pharmacists and other healthcare professionals ("FSA Code of Conduct Healthcare Professionals") as well as guidelines relating to such code in order to base such interaction 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. All measures to inform the public are to comply with applicable data protection law, in particular with respect to protection of personal health data.

In this, the members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-Regulation for the Pharmaceutical Industry") are guided by the following ethical guidelines:

(IFPMA ethos)

The association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (FSA) (Voluntary Self-Regulation for the Pharmaceutical Industry)" 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

Section 1 Scope

- (1) The Code shall govern the disclosure of interaction of the member companies, including their domestic subsidiaries and other affiliates, with HCPs and HCOs, provided that the affiliates have acknowledged the binding nature of the Code of Conduct in a separate written agreement. The accountability for infringements of affiliated dependent companies, which are neither members of the FSA or have not acknowledged the binding nature of the Code, is in accordance with Section 1 para. 3 of the FSA Code of Procedure. The member companies should work towards ensuring that all their affiliates comply with this Code of Conduct when carrying out activities in Germany within the meaning of paragraph 2 or with healthcare professionals working in Germany, even if they have not expressly acknowledged it themselves and they are otherwise not bound to the Code.
- (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*) and to which at the least the FSA Code of Conduct Healthcare Professionals also applies. This Code shall not apply in connection with the purchase and sale of medicinal products.

- (3) In the event a member company grants transfers of value to HCPs or HCOs not based in Germany but in another European country and exercising their 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 Section 7 and Section 8 of this Code as well as all other required information so that such information is published subject to respective National Code. The same shall apply *mutatis mutandis* in the event that foreign affiliated companies in Europe should grant transfers of value to HCPs 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.

Section 2 Definitions

The following definitions are within the context of the Code:

1. "Healthcare Professionals" or "HCPs" are European-based and full-time physicians and pharmacists, as well as any member of the medical, dental, pharmaceutical or other nursing professions who in the course of their professional activities are authorised to prescribe, recommend or use or lawfully trade in medicinal products for human use. This also includes employees of public authorities or employees of the funders responsible at that body for prescribing, procuring, supplying, administering or deciding on the reimbursement of medicines, as well as employees of the member companies who, in addition to working for the company, practise full-time as physicians, pharmacists or other HCPs. It excludes, however, all other employees of a member company, wholesaler or other person trading with pharmaceuticals.
2. "Reporting period" means the annual disclosure cycle under this Code and covers a full calendar year.

3. "Third parties" are natural or legal persons representing member companies or collaborating with other third parties on behalf of a member company or in connection with a pharmaceutical of the member company, e.g. distribution partners, wholesalers, consultants, contract research institutes, professional convention organisers, external field 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 27 June 2019, including the appendices, which are expressly referred to as binding and form part of the EFPIA Code.
6. "Recipients" are those HCPs and HCOs receiving transfers of value subject to disclosure according to the provisions of this Code. Wholesalers, distributors or retailers of medicinal products are not "recipients" within the meaning of this Code.
7. "Europe" refers to the countries where National Codes of a member association are applicable. At the time this Code of Conduct was last amended, these are the following countries: Belgium, Bosnia and Herzegovina, Bulgaria, Denmark, Germany, Estonia, Finland, France, Greece, Ireland, Iceland, Italy, Croatia, Latvia, Lithuania, Malta, Netherlands, Northern Macedonia, Norway, Austria, Poland, Portugal, Romania, Russia, Sweden, Switzerland, Serbia, Slovakia, Slovenia, Spain, Czech Republic, Turkey, Hungary, Ukraine, United Kingdom, Cyprus.
8. "Financial support" means providing funds or transfers of value to recipients, provided that this also pursues the company's own image advertising or public relations objectives. This includes sponsoring, which also involves the rental of stand space and rooms for external training events.
9. "Events" are professional and educational events, as well as congresses, conferences, symposia, and other similar events in the field of pharmaceutical and medical research and development, dedicated to specific clinical illnesses and their therapy, on health policy topics or such events that serve to promote the professional exchange of HCPs.
10. "FSA" is the Association of Voluntary Self-Regulation for the Pharmaceutical Industry ("Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.").

