

**Statutes of the Association  
"Freiwillige Selbstkontrolle  
für die Arzneimittelindustrie e.V."**

**("FS Arzneimittelindustrie" Statutes)**

**Version from 15 November 2016**

<b>Contents</b>	<b>Page</b>
<b>Section 1: General points</b>	4
Clause 1 Name and registered office	4
Clause 2 Object and duties	4
<b>Section 2: Membership</b>	5
Clause 3 Membership	5
Clause 4 Cessation of membership	6
Clause 5 Membership subscription [fees]	7
Clause 6 Rights and obligations of members	7
<b>Section 3: Executive bodies of the Association</b>	9
Clause 7 Executive bodies	9
<u>Subsection 1: Board of Management</u>	
Clause 8 Composition	9
Clause 9 Election and term of office	9
Clause 10 Responsibility	9
Clause 11 Meetings and resolutions	11
<u>Subsection 2: General Meeting</u>	
Clause 12 Composition and voting rights	11
Clause 13 Responsibility	12
Clause 14 Convening meetings	13
Clause 15 Resolutions	13
<u>Subsection 3: Managing Director and committees</u>	
Clause 16 Appointment	14
Clause 17 Responsibility	15
Clause 18 Rules of business	15
Clause 19 Committees	16
<u>Subsection 4: Advisory Board</u>	
Clause 20 Composition	16
Clause 21 Responsibility	16
Clause 22 Rules of business	17
<u>Subsection 5: Chambers of First and Second Instance</u>	
Clause 23 Composition of the Chamber of First Instance	17
Clause 24 Composition of the Chamber of Second Instance	18
Clause 25 Term of appointment of the members of the Chambers of First and Second Instance	19
Clause 26 Duties	19
Clause 27 Principles of the procedure	20
Clause 28 Penalty options of the Chambers of First and Second Instance	21
Clause 29 Reports on the work of the Chambers	22
Clause 30 Rules of Procedure	22
<b>Section 4: Sundry points</b>	22
Clause 31 Discretion obligation	22
Clause 32 Criterion for service within the Association	23
Clause 33 Filing claim deadline	23

<b>Section 5:</b>	<b>Winding up</b>	23
	Clause 34 Winding up	23

## **Section 1: General points**

### **Clause 1**

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

- (1) The Association bears the name "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." ("FS Arzneimittel-industrie") and is registered in the Register of Associations.
- (2) The Association's registered office is in Berlin.
- (3) The Association's financial year is the calendar year.

### **Clause 2**

#### **Object and duties**

- (1) The object of the Association is to strengthen the corporate responsibility of the pharmaceutical industry, which is understood as a lasting corporate commitment towards all stakeholders. The object of the Association is fulfilled due to the fact that criteria for fair competition, in particular in cooperation of the pharmaceutical industry with healthcare professionals and institutions of health service has been established and are constantly being further developed, and to implement an effective enforcement system as part of self-monitoring. Such self monitoring of fairness also applies to a cooperation between the pharmaceutical industry and the institutions of health service and/or health policy and/or their employees, as well as other ministries authorities and public institutions and/or their employees (these institutions and their employees hereafter collectively referred to as "Partners in the Health System"). To this end, the specific object of the Association is to lay down rules of procedure and to organise and implement voluntary self-monitoring of the pharmaceutical industry. This includes for example the preparation of standards and monitoring of the same as regards (i) information relating to pharmaceuticals and their possible applications, and advertising for pharmaceuticals to members of specialist groups, (ii) cooperation by companies within the pharmaceutical industry with members of specialist groups and medical institutions, during observation of new pharmaceuticals in the market or under development, (iii) cooperation between pharmaceutical companies and Partners in the Health System).

In this context, the Association shall in particular examine behaviour by companies in the pharmaceutical industry which has been the subject of complaint, with respect to its fairness and compatibility with the Rules of Procedure laid down by the Association and with the existing statutory provisions, and shall take action against breaches.

