

**Statutes of the association  
Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.  
("Voluntary self-regulation of the the pharmaceutical industry")**

**("FSA Statutes of the Association")**

*This is a translation provided by the FSA for service reasons.  
Only the German version of the FSA Statutes (FSA-Satzung) is binding.*

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## Table of contents

<b>Section 1</b>	<b>General</b>
	§ 1 Name and registered office
	§ 2 Purpose and tasks
<b>Section 2</b>	<b>Membership</b>
	§ 3 Membership
	§ 4 Termination of membership
	§ 5 Membership fee
	§ 6 Duties of the members
<b>Section 3</b>	<b>Executive bodies of the association</b>
	§ 7 Executive bodies
Subsection 1	Management Board
	§ 8 Composition
	§ 9 Election and term of office
	§ 10 Responsibility
	§ 11 Meetings and resolutions
Subsection 2	General meeting
	§ 12 Composition and voting rights
	§ 13 Responsibility
	§ 14 Convening
	§ 15 Resolutions
Subsection 3	Managing directors and committees
	§ 16 Order
	§ 17 Responsibility
	§ 18 Rules of Procedure
	§ 19 Committees
Subsection 4	Advisory Board
	§ 20 Composition
	§ 21 Responsibility
	§ 22 Rules of Procedure
Subsection 5	1st and 2nd instance panels
	§ 23 Composition of the 1st instance panel
	§ 24 Composition of the 2nd instance panel
	§ 25 Duration of the appointment of the members of the 1st and 2nd instance panels
	§ 26 Tasks
	§ 27 Principles of the procedure
	§ 28 Sanction options of the judicial bodies 1. and 2nd instance
	§ 29 Reports on the work of the panels
	§ 30 Rules of procedure
<b>Section 4</b>	<b>Miscellaneous</b>
	§ 31 Duty of confidentiality
	§ 32 Prerequisite for participation in the association
	§ 33 Term of action
<b>Section 5</b>	<b>Resolution</b>
	§ 34 Dissolution

## **Section 1: General**

### **§ 1**

#### **Name and registered office**

- (1) The association bears the name "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." ("FS Arzneimittelindustrie") and is entered in the register of associations.
- (2) The Association has its registered office in Berlin.
- (3) The Association's financial year is the calendar year.

### **§ 2**

#### **Purpose and tasks**

- (1) The purpose of the association is to strengthen the corporate responsibility of the pharmaceutical industry, understood as sustainable corporate responsibility towards all stakeholders. The purpose of the Association shall be fulfilled by establishing and further developing criteria for fairness, in particular in the cooperation of the pharmaceutical industry with healthcare professionals and medical institutions, and by implementing an effective enforcement system for these within the framework of self-regulation. The self-regulation of fairness also extends to the cooperation of the pharmaceutical industry with institutions or employees of the healthcare system and healthcare policy as well as with other ministries, authorities and other public institutions and their employees (these institutions and employees together, "healthcare partners"). To this end, the association's main purpose is to define rules of conduct and to organize and implement voluntary self-regulation of the pharmaceutical industry. This includes, for example, the development of standards and their monitoring (i) with regard to information about medicinal products and their possible uses and the advertising of medicinal products to healthcare professionals, medical institutions and partners in the healthcare system, as well as (ii) with regard to the cooperation of companies in the pharmaceutical industry with healthcare professionals, medical institutions and partners in the healthcare system in the observation of medicinal products currently on the market or in the development of new medicinal products. In particular, the Association will review objectionable conduct by companies in the pharmaceutical industry for its fairness and compatibility with the rules of conduct defined by the Association and with existing statutory provisions and take action against violations.
  - (1a) The Association has also set itself the task of supporting innovative healthcare products, which are increasingly also being developed and marketed by the pharmaceutical industry, from the outset with regard to the integrity of cooperation with healthcare professionals and partners in the healthcare sector, thereby strengthening trust in a permanently efficient healthcare industry and its products. Accordingly, the purposes of the association listed in § 2 (1) also relate to digital health applications within the meaning of § 33a SGB V ("Digital Health Applications"), in particular strengthening corporate responsibility, establishing and further developing criteria for the integrity of cooperation with stakeholders, implementing voluntary self-regulation, etc. This applies both to digital health applications that are already on the market and to those under development. The association is also responsible for reviewing objectionable behavior by the healthcare industry in connection with digital health applications and taking action against violations.
- (2) The Association bases its activities on the Europe-wide standards for ethical pharmaceutical marketing laid down by the European Federation of Pharmaceutical Industries and Associations ("EFPIA"). These standards are laid down in the EFPIA