11. "Transfers of values" are payments (e.g. consulting fees) as well as non-monetary benefits (e.g. services of a member company or payments to contracted agencies). Transfers of values can be rendered directly or indirectly in favour of the recipient. Indirect rendering of transfers of values is where they are not made by the member company but rather are provided by a third party for a member company in favour of the recipient.
12. "Healthcare Organisation (HCO)" means any medical or scientific institution or association based in Europe, irrespective of its legal entity, comprising healthcare professionals (e.g. medical learned societies) and/or provides or conducts medical services or research through them (e.g. hospitals, university clinics or further training and research institutions). This also includes institutions through which HCPs render their services (such as consulting firms), 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 Section 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 as HCOs 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").
13. "Code of Conduct" refers to the FSA Transparency Code.
14. "Contribution to costs" is support that may encompass the costs of hospitality, travel, accommodation (including hotel breakfast, if applicable) and/or registration to enable participation of an individual member of a self-help organisation in an event organised by a member company and/or a third party. Costs for hospitality are not covered by the cost contribution within the scope of this Code.
15. "Market research activities" means the systematic collection and evaluation of information using statistical and analytical methods as a basis for entrepreneurial decisions.
16. "Member companies" are the member companies as defined by the FSA charter and their domestic subsidiaries and the other affiliated companies (all companies that are part of the same corporate group as the member company) that have acknowledged the binding nature of the Code in a separate written agreement.
17. "Member association" means an association which is a member of EFPIA and which represents pharmaceutical companies at the national level.
18. "National Code" means the code of conduct of a member association implementing the relevant provisions of the EFPIA Code.
19. "Personal health data" means any information pertaining to the physical or mental health or to the genetic characteristics inherited or acquired, of an identified or identifiable natural person, including the provision of health services, from

which information concerning their state of health can be derived¹.

20. "Donations and other benefits" relate to the provision of transfers of value to HCOs, made available voluntarily for the purposes of supporting healthcare, scientific research or further training, without the recipient's being obliged to provide a quid pro quo.
21. "Sponsoring" means 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.

Section 3 General principles of interpretation

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 transfers of value to HCPs. In cases of doubt, preference should be given to disclosure of transfers of value whose purpose is to attribute such benefits to individual HCPs (instead of to HCOs).

Section 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 FSA will publish such guidelines on the internet (www.fsa-pharma.de).

¹ The definition is based on the definitions of 'personal data', 'genetic data' and 'health data' in Art. 4 para. 1, 13 and 15 of the General Data Protection Regulation.

Chapter 2: Recording and disclosure of Transfers of Value

Section 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.

Section 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 *Regulation 536/2014/EC*), and non-interventional studies within the meaning of Section 19 para. 1 and 2 of the FSA Code of Conduct Healthcare Professionals;
2. *Donations (monetary- or donations in kind) and other payments;*
3. *Transfers of value in connection with training events*, in particular for supporting participation of HCPs in training events within the meaning of Section 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 HCOs in connection with the preparation, organisation or holding of such events (sponsoring);
4. *Fees for service and consultancy or other payments of a member company* for deliverables rendered by an HCP or an HCO on the basis of a contract between the two, it being understood that contractual 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, consultancy services or other contractual deliverables and the outlays reimbursed in this connection (such as travel expenses). Fees for market research activities shall constitute payments in the context of this provision to the extent that the name of the HCP who performs such market research activities directly or indirectly for the company is known to the member company.