- (2) The activities of the Association are based on the European standards of ethical pharmaceuticals marketing laid down by the European Federation of Pharmaceutical Industries and

Associations ("EFPIA"). These standards are laid down in their own Codes (Code of Practice for the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, "EFPIA-Code", and "Code of Practice on Relationships between Pharmaceutical Industry and Patient Organisations", EFPIA Code for the Organisation of the Patients are called EFPIA Codes hereinafter). The Statutes, Codes and Rules of Procedure of the Association must at least conform to the related binding specifications of the EFPIA. The binding specifications of EFPIA include in particular the EFPIA Code and the EFPIA Patient Organisation Codes.

- (3) For the implementation of the EFPIA Codes the Association has resolved the "FSA Code for the cooperation with expert groups" ("FSA Code Expert Group"). For the implementation of the EFPIA Codes and the preparation of standards of cooperation with Partners in the Health System the Association may establish further Codes (along with the FSA Code Expert Group named hereinafter "Codes").
- (4) For the purposes of promotion, adherence to and achievement of acceptance of the Rules of Procedure, the Association may organise or arrange for the organisation of appropriate events, publications and similar measures.  
The Association advises members on the interpretation and implementation of the Codes and the relevant statutes, along with legal political developments affecting the purpose of the Association. For this, it offers training courses and seminars in which the members are presented with possible courses of action based on concrete cases involving past decisions by the Arbitration Panel and the courts. In order to exchange information on current developments, the Association operates a communications platform for its members. The members are meaningfully involved in the further development of the Codes. Advisory of members does not bind the Chamber of the First and Second Instance.
- (5) The Association has no commercial objects of its own. It serves to promote commercial interests within the meaning of Section 13(1) UWG [*Unfair Competition Act*] and Section 3(1) No. 2 of the Unterlassungsklagengesetz (UKlaG) [*Prohibitory Actions Act*]. On that basis, it shall also take action against non-members in the event of statutory breaches.

## **Section 2: Membership**

### **Clause 3 Membership**

- (1) Any company within the pharmaceutical industry with its registered office in Germany, which puts pharmaceuticals into circulation in Germany, either itself or through affiliated companies, may be a member of the Association.

In addition, association membership is available to any company active in pharmaceutical research and development with the objective, either itself or through affiliated companies, of putting pharmaceuticals into circulation in the future in Germany.

- (2) All companies within a Group which meet the criteria for membership set out in (1) may become members of the Association. Group members who are members of the Association shall be obliged to ensure that the dependent companies affiliated with them also become members of the Association or agree in writing to be subject to its control and penalty, if such companies also meet the criteria for membership set out in (1) and put ethical pharmaceuticals into circulation in Germany.
- (3) Membership shall be acquired on the basis of a written application for admission to be sent to the Board of Management of the Association. The Board of Management shall decide on an application for admission.

#### **Clause 4 Cessation of membership**

- (1) Membership shall cease
  - a) through retirement;
  - b) through winding up of the member company;
  - c) in the event that a criterion for becoming a member is found to have lapsed;
  - d) through exclusion;
  - e) through the opening of insolvency proceedings in relation to the assets of a member.
- (2) Retirement shall take place by means of a written declaration to the Board of Management of the Association. Retirement may only be declared at the end of the calendar year, subject to six months' notice. The period mentioned in sentence 2 may be extended in the event of pending complaint proceedings, to the point at which such proceedings are concluded, albeit at most for a total of two years.
- (3) Exclusion of a member shall require a resolution of the Board of Management, which must have the approval of two thirds of its members. Exclusion may be resolved if a member is in arrears with payment of membership subscriptions or of special levies, despite two written warnings and setting of additional time. Exclusion shall also be possible if the member has culpably committed a gross breach of the obligations arising out of membership. This shall be the case in particular in the event of gross breaches by the member against the Codes resolved by the Association and the Rules of Procedure relating to the implementation, supervision and penalties in relation to these Codes and a breach of the obligation arising out of Clause 3 (2) of these Statutes, which is found by the Chamber of Second Instance. The member shall be notified of the exclusion by registered letter. The resolution shall become effective at the time of service. The member shall be given the opportunity to

submit observations before the resolution is passed. The exclusion shall be published on the Association's website and in its annual report, and shall be notified to the organisation(s) within the pharmaceutical industry to which the member also belongs.