Code of Conduct. The statutes, codes and rules of procedure of the association must at least comply with the respective binding requirements of the EFPIA. EFPIA's binding requirements include, in particular, the EFPIA Code of Conduct.

- (3) In order to implement the EFPIA Code of Conduct, the association has adopted the "FSA Code of Conduct for Cooperation with Healthcare Professionals" ("FSA Code of Conduct for Healthcare Professionals"), the "FSA Code of Conduct for Cooperation with Patient Self-Help Organizations" ("FSA Code of Conduct for Patient Organizations") and the "FSA Transparency Code". In order to implement the EFPIA Codes and to structure the cooperation with partners in the healthcare sector, the association may define further codes (hereinafter also referred to collectively as "Codes").
- (4) The Association may also organize or arrange for the organization of suitable events, publications and similar measures for the purpose of promoting, complying with and achieving acceptance of the Code of Conduct. The Association shall advise members on the interpretation and implementation of the Codes and the relevant laws as well as on legal policy developments relating to the purpose of the Association. To this end, it offers training courses and seminars in which members are shown possible courses of action on the basis of specific cases from court rulings and case law. The association operates a communication platform for members to exchange information on current developments. Members are appropriately involved in the further development of the codes. The advice of the members does not bind the 1st and 2nd instance courts.
- (5) The association does not pursue any commercial purposes. It serves to promote commercial interests within the meaning of § 13 (1) UWG and § 3 (1) (2) of the Injunctions Act (UKlaG). On this basis, it will also take action against non-members in the event of violations of the law.

## **Section 2: Membership**

### **§ 3 Membership**

- (1) Any company in the pharmaceutical industry based in Germany that markets medicinal products in Germany itself or through affiliated companies may become a member of the Association. In addition, any company that is active in the field of pharmaceutical research or development with the aim of placing medicinal products on the market in Germany in the future, either itself or through affiliated companies, may become a member of the Association.
- (1a) Any company based in Germany that markets digital health applications in Germany itself or through affiliated companies may become a member of the Association. In addition, any company that is active in the field of research and/or development of digital health applications with the aim of marketing digital health applications in Germany itself or through affiliated companies in the future may become a member of the Association.
- (2) All companies in a group that fulfill the membership requirements under § 3 (1) may become members of the Association. Group members who are members of the Association are obliged to ensure that the dependent companies affiliated with them also become members of the Association or submit to its control and sanctioning in writing if these companies also fulfill the membership requirements pursuant to § 3 (1) and place prescription-only medicinal products on the market in Germany.

- (3) The acquisition of membership requires a written application for membership to be submitted to the Executive Board of the Association. The Board of Directors shall decide on an application for membership.

