FSA Code of Conduct on the Interaction with Healthcare Professionals and Healthcare Organisations ("FSA Code of Conduct HCP HCO")

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

Health is man's greatest asset. Medicinal products make a significant contribution to health and well-being. The research, development, manufacture and distribution of medicinal products place high demands on companies in the pharmaceutical industry. The patient is at the center of efforts to prevent, cure or alleviate the consequences of diseases with effective medicines.

The members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." see it as their task to provide the knowledge required for the proper selection and use of medicinal products by providing accurate and objective scientific information on medicinal products. Medicinal products are technically sophisticated and complex goods that need to be explained in detail. It is therefore one of the indispensable tasks of every pharmaceutical company to communicate all necessary and appropriate information about the significance and properties of medicinal products to healthcare professionals. Not only the possible applications and benefits of medicinal products, but also the limitations and risks of their use should be presented, taking into account the latest findings of medical science.

Furthermore, both the research and development of effective medicinal products is inconceivable without close professional cooperation with doctors, pharmacists and other healthcare professionals. Healthcare professionals support the research and development of new medicines with their independent expertise. They thus make a significant contribution to the pharmaceutical industry's ability to develop innovative medicines and thus improve the health and well-being of patients. At the same time, the trusting relationship between doctor and patient is the basis of every therapy. The treatment decision is the sole responsibility of the medical profession. Pharmacists ensure that appropriate advice is given when dispensing the medicine prescribed by the treating doctor. Any cooperation between the members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V." and healthcare professionals should meet the high standards of integrity that patients, government agencies and other interest groups as well as the public can expect from the pharmaceutical industry.

Advertising is an essential element of the market economy and an expression of intense competition in the pharmaceutical industry. Fair competition should not be restricted by this Code. Rather, the members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (Voluntary Self-Regulation of the Pharmaceutical Industry) adhere to the principle that medicinal products must be advertised appropriately and that unfair practices and conflicts of professional ethics with healthcare professionals must be avoided. All measures in advertising and cooperation with physicians and other healthcare professionals must be within an appropriate framework and within the limits of the applicable laws (including pharmaceutical and competition law, copyright and industrial property rights, anti-corruption laws and data protection laws, in particular for the protection of personal data including personal health data). The principles of separation, transparency, documentation and, in the case of reciprocal services, equivalence, as set out in the "Common Position" of the associations (Common Position of the Associations on the Criminal Law Assessment of Cooperation between Industry, Medical Institutions and their Employees) for the hospital sector, also provide valuable points of reference for cooperation between the pharmaceutical industry and doctors and other healthcare professionals in the private practice sector. The members of the "Voluntary Self-Regulation of the Pharmaceutical Industry" association always strive to maintain the highest ethical standards.

The members of the "Voluntary Self-Regulation of the Pharmaceutical Industry" association are guided by the following ethical guidelines:

[Graphic Ethos]

With the aim of promoting conduct in line with these principles, consolidating the confidence of the general public that the selection of their medicines is based on the benefits of each product and the health needs of patients, and ensuring fair competition in advertising and cooperation with doctors and other healthcare professionals, the General Assembly of the "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." association 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: Scope of application

§ 1
Area of application

(1) The Code applies to member companies as well as their domestic subsidiaries and other affiliated companies, provided that the affiliated companies have recognized the binding nature of the Code in 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. 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 healthcare professionals working in Germany, even if they have not expressly recognized it themselves and the Code is not otherwise binding on them.

(2) The Code applies
1. to product-related advertising for medicinal products within the meaning of § 2 of the German Medicinal Products Act (AMG), as regulated in Section 3 of this Code, if
   a) they are prescription-only medicinal products for human use in accordance with § 48 of the German Medicinal Products Act (AMG) and
   b) the advertising is made to professionals within the meaning of § 2 of this Code and
2. to the cooperation of member companies with HCP in the area of research, development, manufacture and distribution of prescription-only medicinal products for human use, as regulated in Section 4 of this Code.

(2a) The Code shall apply to digital health applications (DiGA) within the meaning of § 2 No. 3a.

(3) The Code does not apply to non-promotional information; for the purposes of this Code, this includes in particular
1. the labeling of a medicinal product as well as the package leaflet or the labeling of a DiGA and the instructions for use;
2. Correspondence and documents that do not serve advertising purposes and that are required to answer a specific inquiry about a specific medicinal product or a specific DiGA;
3. Factual information such as announcements of package changes, warnings about side effects and reference materials (e.g. product catalogs and price lists that do not contain product-specific statements);
4. factual information relating to diseases or human health;
5. Company-related information, e.g. to investors or current or future employees, including financial data, reports on research and development programs and information on regulatory developments affecting the company and its products.

(4) For activities pursuant to paragraph 2 with a cross-border dimension, it must be assessed on a case-by-case basis which codes are to be applied (EFPIA Code and/or a National Code and/or several National Codes). The following principles shall apply:
1. The Code shall apply to any activity pursuant to paragraph 2 that is carried out, financially supported (sponsoring) or organized by or on behalf of a member company. If the activity takes place outside Germany, the National Code of the member association of the country in which the activity takes place shall also apply.
2. In the case of an international training event at which a member company supports the participation of an HCP as described in § 20, the rules of this Code

shall apply with regard to the cost contribution and the rules of this Code, provided that the HCP practises his profession full-time in Germany. If the HCP exercises his profession outside Germany, the National Code of the country in which the HCP works full-time shall also apply.