- (4) The Board of Management must resolve on the lapse of a criterion for acquiring membership and subsequent termination of membership. Clause (3) sentences 5 to 7 shall apply accordingly. The member must immediately inform the Board of Management of the lapse of a criterion for acquiring membership.

#### **Clause 5 Membership subscription [fees]**

- (1) The members are obliged to pay membership subscription [fees]. Further details are specified in the fee scale.
- (2) In order to finance special projects or to remedy financial difficulties of the Association, special levies upon members are allowed up to an amount of 1 million Euros per year. The entire amount shall be allocated among the individual members, as specified in para. 1.

#### **Clause 6 Rights and Obligations of members**

- (1) The members shall be obliged towards the Association,
- a) to adhere to the Statutes, the Rules of Procedure, the Codes, the resolutions of the General Meeting and other provisions which are binding under association law;
  - b) to support the Association and its executive bodies in performance of its duty;
  - c) to pay the subscriptions;
  - d) to collaborate with the Association, so that it is able to comprehensively and promptly fulfil its duties related to its object;
  - e) to be involved in the production all necessary legal documents with a view to the timely implementation of the EFPIA specifications, in particular the EFPIA Codes; this shall apply in particular if the object of the Association must be altered.
- (2) Members and their related companies may voluntarily accept the FSA Code Expert Groups for non-prescription pharmaceuticals.

- (3) Members shall in addition be specifically obliged to adhere to the statutory provisions for advertising and information for pharmaceuticals and other relevant statutes, including national and international codes, which are applicable during the member's activity in Germany.
- (4) The members are entitled to information and advisory services deriving from the Object of the Association (§ 2). This may include the staging of seminars and training sessions for the members. In addition, the members may individually and for a specific purpose seek out advice from the Association's administrative offices concerning the application and interpretation of the Association's Codes and thus be advised in the context of current laws and regulations, as well as implementation of the Association's Codes. For the purpose of exchanging information about current developments, the Association maintains a communications platform for its members. The members receive access to all the relevant standards, rulings and decisions by the Arbitration Panels. The members are to be meaningfully involved in the further development of standards. The members can and should inform the administrative offices of any suspected breaches of the Codes of Conduct established by the Association, in order to enforce these Codes of Conduct.

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

#### **Clause 7 Executive bodies**

- (1) Executive bodies of the Association shall be the Board of Management, the General Meeting, the Advisory Board, the Chambers of First and Second Instance and the Managing Directors.
- (2) The Association's liability for culpable acts by its executive bodies under the terms of Section 31 BGB [*German Civil Code*] shall be restricted towards Association members to intentional acts.

#### **Subsection 1: Board of Management**

#### **Clause 8 Composition**

The Board of Management within the meaning of Section 26 BGB shall comprise the Chairman, the Deputy Chairmen and at least four and at most twelve further Board of Management members. The General Meeting shall decide on the actual number of Board of Management members within the scope of what is specified in sentence 1.

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

- (1) The members of the Board of Management shall be elected by the General Meeting.
- (2) The term of office of the Board of Management shall be three years. It should be the calendar year and should commence on 1 January of each year. The former Board of Management shall remain in office until the term of office of the new Board of Management has commenced. This shall not apply to individual Board of Management members, unless they are retiring from office in accordance with Clause 32 (1).
- (3) The members of the Board of Management shall select the Chairman and his Deputy/ies from amongst their members.

#### **Clause 10 Responsibility**

- (1) The Association shall be represented in court and out of court by two members of the Board of Management. Inasmuch as the Board of Management wishes to conclude legal transactions having an equivalent value of more than EUR 100,000.00, it shall

require the consent of the General Meeting. Such consent may also be granted via the approval of a budget. The investment of liquid funds of the Association up to their use in line with the budget shall not require such consent.