#### **§ 4**

#### **Termination of membership**

- (1) Membership ends
- a) by resignation;
  - b) the member company ceases to exist;
  - c) when it is determined that a condition for acquiring membership no longer applies;
  - d) by exclusion;
  - e) by initiating insolvency proceedings against the member's assets.
- (2) Resignation shall be effected by written declaration to the Association's Executive Board. Resignation may only be declared with a notice period of six months to the end of the calendar year. In the event of pending objection proceedings, the notice period pursuant to sentence 2 shall be extended to the date on which these proceedings are concluded, but for no longer than two years in total.
- (3) The expulsion of a member requires a resolution of the Executive Board, which must have the approval of two thirds of its members. Expulsion may be decided if a member is in arrears with the payment of membership fees or contributions despite two written reminders and the setting of a deadline. Expulsion is also possible if the member has culpably and grossly violated the obligations arising from membership. This is particularly the case in the event of gross violations by the member of the codes adopted by the association and the rules of procedure for the implementation, monitoring and sanctioning of these codes as well as a violation of the obligation arising from § 3 (2) of these Statutes of the Association, as determined by the 2nd instance adjudicating body. The member must be informed of the exclusion by registered letter. The decision shall take effect upon delivery. The member must be given the opportunity to comment before the resolution is passed. The exclusion shall be published on the Association's homepage on the Internet as well as in the Association's annual report and communicated to the association or associations of the pharmaceutical industry to which the member also belongs.
- (4) The cessation of a requirement for the acquisition of membership and thus the termination of membership shall be determined by the Board of Directors by resolution. Paragraph (3) sentences 5 to 7 shall apply accordingly. The member must inform the Board of Directors immediately of the cessation of a requirement for the acquisition of membership.

#### **§ 5**

#### **Membership fee**

- (1) Members are obliged to pay membership fees. Further details are set out in the membership fee regulations.
- (2) In order to finance special projects or to eliminate financial difficulties of the Association, levies of a maximum of EUR 1 million per year may be charged. The total amount shall be allocated to the individual members in accordance with paragraph 1.

## **§ 6 Rights and obligations of members**

- (1) The members are obligated to the association,
  - a) comply with the Statutes of the Association, the Rules of Procedure, the Codes, the resolutions of the General Assembly and other binding provisions of association law;
  - b) to support the association and its bodies in the fulfillment of their tasks;
  - c) to pay the contributions;
  - d) to ensure cooperation with the association so that it can fulfill its tasks in accordance with the purpose of the association in a comprehensive and timely manner
  - e) to participate in all necessary legal acts for the timely implementation of the binding EFPIA requirements, in particular the EFPIA Codes; this also applies if the purpose of the association has to be changed for this purpose.
- (2) Members and their affiliated companies may voluntarily submit to the FSA Code of Conduct for Healthcare Professionals for non-prescription medicinal products.
- (3) Members are also obliged in particular to comply with the statutory provisions on advertising and information for medicinal products and digital health applications as well as other relevant laws including national and international codes that are applicable to the member's activities in Germany.
- (4) Members are entitled to the information and advisory services resulting from the purpose of the Association (§ 2). To this end, seminars and training courses are held for members. In addition, members can obtain individual advice from the Association's office on the application and interpretation of the Association's Codes and related laws and regulations as well as the internal implementation of the Association's Codes. The association operates a communication platform for members to exchange information on current developments. This gives members access to all relevant standards, rulings and court decisions. Members must be appropriately involved in the further development of the standards. Members can and should inform the office in the event of suspected breaches of the rules of conduct laid down by the association in order to enforce the rules of conduct.

### **Section 3: Executive Bodies of the Association**

#### **§ 7 Executive bodies**

- (1) The bodies of the Association are the Executive Board, the General Assembly, the Advisory Board, the 1st and 2nd instance panels and the Managing Director.
- (2) The liability of the association for culpable actions of its bodies in accordance with § 31 BGB is limited to intent vis-à-vis the members of the association.

#### **Subsection 1: Executive Board**

#### **§ 8 Composition**

The Executive Board of the association within the meaning of § 26 BGB consists of the Chairperson, the Deputy Chairperson(s) and a minimum of four and a maximum of 12

other members of the Executive Board. The General Assembly shall decide on the specific number of Board members within the framework of the requirements of sentence 1.

## **§ 9 Election and term of office**

- (1) The members of the Executive Board are elected by the General Assembly.
- (2) The term of office of the Board of Directors is three years. It shall correspond to the calendar years and begin on January 1 of each year. The previous Management Board shall remain in office until the term of office of the new Management Board has begun. This does not apply to individual members of the Management Board if they resign from office in accordance with § 32 (1).
- (3) The members of the Board of Directors elect the Chairman and his deputy(s) from among their number.