Section 7 Individual and aggregate disclosure

- (1) For each individual recipient the disclosure must contain individual information, specifying the name of the recipient (Section 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 Section 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 HCP:
 - a) Cost contribution in connection with training events:
 - (i) Conference and participation fees;
 - (ii) Travel and accommodation expenses.
 - b) Service, consultancy and other payments for contractual deliverables by HCPs, with a distinction to be made between remuneration and reimbursement of outlays.
 2. Transfers of value to a HCO:
 - a) Donations (monetary- or donations in kind) and other payments;
 - b) Sponsoring in connection with training events:
 - (i) Conference and participation fees;
 - (ii) Financial support by HCOs 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 Section 7 para. 2 of this Code have been allocated through a HCO indirectly to a HCP, disclosure shall take place only once, where possible subject to Section 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" (Section 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 Section 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 Section 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) Payments to independent contract research institutes which are not composed of prescribing HCPs or are connected with medical facilities (e.g. CROs) only constitute payments to be disclosed according to this Code, if member companies provide transfers of value to recipients to other recipients within the meaning of the Code (referred to as "pass-through costs").

Section 8 Information regarding the recipients

- (1) When disclosing the information pursuant to Section 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) The disclosure of information must be made using the sample attached as appendix 1 to this Code.

Section 9 Reporting period

- (1) The reporting period is the calendar year.
- (2) The first reporting period shall be calendar year 2019.

Section 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. The report should be published between 20 and 30 June of the following year. If a member company seeks earlier publication, the disclosure obligations under the FSA Code of Conduct Patient Organisations must be fulfilled at the same time.

Section 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 (i) national rules or regulations require a shorter period or (ii) the relevant legal basis for publication under data protection law (e.g. legitimate interest, legal obligation or consent) is no longer applicable or can no longer justify the storage and/or publication of the data.

Section 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.

Section 13 Methodology

- (1) Each member company shall prepare a notice 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 Section 3 of the Code.

Section 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

Section 15 Effectiveness

The Code in its version adopted by the general assembly on 14 November 2019 shall take effect on the same day, 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 Code in the present version as competitive regulations with decision of 9 March 2020 received on 09.03.2020.

Template (ABC Pharma)												Date of publication: June 30, 2016	
Full Name	HCP's City of Principal Practice/ HCO's city where registered	Country of Principal Practice	Principal Practice Address	Unique country identifier (optional)	Donations and Grants to HCOs § 7 para. 2 No. 5a)	Contribution to costs of Events § 7 para. 2 No. 1 a) (I), (II), § 7 para. 2 No. 2 b) (I), (II), (III)			Fee for service and consultancy § 7 para. 2 No. 1 b), para. 2 No. 2 c)		Total optional		
						Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract			
§ 8 para. 1 No. 1	§ 8 para. 1 No. 2	§ 8 para. 1 No. 2	§ 8 para. 1 No. 2	§ 8 para. 1 No. 3									
Individual named disclosure - one per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)													
Dr. Sample	Sampletown	Sample State	Sample St. 1		N/A	N/A			1 500,00 €				
					N/A	N/A							
HCPs													
Other , not included above - where information cannot be disclosed on an individual basis for legal reasons													
Aggregate amount attributable to transfers of value to such Recipients - § 7 para. 5													
Number of Recipients in aggregate disclosure - § 7 para. 5													
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - § 7 para. 5													
Individual named disclosure - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)													
Sample Clinic	Sampletown	Sample State	Sample St. 2-3		3 000 €								
HCOs													
Other , not included above - where information cannot be disclosed on an individual basis for legal reasons													
Aggregate amount attributable to transfers of value to such Recipients - § 7 para. 5													
Number of Recipients in aggregate disclosure - § 7 para. 5													
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - § 7 para. 5													
Aggregate disclosure													
R&D	Transfers of Value re Research & Development as defined § 7 para. 5										Total amount		

The regulations referred to are those of the FSA-Transparency Code: HCP = Healthcare Professional as laid down in § 2 Section 3 FSA-Transparency Code; HCO = Organisation as laid down in § 2 Section 2 FSA-Transparency Code