- (2) The Board of Management shall be responsible for all the affairs of the Association, inasmuch as they are not assigned by law or by these Statutes to another executive body of the Association.
- (3) The Board of Management shall specifically be responsible for
  - a) Appointment and recall from office of the Managing Director and of any further Deputy Managing Directors or other members of the Chamber of the First Instance;
  - b) Issue of by-laws for the work of the Board of Management, the office and the Advisory Board;
  - c) Formation of committees;
  - d) Statement of loss of membership;
  - e) Preparation for and convening the General Meeting and drawing up the agenda;
  - f) Implementation of resolutions of the General Meeting;
  - g) Resolution in relation to the inclusion and exclusion of members and statement of the lapse of membership criteria;
  - h) Presentation of the Association's budget plan, annual financial statements and annual report to the General Meeting;
  - i) Giving direction to the Managing Director and the Deputy Managing Directors, inasmuch as these do not relate to their function as a Chamber of First Instance;
  - j) Issue of business distribution plans, which set out the responsibilities of the Chambers of First and Second Instance;
  - k) Proposals to the General Meeting for laying down, preparing, amending or supplementing the Association's Codes;
  - l) Proposal to the General Meeting for the preparation, amendment or supplementation of Rules of Procedure for the implementation, supervision and penalties in relation to the Codes laid down by the Association.
  - m) The issue of interpretation guidelines in order to precisely clarify unclear legal terms used in the Codes.
- (4) The Board of Management is authorised to make amendments to the Statutes, the Codes and the Rules of Procedure, which become necessary on the basis of specifications of the Register of Associations or the Federal Cartel Office. This also applies to any revision to the purpose of the Association. In addition, the Board of Management may submit the amendment in question to the Meeting of Members for a resolution.
- (5) The decisions of the Board of Management shall be made in the form of resolutions.

**Clause 11**  
**Meetings and resolutions**

- (1) The Board of Management shall make resolutions during meetings or teleconferences, which shall be convened by the Chairman, or if he is unavailable, by a Deputy. The invitation shall be sent out at least two weeks prior to the meeting. The agenda should be attached to the invitation. In urgent cases, this period may be reduced. Members of the Board of Management may also participate in meetings via teleconferencing.
- (2) The Board of Management shall be quorate provided at least half of its members are present. Unless envisaged otherwise, the Board of Management shall decide by a majority of votes cast. In the event of a tie, the Chairman shall have a casting vote.  

The inclusion and exclusion of a member shall require a majority of two thirds of the members of the Board of Management. Absent Board of Management members may participate in the resolution in that they request members who are present to submit their written vote.
- (3) The Board of Management may arrange for written resolution, provided two thirds of the Board of Management members approve of this procedure. The sentences 2 to 4 of para. 2 shall apply accordingly.
- (4) The Managing Director, and on the basis of a resolution by the Board of Management, also Deputy Managing Directors and other members of the office, shall be obliged to attend meetings of the Board of Management.
- (5) A memorandum of every Board of Management meeting is to be prepared, and is to be signed by the Chairman.

**Subsection 2: General Meeting**

**Clause 12**  
**Composition and voting right**

- (1) The General Meeting shall be composed of all the members of the Association. Rights shall be exercised by representatives of the members who are furnished with a written authority. Representatives may only be individuals who work in the member company concerned on the basis of articles of employment or an employment contract at the time of the General Meeting. This shall not affect Clause 15 (4).
- (2) Every EUR 1,000.00 of annual subscription fees billed in accordance with Clause 5 or the subscription rules shall afford the right to one vote. Clause 2 Para. 2 of the Member Fee regulations does not apply in the regard. To the extent that several subsidiaries within a corporate group are members of the

association, the group holding company may also pay the annual subscription on behalf of its subsidiaries. In this case, the group holding company assumes the voting rights for the subsidiaries unless and until any subsidiary files an objection with the association against the representation of its voting rights. Along with the objection, the objecting member's annual sales relevant to calculating the annual subscription must be disclosed. The voting rights to which the objecting member is entitled shall be taken away from the group holding company.

**Clause 13  
Responsibility**

- (1) The General Meeting shall only resolve on matters which are assigned to it by law or by these Statutes.
- (2) The General Meeting shall be responsible for the following matters in particular:
  - a) Winding up the Association;
  - b) Amendment of the Statutes;
  - c) Approval of the budget plan;
  - d) Approval of the admission fees, annual subscriptions and special levies;
  - e) Discharge of the Board of Management and of the Managing Director;
  - f) Taking receipt of the annual report;
  - g) Approval of the annual financial statements;
  - h) Appointment of the auditors;
  - i) Election and recall from office of members of the Board of Management;
  - j) Laying down, amending and supplementing the Codes of the Association;
  - k) Laying down, amending and supplementing the Rules of Procedure for implementation, supervision and penalties in relation to the Codes laid down by the Association.