## **§ 10 Responsibility**

- (1) The association is represented in and out of court by two members of the Executive Board. If the Executive Board wishes to conclude legal transactions with an object value of more than EUR 100,000.00, it requires the approval of the General Assembly. This approval can also be granted by approving a budget. This approval is not required for the investment of the Association's liquid funds until they are used in accordance with the budget.
- (2) The Board of Directors is responsible for all matters of the Association, unless they are assigned to another body of the Association by law or by these Statutes of the Association.
- (3) The Executive Board is responsible in particular for
  - a) Appointment and dismissal of the managing director and any other deputy managing directors or other members of the court of first instance;
  - b) issuing rules of procedure for the work of the Executive Board, the office and the Advisory Board;
  - c) Formation of committees;
  - d) Determination of the loss of membership;
  - e) preparing and convening the General Assembly and drawing up the agenda;
  - f) implementation of resolutions of the General Assembly;
  - g) passing resolutions on the admission and expulsion of members as well as determining the cessation of membership requirements;
  - h) Presentation of the Association's budget, the annual financial statements and the annual report to the General Assembly;
  - i) Issuing instructions to the managing director and the deputy managing directors, insofar as these do not relate to their function as the court of first instance;
  - j) issuing business distribution plans, from which the responsibilities for the 1st and 2nd instance panels are derived;
  - k) making proposals to the General Assembly for the establishment, creation, amendment or supplementation of the Association's codes;
  - l) Proposals to the General Assembly for the creation, amendment or supplementation of rules of procedure for the implementation, monitoring and sanctioning of the codes established by the Association;
  - m) Issuing interpretative guidelines to clarify undefined legal terms in the Codes.
- (4) The Executive Board is authorized to make amendments to the Statutes of the Association, the Codes and the Rules of Procedure that become necessary due to

requirements of the Register of Associations or the Federal Cartel Office. This also applies to changes to the purpose of the association. In addition, the Executive Board may also submit the subject of the respective amendment to the General Assembly for resolution.

- (5) The decisions of the Executive Board are made in the form of resolutions.

## **§ 11 Meetings and resolutions**

- (1) The Board of Directors makes decisions in meetings or telephone conferences, which are convened by the Chairman or, if he is unable to do so, by a deputy. The notice period shall be at least two weeks. The agenda should be attached to the invitation. In urgent cases, the notice period may be shortened. Members of the Board of Directors may also participate in a meeting by joining in by telephone.
- (2) The Board of Directors is quorate if at least half of its members participate in the passing of resolutions. Unless otherwise provided, the Board of Directors shall decide by a majority of the votes cast. In the event of a tie, the Chairman shall have the casting vote. The admission or exclusion of a member requires a two-thirds majority of the members of the Board of Directors. Absent members of the Board of Directors may participate in the decision-making process by having their written votes submitted by members who are present.
- (3) The Board of Directors may pass resolutions by written procedure if two thirds of the members of the Board of Directors agree to this procedure. Sentences 2 to 4 of paragraph 2 apply accordingly.
- (4) The Managing Director and, by resolution of the Board of Directors, Deputy Managing Directors and other employees of the office are obliged to attend meetings of the Board of Directors.
- (5) A record of the results of each Board meeting must be drawn up and signed by the Chairman.

## **Subsection 2: General Assembly**

### **§ 12 Composition and voting rights**

- (1) All members of the Association form the General Assembly. Rights are exercised by representatives of the members who are authorized in writing. Representatives may only be persons who are working in the respective member company on the basis of an employment contract at the time of the General Assembly. § 15 (4) remains unaffected.
- (2) Each EUR 1,000.00 annual membership fee calculated in accordance with § 5 or the membership fee regulations grants one vote. § 2 (2) of the membership fee regulations shall not apply in this context. If several dependent companies in a group are members of the association, the group parent company may also pay the annual membership fee for the dependent companies. In this case, the group parent company shall exercise the voting rights for the dependent companies to the extent that and for as long as no dependent company objects to the exercise of voting rights vis-à-vis the association. When the association member objects, the annual turnover of the objecting member relevant for the calculation of the fee must be communicated. The voting rights to which the objecting member is entitled are deducted from the voting rights of the group parent company.