3. Should the provisions of the Applicable Codes contradict each other, the stricter provisions shall apply. This does not apply to the regulations where the host country principle applies (hospitality).

§ 2
Definitions

For the purposes of this Code:

1. "Healthcare professionals" (HCP) 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 DiGA 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. "Applicable Code" means the EFPIA Code and / or the National Code or the National Codes that apply in accordance with the provisions of this Code, in particular § 1 para. 4.

3. "Medicinal products" are medicinal products within the meaning of § 2 AMG.

3a. "Digital health applications" or "DiGA" are digital technologies that fall under the term "digital health applications" as defined in § 33a SGB V.

4. "Third parties" are natural or legal persons who represent member companies or who work together 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 sales 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.

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

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

7. "Recipients" are all HCPs or HCOs based in Europe and working there full-time.

8. "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, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom.

9. "Financial support" is the granting of money and 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.

10. "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 disease patterns and their treatment, on health policy topics or those that serve the professional exchange of experience between healthcare professionals.

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

12. "Host country principle" refers to the maximum financial limit for hospitality (meals and drinks) set out in a National Code.

13. "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.

14. "Information and training materials" refers to low-value materials that are directly related to the professional practice of HCPs and are directly related to patient care.

15. "International training events" are training events where the company organizing, conducting or supporting the event or its participants is not based in the country where the event is held.

16. "Code" is the FSA Code of Professional Practice.

17. "Cost contribution" is a support that may cover the costs of hospitality, travel, accommodation (including hotel breakfast if applicable) and/or registration to enable an individual HCP to attend an event organized by a member company and/or a third party.

18. "Medical consumables and demonstration items" refer to low-value items that are directly related to the training of HCPs and thus improve the provision of medical services or patient care, but do not replace the usual practice supplies.

18a. "Medical device consultants" are persons within the meaning of § 83 MPDG who professionally inform healthcare professionals within the meaning of § 3 No. 2 MPDG about DiGA or instruct them in the proper handling of DiGA and

who have the necessary expertise and experience within the meaning of § 83 (2) MPDG."

19. "Employees of the member company" are employees or agents who are employed by a member company and who deal with all matters covered by this Code. Employees or agents of third parties who work for the company under a contract with a third party are treated in the same way.

20. "Member companies" are the member companies as defined in 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.

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

22. "Samples" are samples within the meaning of Art. 96 of Directive 2001/83/EC.

23. "National Code" is the code of a member association that implements the relevant provisions of the EFPIA Code.

24. "Non-interventional studies" or "non-interventional trials", which also include observational studies, are prospective studies in which findings are obtained from the treatment of patients with medicinal products in accordance with the information specified in the marketing authorization for its use (e.g. on the safety or efficacy of medicinal products). The principle of non-intervention applies to all therapeutic and diagnostic measures.

25. "Personal data concerning health" 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 healthcare services, which reveal information about their health status[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.

26. "Pharma consultants" are persons within the meaning of § 75 (1) AMG who are commissioned by pharmaceutical companies to visit HCPs on a full-time basis in order to provide them with specialist information on medicinal products and who have the necessary expertise within the meaning of § 75 (2) AMG.

27. "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.

28. "Events" means all professional, promotional, scientific and educational events, all congresses, conferences, symposia and similar events (including advisory board meetings, visits to research or manufacturing sites and planning, training or investigator meetings for clinical trials and non-interventional studies) organized or financially supported by or on behalf of a Member Company.

29. "Venue" refers to the geographical place where an event takes place (e.g. the city, the town).

30. "Venue" means the place where the event takes place (e.g. a hotel or convention center).

31. "Prescription-only medicinal products" are medicinal products for human use which, in accordance with § 48 of the German Medicinal Products Act (AMG) in conjunction with the Ordinance on the Prescription-only Supply of Medicinal Products, may only be supplied to consumers if they have been prescribed by a doctor or dentist.

32. "Advertising" means all measures within the meaning of Art. 86 of Directive 2001/83/EC carried out by or on behalf of a member company. This also applies accordingly to measures relating to DiGA. The measures covered also include those that use digital communication methods and channels, such as websites and social media.

§ 3
Responsibility for the conduct of third parties

(1) The obligations under this Code also apply to companies if they commission third parties to design or carry out the activities covered by this Code on their behalf.

(2) Companies shall also take reasonable steps to ensure that other natural or legal persons with whom they cooperate (e.g. joint venture partners, licensees) also comply with the minimum standards set out in the Applicable Codes.

Section 2: Principles of interpretation

§ 4
General principles of interpretation

(1) When applying this Code, not only the wording of the individual provisions, but also its spirit and intention as well as the applicable laws, in particular the provisions of the AMG, the MDR, the MPDG, the Heilmittelwerbegesetz (HWG), the Gesetz gegen unlauteren Wettbewerb (UWG) and the Strafgesetzbuch (StGB) and the generally recognized principles of HCP professional law must be observed.

(2) The companies must be measured against high ethical standards at all times. In particular, their conduct must not bring the pharmaceutical industry into disrepute, reduce confidence in it or be offensive. In addition, the special nature of medicinal products and DiGA as well as the professional understanding of the professional circles addressed must be taken into account.