**Clause 14  
Convening meetings**

- (1) The ordinary General Meeting shall meet once every financial year. The meeting should where possible be held during the 4<sup>th</sup> quarter.
- (2) Extraordinary General Meetings may be convened at any time for a special reason under a resolution of the Board of Management or in response to an application by at least one quarter of the votes of the Association members.
- (3) The General Meeting shall be convened in writing by the Chairman of the Board of Management, or if he is unavailable, by his Deputy.
- (4) The invitation must specify the location, date and time of the General Meeting and the agenda.
- (5) Every member may apply in writing to the Board of Management for a supplement to the Agenda, at least one week before the General Meeting. The person chairing the meeting must announce the supplement at the beginning of the General Meeting. The General Meeting shall resolve on applications and supplements to the agenda which are not made until the General Meeting.
- (6) There should be a period of 30 days, and there must, however, be a period of 20 days, between the date of dispatch of the invitation and the date of the meeting. In especially urgent circumstances, the invitation period for extraordinary General Meetings may be reduced to three days.

**Clause 15  
Resolutions**

- (1) The Chairman of the Board of Management, or if he is unavailable, his Deputy, or if the latter is unavailable, another Board of Management member who is present, shall chair the General Meeting. The sequence shall be based on the length of membership of the Board of Management, and in the event of equal length of membership, it shall be based on age. If no Board of Management member is present, then the meeting shall determine by resolution who is to chair the meeting.
- (2) The person chairing the meeting shall determine the sequence and type of voting. Votes shall generally speaking be conducted openly. Voting is to be conducted in writing and in secret if one third of the votes of the members present apply for such procedure.
- (3) The General Meeting shall be quorate provided at least two thirds of the votes of all members are represented. In the event that the meeting is not quorate, the Executive Board shall be obliged

to convene a second General Meeting with the same agenda within four weeks, which shall be quorate irrespective of the number of votes represented. Mention must be made of this fact in the invitation.

- (4) Absent members may arrange to be represented during resolution provided, if they (i) arrange written votes to be submitted on their behalf by members who are present during the General Meeting, or if (ii) they submit to the Association their written vote before the resolution is passed. The written votes for the determination of a majority for the resolution have to be considered as votes from attending members for the respective resolution.
- (5) With prior approval by two-thirds' majority, resolutions can also be passed by written vote. To the extent that reference is made in these statutes to the number of members present required for a resolution, during the course of the written vote, there shall be a reference not to the members present but rather to those members who pursuant to Section 1 took part in the vote for approval to pass a written vote.
- (6) Unless the Statutes determine otherwise, decisions shall be taken on the basis of a simple majority of valid votes cast.
- (7) The resolution on amendment of the Statutes the Rules of Procedure and the subscription rules and of the Codes of the Association shall require a majority of three quarters of the votes of all members present. The same shall apply to amendments to the object of the Association. All amendments, including those to the object of the Association, which take place on the basis of binding specifications of the EFPIA, shall only require a simple majority of all members present.
- (8) Members of the Board of Management and the Managing Director shall be obliged to attend the General Meeting, unless the General Meeting resolves otherwise.
- (9) The members of the Board of Management shall have the right to attend the General Meeting without having a right to vote. They shall also have the right to make applications and to comment on agenda points.
- (10) Minutes are to be recorded of resolutions of the General Meeting, and these are to be signed by the person chairing the meeting.

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

#### **Clause 16 Appointment**

The Managing Director shall be appointed by the Board of Management.

