

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

**("FSA Rules of Procedure")**

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

in the version dated 01.12.2011, last amended on 20.03.2024

## Table of contents

### Introduction

#### Section 1

#### General information

§ 1 Principles

#### Section 2

#### General procedural rules

##### Subsection 1

Initiation of proceedings

§ 2 Right of complaint

§ 3 Further rights of the complainant

§ 4 Content and form of the complaint

§ 4a Guidelines of the Executive Board

##### Subsection 2

Principles and course of the proceedings

§ 5 Responsibilities

§ 6 Procedure of the proceedings

§ 7 Oral hearing

§ 8 Representation of the member concerned

§ 9 Rights to inspect files

§ 10 Term

§ 11 Decisions

##### Subsection 3

Miscellaneous

§ 12 Cases of prevention

§ 13 Conflict of interest

§ 14 File management

§ 15 Duty to provide information and reports on work  
the adjudicating body

§ 16 Secrecy

#### Section 3

#### Arbitration Board

§ 17 Duration of the appointment of the members of  
the Chambers of 1st and 2nd instance

##### Subsection 1

Chamber of 1st instance

§ 18 Composition

§ 19 Tasks

§ 20 Regulatory proceedings before the Chamber  
of 1st instance

§ 21 Continuation of the proceedings before the  
Chamber of 1st instance

§ 22 Sanctions of the Chamber of 1st instance

##### Subsection 2

Chamber of 2nd instance

§ 23 Composition

§ 24 Sanctions of the Chamber of 2nd instance

#### Section 4

#### Legal remedies

##### Subsection 1

Appeal against decisions of the Chamber of  
1st instance

§ 25 Objection / complaint due to inactivity

##### Subsection 2

Appeal against decisions of the Chamber of  
2nd instance

§ 26 Appealability of decisions

Subsection 3 Reopening of the proceedings  
§ 27 Resumption of the proceedings

Subsection 4 Suspension of the proceedings  
§ 28 Suspension of the proceedings

**Section 5**

**Costs of the proceedings**

§ 29 Regulatory procedure

§ 30 Costs for continuation of the proceedings before  
the Chamber of 1st instance

§ 31 Proceedings before the Chamber of 2nd instance

§ 32 Necessary expenses

§ 33 Payment of procedural fees and  
necessary expenses / value added tax

§ 34 Resumption of the proceedings

## **Introduction**

The research, development, manufacture and distribution of medicinal products are of great importance for human health and well-being. The research and development of effective medicinal products requires close professional cooperation with physicians and other healthcare professionals. At the same time, it is one of the tasks of pharmaceutical companies to provide accurate and appropriate information about medicinal products that is necessary for the proper selection, dispensing and use of medicinal products. In order to promote fair competition in advertising and cooperation with healthcare professionals, the General Assembly of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." ("*Voluntary self-regulation of the pharmaceutical industry*") has adopted the "FSA Code of Conduct for the Interaction with Healthcare Professionals" ("FSA Code of Conduct HCP HCO") and the "FSA Code of Conduct for Interactions with Patient Organisations" ("FSA Code of Conduct Patient Organisations") (together also referred to as the "Codes").

The members of the Association are aware that public confidence in the integrity of pharmaceutical companies in their advertising and cooperation with healthcare professionals depends crucially on effective monitoring and enforcement of the provisions of the Codes. In addition to effective and transparent sanctioning of violations, this requires the right of everyone to have complaints reviewed in a two-stage procedure involving representatives of the member companies as well as representatives of healthcare professionals, patient representatives and independent members. With the aim of establishing such a procedure and thereby ensuring consistent implementation and enforcement of the Codes, the General Assembly of the Association has adopted the following

### **Rules of Procedure of the Association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V."**

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 application of the FSA Codes and the Code of Practice beyond medicinal products to include DiGA.

## **Section 1: General**

### **§ 1 Principles**

- (1) The provisions of these Rules of Procedure serve to monitor and sanction the Codes vis-à-vis the members of FS Arzneimittelindustrie e.V. (hereinafter referred to as the "Association") and the companies affiliated with the members that have submitted in writing to the Articles of Association, these Rules of Procedure and the Codes ("Subject Companies").
- (2) The Chambers of 1st and 2nd instance are appointed to fulfill the tasks specified in § 1 (1). They shall act in accordance with these Rules of Procedure and sanction violations of the Codes by members of the Association and by subject companies in accordance with these Rules of Procedure. They are not subject to any instructions and are not bound by any prior advice given to the member companies by the Association.
- (3) In the case of a group of companies, the affiliated company shall be prosecuted first if it is itself a member of the Association or a subject company. Otherwise, violations by affiliated dependent companies that are neither members of the association nor subject companies shall be attributed to the member that controls the company in question. In multi-level corporate groups, attribution is made to the next higher controlling company, which is itself a member of the association or a subject company.
- (4) In all other respects, the provisions of these Rules of Procedure applicable to the members shall apply mutatis mutandis to the subject companies.