§ 5
Advertising

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

1. advertising should enable the professional circles addressed to form their own opinion of the therapeutic value of a medicinal product or the therapeutic benefits and positive health care effects of a DiGA. It must therefore be accurate, balanced, fair, objective and complete enough to give a correct overall impression. It must also be based on an up-to-date evaluation of all relevant evidence and reflect this evidence clearly and concisely.
2. advertising should support the rational use of medicinal products and DiGA by presenting them objectively and without exaggerating their properties.
3. pharmaceutical consultants and medical device consultants must fulfill their duties responsibly and ethically.

§ 6
Cooperation

(1) When applying Section 4 of this Code, the following principles of interpretation in particular must be taken into account:
   1 HCPs may not be unfairly influenced in their treatment, prescription and procurement decisions. It is therefore prohibited to offer, promise or grant them or a third party unfair advantages. In particular, the possible forms of cooperation described in detail in Section 4 below may not be unfairly misused to influence the freedom of HCPs in their treatment, prescription and procurement decisions.
   2. In particular, benefits granted in violation of the provisions of the HWG, the UWG, the StGB or the generally recognized principles of the professional law applicable to HCPs are unfair.

(2) The FSA may also issue binding guidelines on the interpretation of this Code by the Executive Board beyond the cases prescribed in this Code. The FSA shall publish these guidelines on the Internet (www.fsa-pharma.de).

Section 3: Advertising

§ 7
Prohibition of misleading statements

(1) Misleading advertising is not permitted, irrespective of whether the misleading advertising is caused by distortion, exaggeration, special emphasis or omissions or in any other way.

(2) Medicinal products are considered to be misleading in particular if
   1. medicinal products are attributed a therapeutic efficacy, effects or usability that they do not have,
   2. The impression is falsely created that success can be expected with certainty,
   3. false or misleading statements are made about the composition or nature of medicinal products.

(2a) DiGA is considered to be misleading in particular if the advertising
   1. ascribes functions and properties to the product that it does not possess,
   2. gives a false impression regarding the treatment or diagnosis and the functions or properties that the product does not possess,
   3. does not inform the user or patient of the expected risks associated with the use of the product in accordance with its intended purpose,
   4. recommends other uses for the product than those for which it is stated that they are part of the intended purpose for which the conformity assessment was carried out.

(3) When assessing whether the concealment of a fact is misleading, particular account must be taken of its potential to influence the prescribing decision of the healthcare professionals concerned.

(4) Advertising for medicinal products must be sufficiently scientifically substantiated and must not contradict the information in the Information for healthcare professionals. This applies in particular to advertising claims that refer to specific benefits, qualities or properties of a medicinal product or an active substance. Advertising claims about side effects must also reflect all available evidence or be substantiated by clinical experience. Statements that are already contained in the marketing authorization of the medicinal product do not require any further

scientific substantiation. Upon request by HCP, it must be possible to provide the relevant scientific evidence immediately and to an appropriate extent.

(4a) Advertising for DiGA must be sufficiently scientifically substantiated and must not contradict the performance data in the instructions for use and the decision of the BfArM on inclusion in the DiGA directory. This applies in particular to advertising claims that refer to certain advantages, qualities, functions or properties of the DiGA. Advertising claims about side effects must also reflect all available evidence or be substantiated by clinical experience. Statements that are already contained in the instructions for use of the DiGA or that the BfArM has reviewed and positively assessed as part of the procedure for inclusion in the DiGA directory do not require any further scientific validation. Upon request by HCP, it must be possible to provide the relevant scientific evidence directly and to an appropriate extent.

(5) Medicinal products or DiGA may only be described as "safe" if this is scientifically substantiated.

(6) General statements that a medicinal product or a DiGA does not harbor any side effects, toxic hazards or risks of addiction or dependence are inadmissible. Statements that certain side effects, toxic dangers or risks of addiction or dependence have not yet become known are only permissible if they are sufficiently scientifically substantiated.

(7) Medicinal products or DiGA may only be designated as "new" within one year of being placed on the market for the first time, and indications only within one year of their first application.

§ 8
Prohibition of surreptitious advertising / transparency requirement

(1) The promotional character of advertising measures must not be concealed. In particular, clinical evaluations, pharmacovigilance or medical device surveillance measures (in the case of DiGAs) and safety studies (including those of a retrospective nature) after a medicinal product has been authorized or after the DiGA has become marketable in accordance with Art. 5 MDR must not constitute covert advertising.

(2) Advertisements paid for or placed by a company must be designed in such a way that they cannot be confused with independent editorial contributions.

(3) In the case of publications by third parties on medicinal products or DiGA and their use that are financed in whole or in part by a company, care must be taken to ensure that these publications contain a clear reference to the financing by the company.

§ 9
Prohibition of advertising for unauthorized medicinal products and unauthorized indications

(1) Advertising for medicinal products requiring marketing authorization shall only be permitted if these have been authorized. Advertising that refers to indications or pharmaceutical forms that are not covered by the marketing authorization is not permitted.