### **§ 13 Responsibility**

- (1) The General Assembly only decides on matters that are assigned to it by law or by these Statutes of the Association.
- (2) The General Assembly is responsible in particular for the following matters:
  - a) Dissolution of the association;
  - b) Amendment of the Statutes of the Association;
  - c) Approval of the budget;
  - d) Determination of admission fees, annual contributions and levies;
  - e) Discharge of the Board of Directors and the Managing Director;
  - f) Acceptance of the annual report;
  - g) Adoption of the annual financial statements;
  - h) appointment of the auditors;
  - i) Election and dismissal of the members of the Executive Board;
  - j) Defining, amending and supplementing the association's codes;
  - k) Establishing, amending and supplementing rules of procedure for the implementation, monitoring and sanctioning of the codes established by the association.

### **§ 14 Convocation**

- (1) The ordinary General Assembly of Members shall meet once per financial year. If possible, it should take place in the 4th quarter.
- (2) Extraordinary General Assemblies may be convened at any time for special reasons by resolution of the Board of Directors or at the request of at least a quarter of the votes of the members of the Association.
- (3) The General Assembly is convened in writing by the Chairman of the Board of Directors or, if he is unable to do so, by his deputy.
- (4) The invitation must state the place, day and hour of the General Assembly as well as the agenda.
- (5) Any member may submit a written request to the Executive Board to add items to the agenda no later than one week before the General Assembly. The chairman of the meeting must announce the addition at the beginning of the General Assembly. The General Assembly shall decide on motions and additions to the agenda that are not submitted until the General Assembly.
- (6) There should be 30 days, but no less than 20 days, between the date on which the invitation is sent and the date of the meeting. In particularly urgent cases, the invitation period for extraordinary General Assemblies may be shortened to up to three days.

### **§ 15 Resolutions**

- (1) The General Assembly is chaired by the Chairman of the Board of Directors or, if he is unable to attend, by his deputy or, if he is unable to attend, by another member of the Board of Directors present. The order of precedence is based on the length of membership of the Board of Directors and, in the case of equal length of membership, on age. If no member of the Management Board is present, the meeting shall appoint the chairperson by resolution.

- (2) The chairman of the meeting determines the order and type of voting. Votes are always conducted openly. Voting shall be conducted in writing and by secret ballot if one third of the votes of the members present so request.
- (3) The General Assembly constitutes a quorum if at least two thirds of the votes of all members are represented. If there is no quorum, the Board of Directors is obliged to convene a second General Assembly with the same agenda within four weeks; this shall constitute a quorum regardless of the number of votes represented. This must be indicated in the invitation.
- (4) Absent members may be represented in the passing of resolutions if they (i) have written votes submitted by members present at the General Assembly or (ii) submit written votes to the Association prior to the passing of the resolution. For the respective resolution, the written votes are to be taken into account as votes of members present for the determination of the majority requirements for this resolution.
- (5) With the consent of two thirds of the votes of all members, resolutions may also be passed by written vote. Insofar as reference is made in these Statutes of the Association to the members present with regard to the majority required for the passing of resolutions, the members who participated in the vote on the consent pursuant to sentence 1 for the passing of resolutions by written ballot shall be taken as the basis for the written ballot instead of the members present.
- (6) Unless otherwise stipulated in the Statutes of the Association, a simple majority of the valid votes cast shall be decisive in voting.
- (7) A resolution to amend the Statutes of the Association, the Rules of Procedure and the Membership Fee Regulations and the Codes of the Association requires a majority of three quarters of the votes of all members present. This also applies to changes to the purpose of the Association. All changes, including changes to the purpose of the Association, which are made on the basis of binding EFPIA requirements, require only a simple majority of all members present.
- (8) Members of the Executive Board and the Managing Director are obliged to attend the General Assembly unless the General Assembly decides otherwise.
- (9) The members of the Advisory Board have the right to participate in the General Assembly without voting rights. They also have the right to submit motions and to comment on items on the agenda.
- (10) The resolutions of the General Assembly shall be recorded in minutes, which shall be signed by the chairperson of the meeting.