## **Section 2: General procedural rules**

### **Subsection 1: Initiation of proceedings**

#### **§ 2 Right of objection**

- (1) Anyone may submit a complaint to the Association with the allegation that a member has violated the regulations after joining the Association.
  1. of Sections 3 and 4 of the FSA Code of Conduct HCP HCO, taking into account the principles of interpretation set out in Section 2 of this Code, or
  2. of Section 3 of the FSA Code of Conduct Patient Organizations, taking into account the principles of interpretation set out in § 4 of this Code  
or
  3. of Section 2 of the FSA Transparency Code, taking into account the principles of interpretation set out in § 3 of this Code ("Code Violation").
- (2) The right of objection pursuant to § 2 (1) No. 1 is limited for companies to violations of the provisions of Section 4 of the FSA Code of Conduct HCP HCO, taking into account the principles applicable to this. The provisions of the FSA Code for Healthcare Professionals shall not apply to non-prescription medicinal products of members and their affiliated companies, unless the respective member company has voluntarily submitted to the FSA Code for Healthcare Professionals for non-prescription medicinal products as well.
- (3) The Board of Directors and the management may also initiate complaint proceedings against members of the Association independently of each other. This

also applies if the complaint procedure initiated by the Board of Directors or the management is based on an anonymous complaint (§ 4 (3)).

- (4) Only alleged violations committed after the member has joined or signed the declaration of submission may be the subject of a complaint.
- (5) The complaint is inadmissible if, at the time the complaint is lodged, the member concerned has already issued a full cease-and-desist declaration to the complainant or the complainant has obtained a corresponding court decision or, in this respect, court proceedings are pending that have not yet been legally concluded. The prior submission of cease-and-desist declarations (with penalty clause) to third parties does not, however, exclude the obligation of the member concerned to submit a cease-and-desist declaration with penalty clause in accordance with these Rules of Procedure.

### **§ 3**

#### **Further rights of the complainant**

- (1) The complainant has the following rights to information and review in the further proceedings:
  1. the complainant shall be informed of the outcome of the proceedings by being sent the operative part of the decision and the reasons for the decision (§ 11 (5) sentence 2). The complainant shall be informed of his/her procedural rights.
  - 2 The complainant has the right,
    - a) to lodge an appeal against decisions of the Chamber of 1st instance, insofar as his objection does not lead to the determination of a violation of the Code (§ 25 (2));
    - b) in the event of inactivity on the part of the Chamber of 1st instance, to appeal to the Chamber of 2nd instance if the Chamber of 1st instance does not reach a decision within 6 months of receipt of the complaint and the company concerned has not issued a cease-and-desist declaration subject to penalty within this period due to the breach of the Code complained of (§ 25 (3)).

In these cases, the proceedings are continued before the Chamber of 2nd instance.

- (2) The complainant is otherwise not involved in the proceedings.

### **§ 4**

#### **Content and form of the complaint**

- (1) The complaint must be addressed in writing to the managing director of the association and must be substantiated. It should substantiate the objections raised, if possible by enclosing relevant documents (such as letters of invitation to medical conferences, etc.) in the original or as photocopies. The managing director shall forward the complaint to the competent Chamber of 1st instance for consideration.
- (2) Complaints relating to transactions dating back more than one year will not be dealt with.
- (3) Anonymous complaints due to violations of the provisions of Section 3 of the FSA Code of Conduct for Professionals will not be dealt with, with the exception of § 2 (3). Member companies are obliged to submit complaints by disclosing their identity. Other companies and natural persons are required to submit complaints openly and only anonymously if there is a particular need for anonymity.

**§ 4a**  
**Guidelines of the Executive Board**

The Association may issue binding guidelines on the interpretation of these Rules of Procedure by the Executive Board. The Association shall publish these guidelines on the Internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)).

**Subsection 2: Principles and course of the proceedings**

**§ 5**  
**Responsibilities**

- (1) The Chamber of 1st instance is responsible for all complaints in the first instance, unless the Chamber of 2nd instance has jurisdiction (§ 5 (2)). In the case of admissible and well-founded complaints, the Chamber of 1st instance shall demand a declaration of discontinuance with penalty clause from the members ("standard procedure", § 20). If the member refuses to submit such a cease-and-desist declaration, the proceedings will be continued before the Chamber of 1st instance (§ 21). If the complaint proves to be admissible and well-founded in these proceedings, the Chamber of 1st instance shall issue a decision declaring a breach of the Code.
- (2) In the event of repeated violations of the same type (three violations within two years), the Chamber of 2nd instance shall be responsible pursuant to § 20 (8) in conjunction with § 24 (1) and § 25 for deciding on appeals against decisions of the Chamber of 1st instance. Furthermore, the Chamber of 2nd instance is responsible for appeals by the complainant due to inactivity of the Chamber of 1st instance (§ 25 (3)).