**Clause 17  
Responsibility**

- (1) The Managing Director shall manage the business of the Association within the framework of the duties and authorities assigned to him and the instructions given to him by the General Meeting or the Board of Management. He shall be a special representative within the meaning of Section 30 BGB. The activities of the Managing Director shall include in particular management of the business involved in day-to-day administration of the Association, including the conclusion of legal transactions having a volume of no more than EUR 50,000.00 each.
- (2) The Managing Director shall use an office to attend to his duties. The members of the office may attend the General Meeting and the meetings of the Board of Management in an advisory function, if the Board of Management resolves this.
- (3) The Managing Director also has the duty of advising the member companies on Code-compliant conduct in collaboration with healthcare professionals, with patient organizations, as well as with healthcare institutions and their employees (for example, through training sessions, informational events etc.)
- (4) The Managing Director may also take on the duty of a Chamber of First Instance (Clause 23). In this function he shall not be bound by any directions or by the outcome of any previous advisory of Association members. The Chairman of a Chamber of the First Instance may represent the Association during complaints of breaches of competition rules and their prosecution through the courts. This prosecution through the courts may also be conducted in any case by the Managing Director.
- (5) The Managing Director may also institute proceedings for the Association against companies which distribute ethical pharmaceuticals and are not members of the Association, if they have unfairly breached existing legal provisions or the competition rules applicable to them in an unfair member in their pharmaceuticals advertising, during cooperation with members of the specialist groups or medical institutions. Inasmuch as the companies concerned do not undertake to refrain in a manner protected by criminal sanction, then the Association and its Managing Director shall also prosecute such breaches through the courts.

**Clause 18  
Rules of business**

The Board of Management may resolve rules of business for the conduct of business and of the work of the office.

**Clause 19**

### **Committees**

- (1) The Board of Management may establish committees for the specialist consultation and for preparatory work in relation to opinion-forming and decisions.
- (2) The Board of Management shall lay down the number and duties of committees.
- (3) The term of office of the committees shall be two years. This period should coincide with the term of office of the Board of Management.
- (4) The Board of Management shall decide on the membership of the committees at the proposal of its members.
- (5) The Board of Management may issue standard guidelines for the work, appointment and composition of the committees.

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

#### **Clause 20 Composition**

- (1) An Advisory Committee shall be formed as soon as an organisation in the pharmaceutical industry has obliged its members in its Statutes to join the Association.
- (2) Each of the organisations of the pharmaceutical industry, who have obliged their members in their Statutes to join the Association, shall delegate one representative. The rights of the representative of an organisation of the pharmaceutical industry may also be fulfilled by a representative of the representative if he or she has written authorization to that effect.

#### **Clause 21 Responsibility**

- (1) As soon as an Advisory Committee is formed, it shall advise the Board of Management. The approval of three quarters of the members of the Advisory Committee shall be required in cases in which the Statutes, the Association Codes or the Rules of Procedure on implementation, supervision and penalties are to be amended or supplemented.
- (2) The approval of the Advisory Board shall not be required in relation to amendments to the Statutes, the Codes or the Rules of Procedure which are required on formal grounds by courts,

supervisory or financial authorities or which are implemented by the binding specifications of the EFPIA.

- (3) The Board of Management must notify the Advisory Board of its resolutions.

**Clause 22**  
**Rules of business**

The Board of Management may resolve rules of business for the meetings of the Advisory Board.

**Subsection 5: Chambers of First and Second Instance**

**Clause 23**  
**Composition of the Chamber of First Instance**

The Chamber of First Instance may comprise the Managing Director, Deputy Managing Directors or third parties. The Board of Management shall entrust this responsibility to the Managing Director, Deputy Managing Directors or third parties. In case the Board of Management entrusts several persons with the duty of the Chamber of First Instance, then they shall each form their own Chamber of First Instance. In this case the Board of Management shall issue a business distribution plan, which indicates the precise responsibilities.