(2) Unless national laws or regulations provide otherwise, it is permissible to provide information on medicinal products (or their use) that are not authorized or not authorized for this use in the country in which the training event takes place, or to provide information materials or communicate them to the participants in any other

way at an international training event at exhibition stands. However, this only applies if each material is accompanied by a declaration stating in which countries the medicinal product is authorized and also stating that the medicinal product is not authorized nationally or that the indication in question is not covered. Furthermore, the information materials (indication, pharmaceutical form, etc.) must contain explanations indicating that the authorization conditions differ internationally.

§ 10
Mandatory information

(1) All advertising for medicinal products must contain the following information clearly and legibly:
1. the name or company name and registered office of the pharmaceutical entrepreneur,
2. the name of the medicinal product,
3. the composition of the medicinal product pursuant to § 11 (1) sentence 1 No. 6 d) AMG,
4. the areas of application,
5. the contraindications,
6. the side effects,
7. warnings, insofar as they are prescribed for the labeling of containers and outer packaging,
8. the indication "prescription only" and
9. the date of the current status of the information.

(2) In the case of medicinal products containing only one active pharmaceutical ingredient, the indication referred to in paragraph 1 no. 2 shall be followed by the name of this ingredient with the words "active substance"; this shall not apply if the indication referred to in paragraph 1 no. 2 contains the name of the active substance.

(3) The information according to paragraphs 1 and 2 must correspond to that prescribed for the package leaflet according to § 11 AMG.

(4) Paragraphs 1 and 2 shall not apply to reminder advertising. Reminder advertising shall be deemed to exist if it is advertised exclusively with the name of a medicinal product or additionally with the name, company name or trademark of the pharmaceutical entrepreneur or with the active substance as well as with price and quantity information or information on the pack size.

(5) If the pharmaceutical consultant promotes individual medicinal products to HCPs, he/she must submit the relevant expert information. The medical device consultant must submit the respective instructions for use if he/she promotes individual DiGA to the HCP.

§ 11
Reference to publications

Advertising is not permitted if
1. reference is made to scientific, technical or other publications without it being clear from the advertisement whether the publication relates to the medicinal product or the DiGA, the procedure, the treatment, the object or another product itself which is being advertised, and without the name of the author, the date of publication and the reference being stated,
2. quotations, tables, illustrations, other representations or technical statements by third parties taken from scientific publications are not copied verbatim,

unless there is an objectively justified reason for not copying them verbatim. In this case, the modification made must be clearly and recognizably indicated.

§ 12
Comparative advertising

(1) Comparative advertising is any advertising that directly or indirectly makes the medicinal products or DiGA offered by a competitor recognizable .

(2) Comparative advertising that does not objectively refer to one or more essential, relevant, verifiable and typical characteristics of the medicinal products or DIPs being compared is inadmissible.

(3) Comparative advertising must neither be misleading nor disparage or denigrate the medicinal product or the DiGA of a competitor.

§ 13
Unreasonable harassing advertising

(1) Advertising that unreasonably harasses HCPs is not permitted. Unreasonable harassment shall be deemed to exist in particular if advertising is carried out although it is apparent to the advertiser that the addressee does not wish to receive it.

(2) Advertising using fax machines, automatic calling machines or electronic mail is only permitted with the prior express consent of the addressee. The use of electronic mail is not deemed to constitute unreasonable harassment if the company has received the electronic mail address from the HCP as a customer in connection with the sale of a good or service, the company uses the address for direct advertising for its own similar goods or services, the HCP has not objected to the use and the HCP is clearly informed when the address is collected and each time it is used that it can object to the use at any time without incurring any costs other than the transmission costs according to the basic tariffs.

(3) Advertising with a telephone call is only permitted if at least the presumed consent of the recipient has been obtained.

(4) The consent of the advertising addressee may not be obtained by means of enticement or deception, in particular by misleading the identity of the pharmaceutical consultant or medical device consultant or the company represented by them.

(5) Advertising with a message in which the identity of the sender on whose behalf the message is transmitted is concealed or concealed or in which there is no valid address to which the recipient can send a request to stop such messages without incurring any costs other than the transmission costs according to the basic tariffs is not permitted.

(6) Address lists and e-mail address lists may only be used for advertising purposes if the data contained therein is up to date and the relevant data protection regulations are observed. At the request of an HCP, the entry concerning him/her must be removed from the address list and other directories.

§ 14
The “red hand” symbol

(1) For notifications of newly recognized, significant medicinal product-related hazards or for other risk information that should reach the doctor and/or pharmacist immediately if action is required in order to exclude a risk to the patient as far as possible, the symbol of a red hand with the inscription "Important notification about a medicinal product" should be used both on the envelopes and on the letters. When sending a "red hand" letter, all available media can be used and used in accordance with the requirements of a delivery rate that covers as much area as possible. In particularly urgent cases, it may also be necessary to distribute these notifications verbally, by fax or through public appeals, e.g. via the press, radio and television.

(2) A "red hand" letter may not have the character of an advertising mailing or contain advertising statements, either as a whole or in part. Other scientific information, advertisements or promotional mailings may not be marked with the "red hand" symbol or as "Important Notice".

§ 15
Samples

(1) Pharmaceutical companies may only make samples of a medicinal product available to HCPs who may prescribe this product in order to familiarize them with the medicinal product within the framework of § 47 (3) and (4) and § 10 (1) No. 11 AMG.