**§ 6**  
**Course of the procedure**

- (1) If a complaint is not already settled in the standard procedure (§ 20), the chairman of the respective Chamber shall set a date for an oral hearing.
- (2) In the event of a connection between several complaints pending before it, the chairperson of the respective Chamber may order their combination for the purpose of simultaneous hearing and/or decision. The chairman of the Chamber of 2nd instance may order the separation of related proceedings.
- (3) The Chambers shall generally meet at the Association's headquarters in Berlin. At the decision of the chairman of the respective Chamber or at the request of the member concerned, the complaint may be pursued in written proceedings if the chairman deems it unnecessary to hold an oral hearing. If the member concerned objects in writing to the order for a written procedure by the chairperson of the respective Chamber within a one-week period, the chairperson must schedule a date for an oral hearing.
- (4) The chairman of the respective Chamber shall, if necessary, initiate further measures to conduct the proceedings and prepare for the hearing (obtaining additional information, etc.).
- (5) The chairman of the respective Chamber may, at his discretion, invite witnesses and, if necessary, experts. The members affected by the complaint (hereinafter: "affected members") are obliged to allow company employees who are invited as

witnesses or experts to attend the oral hearing, unless there are important reasons under labor law or other important reasons to the contrary.

- (6) The member concerned and the members of the respective Chamber shall also be invited to the oral hearing in any case, and in the case of hearings of the Chamber of 2nd instance also the chairman of the Chamber of 1st instance who made the decision as the Chamber of 1st instance (hereinafter referred to as "parties to the proceedings"). In any case, the managing director of the association may also participate in hearings of the Chamber of 2nd instance. The oral hearing is otherwise not open to the public.
- (7) The invitation shall be sent in writing by registered letter with acknowledgement of receipt. The invitation shall be sent at least three weeks before the hearing. This invitation must also contain the following information:
  1. the content of the objection, including any documents that will enable the member concerned to prepare properly for the hearing,
  2. place and time of the hearing,
  3. the names of the members of the respective Chamber,
  4. the information that members of the Chamber can be rejected due to concerns about a conflict of interest,
  5. the indication that a decision may also be made in the event of unexcused absence by the member concerned or his representative,
  6. the names of invited witnesses, if applicable,
  7. a notice to the member concerned that he/she may be represented by an authorized employee and/or a lawyer at any stage of the proceedings.
- (8) If the proceedings are to be pursued in written proceedings, the chairman of the respective Chamber shall take the necessary procedural measures. § 6 (6) sentence 3 Nos. 1, 3, 4 and 7 shall apply accordingly. The member concerned shall be given the opportunity to comment. The chairperson of the respective Chamber may set deadlines for this.

## **§ 7 Oral hearing**

- (1) The chairperson shall preside over the oral proceedings. After the opening, he shall announce the composition of the Chamber and establish attendance. He shall call the witnesses to testify and dismiss them until they have been questioned. He then questions the member concerned and the witnesses and names and explains the other evidence. Witnesses may also be questioned in writing or in advance by the chairperson or a representative appointed by the chairperson in special circumstances. The result of the questioning shall be presented by the chairperson at the hearing. Questioning may also be conducted by telephone during the hearing. The member concerned has the right to name additional witnesses until the end of the hearing. These witnesses must be present at the hearing, unless they have already been invited to the hearing by the chairperson of the respective Chamber.
- (2) The parties to the proceedings have the right to ask questions at the hearing. The representative of the member concerned shall have the final word.
- (3) If the member fails to appear at the hearing without excuse despite having been duly summoned and is not effectively represented, the Chamber shall decide on the basis of the files. Otherwise, a new date for the oral hearing shall be set by the chairman of the respective Chamber. In the event of an unexcused absence, the invited witnesses or experts shall only be questioned if the respective Chamber deems this to be relevant.



- (4) Minutes shall be taken of the oral proceedings which reflect the essential content of the oral proceedings. Any applications by parties to the proceedings and decisions of the respective Chamber shall be recorded in full or attached to the minutes as an annex.
- (5) All parties to the proceedings may request that individual statements be recorded verbatim.
- (6) The minutes shall be signed by the chairperson and sent to the parties to the proceedings.