**Clause 24**  
**Composition of the Chamber of Second Instance**

- (1) The Chamber of Second Instance shall comprise the Chairman and a minimum of eight and a maximum of twelve additional persons. Of these additional persons, half shall be employees of companies that are members of the Association, one quarter shall be representatives of the medical fraternity and the remaining quarter shall be patient representatives.
- (2) The Board of Management shall determine the number of members of the Chamber of Second Instance and appoint the members of the Chamber of Second Instance in accordance with the provisions in Clause 24, Section 1. The Chairman of the Chamber of Second Instance must be qualified as a Judge and may not work for a member of the Association or for another company within the pharmaceutical industry (neutrality). Those persons representing the medical fraternity must be licensed doctors. The medical fraternity and patient representatives should be appointed on the basis of approvals by medical and patient organisations.
- (3) The Board of Management shall designate a member of the Chamber of Second Instance as Deputy Chairman.
- (4) The Board of Management may designate one or more deputies for every member of the Chamber of Second Instance. Dependent on the business to be dealt with by the Chamber of Second Instance, the Board of Management may set up further Chambers of Second Instance, which shall be manned accordingly. The Board of Management shall resolve a business distribution plan, which shall set out the responsibilities of the individual Chambers and deputising arrangements in the event of unavailability or a conflict of interests.
- (5) In the event that a member of the Chamber of Second Instance is temporarily unavailable, the Chamber of Second Instance may decide without the member in question, albeit with at least seven members, following a resolution by the Chairman.

**Clause 25**  
**Term of appointment of the members**  
**of the Chambers of First and Second Instance**

- (1) The member(s) of the Chamber of First Instance shall (each) be appointed for a period of two to five years. A new appointment shall be made at the end of this period.
- (2) The members of the Chamber of Second Instance shall each be appointed by the Board of Management for a period of two years. A new appointment shall be made at the end of this period.
- (3) The Board of Management may only recall members of the Chambers of First and Second Instance from office with immediate effect during their term of designation on a serious ground.

**Clause 26**  
**Duties**

- (1) The Chambers of First and Second Instance shall supervise and penalise the behaviour of the members of the Association and the affiliated companies within the meaning of Clause 3 (2) in relation to adherence to the Codes laid down by the Association. The Chambers of First and Second Instance are bound neither by directions nor by the outcome of advisory of member companies.
- (2) In the event of a breach of the Code by an affiliated company against one of the Codes of the Association ("Code Breach") within the meaning of Clause 3 (2), such behaviour shall be attributed to the Association member controlling the company in question, inasmuch as the affiliated company is neither a member of the Association itself nor has subjected itself in writing to the control and penalties of the latter. In the case of multi-level groups, the behaviour of the company shall be attributed to the next highest controlling company which is itself a member of the Association, or to whose control and penalties it has subjected itself in writing. Attribution shall also take place in the event of a culpable Code Breach by employees or agents of the company concerned for whom it carries vicarious liability, who are not executives or managers of the company in question.
- (3) The Chamber of First Instance shall have responsibility at first instance for all complaints, inasmuch as the Chamber of Second Instance does not have jurisdiction.
- (4) The Chamber of Second Instance shall have jurisdiction both in the event of repeated breaches of the same kind (three breaches within two years) and to decide on objections against decisions and appeals against failure to act by the Chamber of First Instance.

**Clause 27**  
**Principles of the procedure**

- (1) Anyone may make a complaint of failure to adhere to the Association Codes. Anonymous complaints relating to breaches of the provisions of the 3<sup>rd</sup> section of the FSA Expert Group Code, with the exception of (2), shall not be pursued.
- (2) The Managing Director and Board of Management, independent of one another, may also institute complaint proceedings on their own initiative. The same shall also apply if the complaint proceedings instituted by the Managing Director or Board of Management are based on an anonymous complaint (sentence 2 of Clause 27(1)).
- (3) The procedure to be observed by the Chambers of First and Second Instance during the supervision and penalising of breaches against the Association Code should appropriately safeguard the rights of the complainant and those of a member affected by a complaint, and must in particular afford the legal right to be heard, for review of the decisions of the Chamber of First Instance by the Chamber of Second Instance and also the opportunity to re-open concluded complaint proceedings.
- (4) Measures and decisions instituting proceedings may not be challenged separately, but only in conjunction with a challenge against the final decision of the Chamber of First Instance.

**Clause 28**  
**Penalty options of the Chambers of First and Second Instance**

- (1) In the event of substantiated complaints, the Chamber of First Instance should require the member affected or the subordinated company to give a declaration of discontinuance protected by criminal sanction. If the member or the subordinated company refuses to give such a declaration of discontinuance, then the proceedings shall be continued before the Chamber of First Instance. If the complaint should prove to be well founded during these proceedings, then the Chamber of First Instance shall find a Code breach.