(2) The submission of samples is limited to a period of two years after the first request by the respective HCP. The period referred to in sentence 1 shall begin again in the case of a new marketing authorization pursuant to § 29 (3) of the German Medicinal Products Act (AMG), a major variation of type II pursuant to Annex II No. 2 letter a) or an extension of the marketing authorization pursuant to Annex I No. 2 of Regulation (EC) No. 1234/2008.

(3) The provision of samples must not be misused as an additional incentive to influence treatment, prescription and procurement decisions.

(4) In the case of medicinal products placed on the market before December 31, 2011, the first sample request of the respective HCP made after December 31, 2011 shall be deemed to be the first request within the meaning of paragraph 2 sentence 1.

(5) Test access for DiGA may be provided to HCPs to enable HCPs to familiarize themselves with the safe, effective and appropriate use and functionality of DiGA. They may be granted under the following conditions:

1. the number of test accesses and the duration of activation must be limited to the extent necessary to take account of the HCP's interest in information. The necessity depends in particular on the frequency of the expected application, the duration of the required information acquisition and the number of HCPs who need to gain experience in using the DiGA.
2. it is not permitted to pass on test access to patients for a fee or free of charge. In particular, the test accesses may not be passed on at the expense of the health insurance companies. The HCP must be informed of this in writing before the test accesses are activated.
3. the provision of test access must not be an inappropriate reward or incentive for the HCP to purchase, lease, recommend, prescribe, use, supply or procure products or services from member companies.

4 If the test accesses are no longer required to fulfill the information and testing purpose, they must be blocked immediately.

5 The number and duration of the activation of the test accesses must be documented.

§ 15a
Scientific information

(1) The member companies may, in compliance with § 6 (1) No. 2 of this Code and in particular § 7 HWG, provide HCP
1. information and training materials. This requires that these materials are of low value, are directly related to the professional practice of the HCP and are directly related to patient care.
2. medical consumables and demonstration items that directly serve the training of HCPs and patient care, provided that these items are of low value and do not replace the usual practice requirements of the recipient. Such items also include low-value software applications (in particular apps) that can support the diagnosis and treatment of patients, provided they relate to products and indication areas of the member company.

(2) For the interpretation of the term "low-value" within the meaning of this provision, the Executive Board of the Association shall issue binding guidelines in accordance with § 6 (2).

(3) The provision of information and training materials as well as medical utensils and demonstration items may not circumvent the ban on gifts pursuant to § 21, nor may it constitute an incentive to prescribe, purchase, supply, recommend or administer a specific medicinal product or to prescribe or recommend DiGA.

(4) Information and training materials as well as medical devices and demonstration items may be labeled with the name of the member company. They may only refer to the name of a medicinal product if this is essential for the correct use of the material or object by the patient.

§ 16
Answering individual inquiries

The detection or treatment of diseases is reserved for doctors. In the event of inquiries relating to an individual therapy situation, the company should advise the enquirer to consult a doctor.

Section 4: Cooperation with HCP and HCO

§ 17
Regulations and recommendations

(1) It is inadmissible to offer, grant or promise HCPs or third parties a fee or any other monetary benefit for prescribing and using a medicinal product or recommending a medicinal product to the patient.

(2) It is inadmissible to offer, grant or promise HCP or third parties a fee or other monetary benefit for prescribing, authorizing or recommending a DiGA to the patient.

§ 18
Contractual cooperation with HCP and HCO

(1) Member companies may only commission HCP or HCO ("Contractual Partner") to provide paid services (e.g. for lecturing, consulting, clinical trials, non-

interventional studies including observational studies, participation in meetings of advisory bodies, the organization of training events or for participation in market research activities) if the agreed services are provided for the purpose of supporting healthcare, research or training. The contractual relationship must also meet the following criteria:

1. the contractual partner and the company must agree on a written contract prior to the commencement of the services, which sets out the services to be provided and the remuneration owed for them
2 Before concluding the contract, the member company must have clearly established and documented a justified need for the services to be provided and for the conclusion of the contract with the contractual partner. The contractual service to be provided by the contractual partner must be a scientific or professional activity for the company, which also includes training purposes (prohibition of "sham contracts").
3 The selection of contractual partners must correspond to the respective requirements. The employee responsible for the selection must have the necessary expertise to make an appropriate assessment.
4. the number of contractors commissioned and the scope of the services to be provided by them must not exceed what is reasonably necessary to fulfill the intended tasks.
5 The company must document the contractual relationship and the services provided. The essential documents must be kept for a period of at least 1 year after termination of the contractual relationship. The company must also use the services provided in an appropriate manner.
6 The remuneration may only be in monetary terms and must be proportionate to the service provided. When assessing appropriateness, the scale of fees for doctors can provide a point of reference. Reasonable hourly rates can also be agreed in order to take into account the time required. The contracting parties may also be reimbursed for reasonable expenses and out-of-pocket expenses incurred in the performance of the contractual services incumbent upon them in accordance with para. 4.
7. the conclusion of contracts may not be misused for the purpose of influencing therapy, prescription and procurement decisions, in the case of DiGA also for the purpose of influencing approval decisions and decisions on the conclusion of contracts by the health insurance funds, or for mere advertising purposes. This also applies to clinical studies and observational studies as well as all other studies or data collection (including retrospective studies).