### **Subsection 3: Managing directors and committees**

#### **§ 16 order**

The Managing Director is appointed by the Management Board.

#### **§ 17 Responsibility**

- (1) The Managing Director manages the business of the Association within the scope of the tasks and powers or instructions assigned to him/her by the General Assembly or the Executive Board. He is a special representative within the meaning of § 30

BGB. The activities of the Managing Director include, in particular, the management of the business involved in the day-to-day administration of the Association, including the conclusion of legal transactions with a volume of no more than EUR 50,000.00 each.

- (2) The Managing Director shall make use of an office to carry out his duties. Employees of the office may attend the General Assembly and the meeting of the Board of Directors in an advisory capacity if the Board of Directors so decides.
- (3) The managing director is also responsible for advising member companies on code-compliant conduct when working with healthcare professionals, patient organizations and healthcare facilities and their employees (e.g. through training courses, information events, etc.).
- (4) The managing director can also perform the function of a 1st instance adjudicating body (§ 23). In this function, he is not bound by instructions or the result of a prior consultation with the members of the association. The chairman of a first-instance panel may represent the association in the event of complaints about breaches of competition law and their legal prosecution. In any case, legal action may also be taken by the managing director.
- (5) The managing director may also take action on behalf of the Association against companies that sell prescription-only medicinal products or digital health applications and are not members of the Association if they have unfairly violated the existing statutory provisions or the competition rules applicable to them in their advertising for medicinal products or digital health applications or in related areas when cooperating with healthcare professionals or medical institutions. Such violations will also be prosecuted by the association and its managing director, unless the companies concerned undertake to refrain from doing so in a form that is punishable by law.

## **§ 18 Rules of procedure**

The Board of Directors may adopt rules of procedure for the conduct of business and the work of the office.

## **§ 19 Committees**

- (1) The Board of Directors may set up committees to provide expert advice and prepare opinions and decisions.
- (2) The number and tasks of the committees shall be determined by the Executive Board.
- (3) The term of office of the committees is two years. This period should coincide with the term of office of the Board of Directors.
- (4) The Executive Board decides on the composition of the committees based on proposals from the members.
- (5) The Board of Directors may issue uniform guidelines for the work, appointment and composition of the committees.

#### **Subsection 4: Advisory Board**

##### **§ 20 Composition**

- (1) As soon as an association of the pharmaceutical industry has committed its members to membership in the association in its Statutes of the association, an advisory board shall be formed.
- (2) All pharmaceutical industry associations that have committed their members to membership in the Association in their statutes shall each send one representative to this committee. The rights of the representative of an association of the pharmaceutical industry may also be exercised by a representative of the representative authorized in writing.

##### **§ 21 Responsibility**

- (1) If an Advisory Board exists, it shall advise the Executive Board. The approval of three quarters of the members of the Advisory Board is required in cases in which the Statutes of the Association, the Association's Codes or the procedural regulations for implementation, monitoring and sanctioning are to be amended or supplemented.
- (2) The approval of the Advisory Board is not required in the case of amendments to the Statutes of the Association, the Codes or the Rules of Procedure that are required by courts, supervisory or financial authorities for formal reasons or are implemented by the binding requirements of EFPIA.
- (3) The Advisory Board must be informed by the Executive Board of its resolutions.

##### **§ 22 Rules of procedure**

The Board of Directors may adopt rules of procedure for the meetings of the Advisory Board.

#### **Subsection 5: 1st and 2nd instance panels**

##### **§ 23 Composition of the 1st instance panel**

The court of first instance may consist of the managing director, deputy managing directors or third parties. The Managing Director, Deputy Managing Director or third parties are appointed by the Management Board. If several persons are entrusted by the Board of Directors to act as the 1st instance panel, they shall each form their own 1st instance panel. In this case, the Board of Directors shall issue a schedule of responsibilities from which the exact responsibilities are derived.