This finding must be associated with an obligation on the member or the subordinated company to refrain in future from the behaviour to which the complaint relates, and to pay an administrative fine to the Association in the event of a repeated breach.

- (2) Code breaches may moreover be punishable by a fine of no less than EUR 5,000.00 and up to 20 times the subscription of the member in question, however no more than EUR 400,000.00. If a member pays no subscription in accordance with Section 5, then the turnover of this company realised from the prescription-free pharmaceuticals must be used to calculate the upper limit. Furthermore, a public reprimand may be declared in the event of Code breaches, in particular Code breaches contrary to the obligation pronounced by the Chamber of the First Instance to refrain in the future from behaviour that has already been the subject of a complaint. The fine shall be imposed in favour of a non-profit institution. The beneficiary institution must be named in the decision.
- (3) The liability of the Association, its executive bodies and members thereof shall be based on Sections 839 (2) (3) BGB in the event of decisions of the Chambers of First and Second Instance and shall otherwise be excluded. Liability for intentional action shall not be affected.

**Clause 29**  
**Reports on the work of the Chambers**

- (1) The Managing Director shall report regularly to the Board of Management, the members and the Advisory Board on the complaints dealt with by the Chambers of First and Second Instance.
- (2) In addition, at the end of February of each new calendar year, the Managing Director shall submit a detailed report on the work of the Chambers during the previous calendar year, which summarises the work of the Chambers in all proceedings. All declarations of discontinuance, as well as legally-final determinations of Code breaches, are published, naming the name of the member involved. Cases involving impermissible or unfounded complaints shall be published, to the extent that the given Arbitration Panel approves of publication with regard to the significance of the decision, without reference to the member's name, however.

The names of employees of members affected, or other persons involved, or other companies, organisations etc. must be withheld.

**Clause 30**  
**Rules of Procedure**

- (1) The General Meeting shall resolve Rules of Procedure for the implementation and imposition of penalties for breaches of the Codes laid down by the Association, which shall develop in detail the principles of the procedure and of the penalties laid down in this subsection of the Statutes and shall also lay down responsibilities in the event that there is a conflict of interests in relation to the members of the Chambers of First and Second Instance.
- (2) Procedural fees of up to EUR 10,000.00 per fee circumstance and also the reimbursement of disbursements may furthermore be regulated under detailed provisions of the Rules of Procedure to be resolved on the basis of the authorisation in (1).

**Section 4: Sundry points**

**Clause 31**  
**Discretion obligation**

The members of the Association's executive bodies, the members of committees and the staff of the Association, including the Managing Director and his Deputies, shall be obliged to observe discretion with respect to all operations which are by their nature confidential, or which are explicitly designated as such. Inasmuch as persons other than those listed in sentence 1 should be involved, they shall be accordingly obliged to observe discretion before they take up their activity.

**Clause 32**

**Criterion for service within the Association**

- (1) Only persons who are regularly occupied in a member or in a company affiliated with a member, on the basis of articles of employment or an employment contract, may serve on the executive bodies of the Association and its committees, with the exception of the Managing Director, his Deputies and the staff of the office, the members of the Chambers of First and Second Instance and the members of the Advisory Board.

This right shall expire with immediate effect as soon as the person concerned ends his or her duties in the company where they were employed at the time of their appointment. Clause 24 shall not be affected.

- (2) The Board of Management, the Managing Director, his Deputies or the chairman of a committee or Chamber may call in external experts in an advisory capacity in relation to substantiated individual questions.

**Clause 33  
Filing claim deadline**

The deadline for filing claims against resolutions or other provisions of the bodies of the Association is one month. The deadline begins with the date when the resolution of the provision was implemented.

**Section 5: Winding up**

**Clause 34  
Winding up**

- (1) The resolution on winding up the Association shall take place in a General Meeting specially convened for this purpose. The resolution shall require the approval of three quarters of all the votes of the Association's members.
- (2) Unless the General Meeting resolves otherwise, the Chairman and his Deputy shall together be liquidators with representative authority.
- (3) In the event that the Association is wound up, its assets shall pass to its members.