(2) The companies must oblige their contractual partners to refer to their work for the company in their publications, lectures and other public statements, provided that the subject of the public statement is also the subject of the contractual relationship or any other subject relating to the company. The same applies accordingly to employed medical staff of the company, insofar as they continue to practise their medical profession (as a doctor in private practice or hospital doctor) outside of their work for the company.

(3) The requirements for contractual cooperation set out in § 18 (1) No. 1 and 5 as well as § 18 (2) and the documentation obligations set out in § 18 (1) No. 2 do not apply to the provision of non-recurring, isolated services by HCP in connection with market research activities (e.g. short telephone interviews), provided that the remuneration for these is insignificant. § 24 is also not applicable under these conditions. For the interpretation of the term "minor" within the meaning of this provision, the Executive Board of the Association shall issue binding guidelines in accordance with § 6 (2).

(4) If a contractual partner participates in internal or external training events as part of his contractual activity for the company, the provisions of § 20 shall apply accordingly (e.g. for the selection of the conference venue and/or the conference

location, for the reimbursement of the cost contribution and the prohibition of entertainment and leisure programs). The same applies to the participation of contractual partners in events (such as consultant meetings or participation in investigator meetings for clinical or non-interventional studies).

(5) No remuneration or any other pecuniary benefit may be granted to the contractual partners or third parties for their willingness to receive pharmaceutical consultants or medical device consultants or to receive information from other members of the company. The contractual partners may also not receive remuneration solely for their participation in events within the meaning of § 20.

§ 18a
Transparency in clinical studies

(1) For reasons of transparency, companies must comply with the requirements of § 42b AMG and the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" and the "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature" of IFPMA, EFPIA, JPMA and PhRMA, as amended, for the results of clinical trials in connection with medicinal products.

(2) The same obligation applies to other clinical trials conducted with DiGA within the meaning of § 3 No. 4 MPDG with regard to compliance with the requirements of Art. 77 (5) to (7) MDR and § 64 (3) MPDG.

§ 19
Non-interventional studies

(1) The inclusion and treatment, including diagnosis and monitoring, of patients in non-interventional studies shall not follow a predetermined protocol, but exclusively medical practice. The decision to include a patient in a non-interventional trial must be clearly separated from the decision to prescribe the medicinal product. The data collected must be analyzed using epidemiological methods.

(2) When planning, conducting and evaluating non-interventional studies, all applicable legal regulations as well as the recommendations and guidelines published by the Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (PEI) must be observed. Irrespective of this, the planning, conduct and evaluation of non-interventional studies must also fulfill the following requirements in all cases:

1. the study must pursue a scientific purpose and must not be a covert advertising measure.
2 The planning, management, evaluation and quality assurance of the study must be the responsibility of the head of the medical department (§ 27 (6)) within the company. This also includes budget responsibility.
3 Implementation (e.g. selection of study centers and approaching physicians or other HCPs) and conduct of the study (including support during the duration of the study) must be carried out under the responsibility of the head of the medical department. This also applies if employees from other departments are involved in the implementation and conduct of the study.
4. quality assurance systems are used to ensure the validity and representativeness of the data collected.
5 The study must be based on a written observation plan and a written contract between the HCPs and/or the facilities where the study is conducted on the one hand and the company assuming responsibility as "sponsor" of the study on the other. In particular, the contract must specify the services to be provided and the remuneration owed for them.
6 The company must comply with the notification and documentation obligations under the AMG.

7 The agreed remuneration must be in reasonable proportion to the services to be provided. With regard to the amount of remuneration, § 18 (1) No. 6 applies with the proviso that the remuneration must be calculated in such a way that it does not create an incentive to prescribe a medicinal product. The conduct of the study must also not be misused in any other way to influence treatment, prescription and procurement decisions.

8 If the responsible ethics committee offers advice before the study is conducted, this must be obtained by the scientific study director.

9 Inclusion in the study requires prior written patient consent, insofar as this is required under data protection law. In addition, prior written patient information and consent (regarding the involvement of the study center or the physician or other HCP, the intended involvement of the patients and the intended use of the data to be collected) is recommended.

10 Within 21 days of the start of patient recruitment, information about the intended study (study title, objectives, name of the principal investigator, planned number of study centers and the intended number of cases) must be entered in a publicly accessible register (in accordance with the joint declaration of IFPMA, EFPIA, JPMA and PhRMA on the registration of clinical trials, see § 18a).

11 The study results must be evaluated by the company or by a third party commissioned by the company. The head of the medical department is responsible for the evaluation within the company. A summary of the results must be submitted to the head of the medical department within a reasonable period of time, who must retain the corresponding reports for a period of 10 years. The company must make the summary of results available to all HCPs who participated in the study no later than 12 months after the end of the study (last patient/last visit). Upon request, the summary of the results must be made available to the FSA. The summary of the results of the study must also be made available to the public (e.g. via the Internet) no later than 12 months after its completion. If the study leads to results that are important for the benefit-risk assessment, the summary must also be forwarded to the competent medicinal product authority.

12. pharmaceutical consultants may only be used for administrative purposes in the conduct of the study. They must be deployed under the supervision of the head of the company's medical department (§ 27 para. 6). The use of medical sales representatives in the context of the study may not be combined with promotional activities for medicinal products.