##### **§ 24 Composition of the 2nd instance panel**

- (1) The 2nd instance panel is made up of the chairperson and at least eight and no more than twelve other persons. Half of these further persons must be company employees of the members of the Association, a quarter must be representatives of the medical profession and a further quarter representatives of the patients.

- (2) The Executive Board determines the number of members of the 2nd instance panel and appoints the members of the 2nd instance panel in accordance with the provisions of § 24 (1). The chairperson of the 2nd instance panel must be qualified to hold the office of judge and may not work for a member of the Association or another company in the pharmaceutical industry or in the field of digital health applications (neutrality). The persons representing the medical profession must have a license to practice medicine. The appointment of physician and patient representatives should be based on proposals from physician and patient organizations.
- (3) The Executive Board shall appoint a member of the 2nd instance panel as deputy chairman.
- (4) The Board of Directors may appoint one or more deputies for each member of the 2nd instance panel. Depending on the business volume of the 2nd instance panel, the Board of Directors may establish additional 2nd instance panels as chambers with corresponding appointments. The Board of Directors shall adopt a schedule of responsibilities, from which the responsibilities of the individual chambers and the deputies in the event of incapacity or bias are determined.
- (5) If a member of the 2nd instance panel is prevented from attending at short notice, the 2nd instance panel may decide without the member concerned, but with at least seven members, by decision of the chairperson.

## **§ 25**

### **Duration and appointment of the members of the 1st and 2nd instance panels**

- (1) The member or members of the 1st instance panel shall be appointed for a period of two to five years. At the end of this period, a new appointment shall be made.
- (2) The members of the 2nd instance panel are appointed by the Executive Board for a period of two years. At the end of this period, a new appointment shall be made.
- (3) Members of the 1st and 2nd instance panels may only be dismissed by the Executive Board with immediate effect for good cause during the period of their appointment.

## **§ 26**

### **Tasks**

- (1) The 1st and 2nd instance panels shall monitor and sanction the conduct of the members of the Association and the affiliated companies within the meaning of § 3 (2) with regard to compliance with the codes laid down by the Association. The 1st and 2nd instance panels are not bound by instructions or by the results of the member companies' deliberations.
- (2) In the event of a violation of one of the Association's codes by an affiliated company within the meaning of § 3 para. 2 ("Code Violation"), this conduct shall be attributed to the controlling member of the Association over this company, insofar as the affiliated company is neither itself a member of the Association nor has submitted to its control and sanctioning in writing. In multi-level groups, attribution is made to the next higher controlling company that is itself a member of the association or has submitted to its control and sanctioning in writing. Attribution is also made in the event of a culpable breach of the Code by employees or vicarious agents of the companies concerned who are not directors or officers of these companies.

- (3) The 1st instance panel is responsible for all complaints in the first instance, unless the 2nd instance panel has jurisdiction.
- (4) The 2nd instance panel is responsible for repeated violations of the same type (three violations within two years) and for deciding on appeals against decisions and complaints about inactivity on the part of the 1st instance panel.

## **§ 27**

### **Principles of the procedure**

- (1) Anyone can complain about non-compliance with the association's codes. Anonymous complaints due to violations of the provisions of Section 3 of the FSA Code of Professional Conduct will not be pursued, with the exception of § 27 (2).
- (2) The Board of Directors and the Management Board may also initiate complaint proceedings independently of each other. This also applies if the complaint procedure initiated by the Board of Directors or the Management Board is based on an anonymous complaint (§ 27 (1) sentence 2).
- (3) The procedure to be observed by the 1st and 2nd instance panels when monitoring and sanctioning violations of the Code should adequately protect the rights of the complainant and the members affected by a complaint, in particular by granting a right to be heard, providing for a review of decisions of the 1st instance panel by the 2nd instance panel and also the possibility of reopening completed complaint proceedings.
- (4) Procedural measures and decisions cannot be appealed separately, but only in connection with the appeal against the final decision of the court of first instance.