13 The principles and the internal processes to be observed for the planning, implementation and evaluation as well as suitable quality assurance measures (in particular for the verification of the collected data) are to be specified in more detail in the company's own "Standard Operating Procedures". In addition to the legal framework and the recommendations of the BfArM and the PEI, the relevant provisions of the Code must also be implemented.

(3) The companies must observe the criteria specified in para. 2 not only for the non-interventional studies covered by para. 2, but also for other retrospective studies, insofar as these criteria are reasonably applicable to such studies. In any case, the provisions of § 18 shall apply to these studies.

(4) Other clinical investigations within the meaning of § 3 No. 4 MPDG that are conducted with DiGA must fulfill the legal requirements of Art. 82 MDR and §§ 47 to 70 MPDG. In addition, § 19 (2) Nos. 1, 2, 3, 7, 8, 11, 12 (transferred to medical device consultants) and (3) apply accordingly, unless otherwise regulated in the MDR or the MPDG.

§ 20
Invitation to job-related scientific (training) events

(1) The member companies may invite HCPs to their own professional (continuing education) events that deal in particular with their research areas, medicinal products, DiGA and their indications (internal (continuing education) events).

(2) An appropriate contribution to costs may be reimbursed for those invited. Travel and necessary accommodation costs may only be reimbursed if the professional scientific character of the internal (further training) event is clearly in the foreground. Appropriate hospitality for participants is also possible as part of such training events. Entertainment and leisure activities (e.g. theater, concerts, sporting events) for participants may neither be financed nor organized. The attendance of the participants and the program of the event must be documented.

(3) The cost contribution may not exceed a reasonable amount and must be of minor importance, particularly in relation to the professional scientific purpose of the internal event. The selection of the conference venue and the conference location for internal training events and the invitation of HCPs to attend must be based solely on objective considerations. Such a reason is not, for example, the recreational value of the conference venue. Companies should also avoid conference venues that are known for their entertainment value or are considered extravagant.

(4) The invitation of HCP to professional training events of third parties (external training events) may only extend to an appropriate contribution to costs; the costs of hospitality for the participants may not be covered. In addition, the scientific nature of the events must be clearly in the foreground and the company must have an objective interest in participating. A contribution to costs may only be made if the event is related both to the member company's field of activity and to the specialist field of the event participant. Entertainment programs may not be supported directly or indirectly by member companies through participation fees.

(5) The financial support of external training events vis-à-vis the organizers is permitted to an appropriate extent. Entertainment programmes may neither be supported financially or otherwise (e.g. through donations) nor organized. Member companies that provide financial support for external training events must ensure that the support is disclosed by the organizer both when the event is announced and when it is held. In addition, the requirements for internal training events apply accordingly to the financial support of external training events for the selection of the venue, the event location and for catering.

(6) If the event is organized by a physician, the type, content and presentation of the continuing education event must be determined solely by the physician organizer.

(7) The invitation, cost contribution or financial support may not extend to accompanying persons for internal and external training events, unless the HCP concerned is absolutely dependent on support from accompanying persons due to illness or disability.

(8) The organization, implementation and/or support of international training events or the payment of cost contributions for their participants is only permitted if
1. the majority of participants come from a country other than the country in which the member company is based, or
2. the resources or expertise required to achieve the purpose of the event are available at the venue (e.g. in the case of recognized specialist congresses with international speakers),

and in view of this, there are logistical reasons for choosing a venue in another country. In the case of external international continuing education events, "logistical reasons" may speak in favour of choosing a venue abroad if it is an established continuing education event that is organized by a recognized national or international medical-scientific professional society or an association of such professional societies at a location suitable for holding such continuing education events in the country where such a professional society is based (e.g. in the case of joint, historically established events of recognized German-speaking professional societies from Germany, Austria and Switzerland at suitable venues in Austria and Switzerland).

(9) In the case of international training events organized, conducted or supported by a member company, the member company must notify its activities in advance to an affiliated company based in the country of the event venue, if any, or obtain appropriate advice for the proper implementation of these activities. If an affiliated company pays a cost contribution for the participation of an HCP in an international training event, it must also notify in advance the payment of the cost contribution to an affiliated company based in the country in which the HCP is professionally active, if any, or seek appropriate advice for the proper implementation of these activities.

(10) The aforementioned paragraphs apply accordingly to other events.

(11) If HCP gives lectures or provides other services at internal or external training events on behalf of member companies, § 18 shall apply.

(12) For the interpretation of the terms "appropriate", "known for their entertainment value" and "extravagant" within the meaning of this provision, the Executive Board of the Association shall issue binding guidelines in accordance with § 6 (2).

§ 21
Gifts

(1) It is generally not permitted to promise, offer or grant gifts to HCP or employees, members, staff or agents of HCO. This applies regardless of whether it is product-related or non-product-related advertising.

(2) The prohibition described in paragraph 1 shall not apply if the corresponding benefits are otherwise permissible under this Code or if an exception regulated in § 7 (1) sentence 1 Nos. 2 to 5 HWG applies

§ 22
Hospitality

(1) Hospitality is only permitted in the context of internal training events and working lunches and to an appropriate and socially acceptable extent. The occasion of a working lunch must be documented. Hospitality for accompanying persons is not permitted unless this is absolutely necessary to support an HCP (see § 20 (7)).

(2) For the assessment of the appropriateness and social adequacy of hospitality abroad, only the code applicable at the respective event location shall apply (host country principle).

(3) For the interpretation of the term "appropriate" within the meaning of this provision, the Executive Board of the Association shall issue binding guidelines in accordance with § 6 (2).

§ 23
Competitions for HCP

(1) Advertising with competitions in which the prize depends solely on chance is also inadmissible vis-à-vis HCP.

(2) Prize competitions are only permitted if participation depends on a scientific or professional achievement by the participating HCP and the prize offered is in reasonable proportion to the scientific or professional achievement to be provided by the participants.

§ 24
Cooperation with HCPs as public officials and/or employees of medical facilities

When working with HCPs who are public officials and/or employees of medical institutions, the information and recommendations of the "Common Position" of the associations must also be observed.

§ 25
Donations and other contributions to HCO

(1) In addition to compliance with the relevant legal requirements, donations and other contributions to HCO require that such contributions
   1. serve the purposes of healthcare (including, for example, the purposes of research, teaching, education and training) or comparable purposes;
   2. properly documented, with this documentation to be retained for a period of at least 5 years after termination of the contractual relationship; and
   3. not be misused as an incentive to influence treatment, prescription and procurement decisions.

(2) Donations and other benefits to individual HCPs are not permitted.

(3) The support of HCPs for participation in training and further education events is the subject of § 20.

§ 25a
Use of logos and copyrighted materials

(1) The member companies may only use the logo or copyrighted materials of HCO (such as the right to use the logo in publications, product information, on the Internet, in advertising or at events) on the basis of a written contract with them.

(2) Contracts under paragraph 1 must clearly indicate the intended purpose and the nature of the use of the logo or copyrighted materials.

§ 26
Promotion of neutrality

The member companies welcome HCO receiving donations or other contributions from various sources. Member companies may therefore not demand that HCOs grant the respective company exclusivity with regard to support, nor may they allow themselves to be granted such exclusivity unsolicited. This applies accordingly to financial support.

Section 5: Obligation and training of employees and authorized third parties

§ 27
Qualifications and duties of employees

(1) Companies shall ensure that their sales representatives, including those engaged through third party contracts, and other representatives of the company who visit HCPs, hospitals or other HCOs in connection with the promotion of medicinal products or DiGAs, are adequately trained and knowledgeable to provide accurate and sufficiently complete information about the medicinal products or DiGAs they present.

(2) The employees of the member company, in particular pharmaceutical consultants and medical device consultants, must be familiar with the obligations of the companies under this Code and all applicable legal requirements. The companies are responsible for ensuring that their employees, in particular the pharmaceutical consultants, comply with these requirements.

(3) Third parties who support member companies in activities under this Code must also be familiar with the requirements of the applicable rules and relevant laws and regulations.

(4) The persons responsible for the selection of contractual partners within the meaning of § 18 must have the necessary specialist knowledge to be able to assess that they can actually provide the contractual services.

(5) Each enterprise must have a scientific service which is responsible for all information on the medicinal products of this enterprise and which fulfills the personal and professional requirements of § 75 (2) AMG. The companies are free to decide how best to set up and organize the scientific service on the basis of the available resources and organizational structures and to which functional units they assign the following tasks separately or jointly. The scientific service is responsible in particular for ensuring that
   1. the medicinal products are not provided with a misleading name, claim or presentation; and
   2. the labeling, package leaflet, information for healthcare professionals and advertising comply with the content of the marketing authorization.

(6) The head of the medical department is responsible for the correctness and supervision of the non-interventional studies conducted in the company (including the associated companies of pharmaceutical consultants and medical device consultants). This also includes regular and appropriate training of the medical sales representatives or other employees of the member company and contracted third parties deployed for this purpose on the requirements to be observed in accordance with § 19 (2) No. 13. The companies are free to decide how they designate the function of the head of the medical department and what other tasks they entrust him with in individual cases. As a rule, the head of the medical department is also responsible for planning and conducting clinical trials. Under no circumstances, however, may he or she also be responsible for marketing or sales. Instead, a separation of functions must be ensured.

(7) The medical sales representatives and medical device consultants shall pass on to the scientific service of their companies any information they receive in connection with the use of the medicinal products or DiGA of that company, in particular reports on adverse reactions.

(8) Pharma consultants and medical device consultants must ensure that the frequency, duration and manner of their visits to HCPs do not unreasonably interfere with practice operations.

§ 28
Obligation and training of employees and authorized third parties

(1) The member companies shall oblige their employees and commissioned third parties who are active in the area of advertising medicinal products or DiGA or who cooperate with HCP to comply with this Code and to ensure compliance with it through suitable organizational precautions, including the establishment and design of the function of a "Compliance Officer" by one or more employees.

(2) The employees must also be informed about the essential principles of the professional regulations and the professional duties of HCP. They must also be trained in the content of this Code. The Association shall support the member companies through training and advisory measures to expand their knowledge of the Code and its interpretation and to avoid violations of the Code.

Section 6: Transitional provision and entry into force

§ 29
Entry into force

The version of the Code adopted by the General Assembly 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 new version of § 20 (5) comes into force on 01.01.2021.

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