## **§ 28**

### **Sanction options of the 1st and 2nd instance panels**

- (1) In the event of justified complaints, the 1st instance panel shall demand a cease-and-desist declaration with penalty clause from the member concerned or the subject company. If the member or the subject company refuses to submit such a cease-and-desist declaration, the proceedings shall be continued before the 1st instance panel. If the complaint proves to be well-founded in these proceedings, the first-instance panel shall issue a decision finding a breach of the Code. This finding shall be combined with the obligation of the member or the subject company to refrain from the conduct complained of in the future and to pay a fine to the association for a repeated violation.
- (2) Violations of the Code shall also be punished with a fine of at least EUR 5,000.00 up to 20 times the contribution of the member concerned, but no more than EUR 400,000.00. If a member does not pay a contribution in accordance with § 5, the calculation of the upper limit shall be based on the turnover achieved by this company with non-prescription medicines and digital health applications. In addition, a public reprimand may be issued in the event of violations of the Code, in particular in the event of violations of the Code contrary to the obligation imposed by the court of first instance to refrain from future conduct that has already been objected to. The fine will be imposed in favor of a charitable institution. The beneficiary organization must be named in the decision.
- (3) The liability of the association, its bodies and members of its bodies shall be governed by § 839 (2) and (3) of the German Civil Code (BGB) in the case of decisions by the courts of first and second instance and is otherwise excluded. Liability for intentional acts remains unaffected.

## **§ 29**

### **Reports on the work of the panels**

- (1) The Managing Director will regularly report to the Executive Board, the members and the Advisory Board on the complaints dealt with by the 1st and 2nd instance panels.
- (2) In addition, at the end of February of each new calendar year, the Managing Director submits a detailed report on the work of the panels in the previous calendar year, which summarizes the activities of the panels in all proceedings. All cease-and-desist declarations and all legally established violations of the Code are published, stating the name of the member concerned. In the case of inadmissible or unfounded complaints, publication will take place if the respective adjudicating body approves publication in view of the significance of the decision, but without mentioning the name of the member. The names of employees of affected members or other persons involved or other companies, organizations, etc. must be made anonymous.

## **§ 30**

### **Rules of procedure**

- (1) The General Assembly shall adopt rules of procedure for the implementation and sanctioning of the codes laid down by the Association, which shall set out in more detail the principles of procedure and sanctions laid down in this subsection of the Statutes of the Association and also define responsibilities in the event of bias on the part of members of the 1st and 2nd instance panels.
- (2) In accordance with the rules of procedure adopted on the basis of the authorization in paragraph 1, procedural fees of up to EUR 10,000.00 per fee item and the reimbursement of expenses may also be regulated.

## **Section 4: Miscellaneous**

## **§ 31**

### **Duty of confidentiality**

The members of the bodies of the Association, the members of committees and the employees of the Association, including the Managing Director and his deputies, are obliged to maintain confidentiality about all processes that are confidential by nature or are expressly designated as such. Insofar as persons other than those named in sentence 1 are involved in the work of the Association, they must be obliged to maintain confidentiality before commencing their activities.

## **§ 32**

### **Prerequisite for participation in the association**

- (1) With the exception of the managing director, his deputies and the employees of the administrative office, the members of the 1st and 2nd instance panels and the members of the Advisory Board, only persons who work full-time for a member or a company affiliated with a member on the basis of an employment contract may participate in the bodies of the association and its committees. This right expires with immediate effect as soon as the person ceases to work for the member to which they belonged at the time of their appointment. § 24 remains unaffected.
- (2) The Executive Board, the Managing Director, his deputy or the chairperson of a committee or panel may consult external experts on justified individual issues.

**§ 33**  
**Time limit for action**

The deadline for legal action against resolutions or other measures of the association's bodies is one month. The period for taking legal action begins on the day the resolution or measure is passed.

**Section 5: Resolution**

**§ 34**  
**Dissolution**

- (1) The resolution to dissolve the association shall be passed at a General Assembly convened specifically for this purpose. The resolution requires the approval of three quarters of all votes of the members of the Association.
- (2) Unless the General Assembly decides otherwise, the Chairman and his deputy are jointly authorized liquidators.
- (3) If the association is dissolved, its assets shall revert to the members of the association.

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