## **§ 8**

### **Representation of the member concerned**

- (1) The member concerned may be represented by an authorized employee and/or a lawyer at any stage of the proceedings.
- (2) The costs of representing or advising the member concerned shall be borne by the member regardless of the outcome of the proceedings.
- (3) Authorized representatives of the member concerned must identify themselves upon request by submitting a power of attorney to the adjudicating body.

## **§ 9**

### **Rights to inspect files**

- (1) The member concerned has the right to inspect the files at any time.
- (2) In addition, the other parties to the proceedings and the Executive Board of the Association also have the right to inspect the files at any time. This does not apply to the complainant.

## **§ 10**

### **Deadlines**

- (1) The member concerned is bound by the observance of deadlines. All procedural acts of the member concerned that are bound by deadlines and must be submitted in writing may be effected either by registered letter, fax, e-mail or by receipted submission to the Association's office. The burden of proof for the receipt of such declarations shall be borne by the member concerned. Upon request, the Association's office shall confirm receipt of declarations by fax or e-mail to the member concerned in order to meet deadlines.
- (2) If a deadline is missed, the member concerned may be granted reinstatement upon request if they were prevented from meeting the deadline through no fault of their own. The application must be submitted in writing within one week of the reason for the impediment ceasing to exist to the respective ruling body to which the original deadline should have been adhered to.

## **§ 11**

### **Decisions**

- (1) If a complaint is not resolved by way of the standard procedure (§ 20), the respective adjudicating bodies shall make a decision if they act in the first instance. If the complaint is admissible and well-founded, a breach of the Code shall be established and the complaint upheld. If the complaint is inadmissible or unfounded, the complaint procedure is discontinued. In addition, the Chambers acting in the 1st instance may also discontinue the objection proceedings by way of

a decision if the facts of the case cannot be clarified in a manner necessary for a decision.

- (2) If the Chamber of 2nd instance takes action following an appeal by a member concerned or the complainant against a decision by the Chamber of 1st instance, the Chamber of 2nd instance may confirm or annul the contested decision. The Chamber of 2nd instance can also make a decision whereby the decision of the Chamber is only amended with regard to the sanctions found. New means of defense of the member concerned are excluded before the Chamber of 2nd instance if they could have already been asserted before the Chamber of 1st instance.
- (3) When passing resolutions within the Chambers, the chairman of the Chamber of 1st instance shall decide in the Chamber of 1st instance and the majority of the votes of the members of the Chamber of 2nd instance shall decide in the Chamber of 2nd instance. In the event of a tie, the objection shall be rejected as unfounded.
- (4) Prior to a decision that is preceded by an oral hearing, the member concerned must be given the opportunity to make a final statement. In addition, the other parties to the proceedings (with the exception of the members of the respective Chamber) are also entitled to make a final statement. The Chamber may announce the decision and its main reasons to the member concerned and the other parties to the proceedings immediately after the oral hearing and after the conclusion of the deliberations. The chairman of the respective Chamber may also inform the parties that the decision will be communicated in writing.
- (5) The final, written decision of the Chamber shall be signed by the chairperson and sent to the member concerned with written reasons within two weeks of the oral hearing or after the conclusion of the written procedure. The complainant shall also be informed in writing of the outcome of the proceedings by being sent the operative part of the decision and the reasons for the decision. The names of employees of the member concerned or other persons or companies, organizations, etc. involved shall be anonymized if necessary.

### **Subsection 3: Miscellaneous**

#### **§ 12 Cases of prevention**

- (1) If a member of the Chamber of 2nd instance is prevented from attending at short notice, the Chamber of 1st instance may decide without the member concerned, but with at least seven members, by decision of the chairperson.
- (2) Further details shall be regulated by the schedule of responsibilities to be drawn up by the Executive Board within the meaning of § 24 (4) of the Articles of Association.

#### **§ 13 Conflict of Interest**

- (1) Members of the respective Chamber may be challenged by the member concerned due to concerns that there is a conflict of interest or may declare themselves a conflict of interest if there is a reason to doubt their impartiality. They must declare themselves to have a conflict of interest if they are employees of the member concerned or the complainant or were or are themselves involved in the disputed matter.

- (2) If the member concerned considers a member of the Chamber to have a conflict of interest, the member concerned must submit a request for recusal to the respective Chamber within a period of one week from receipt of the summons, stating the reasons. The member of the Chamber concerned shall comment on the challenge within a further week of receipt of the challenge. The comments must be forwarded to the member concerned.
- (3) If a member of the Chamber of 1st instance is rejected by the member concerned due to a conflict of interest, the chairman of the Chamber of 2nd instance shall decide on the existence of grounds for rejection. The members of the Chamber of 2nd instance shall decide on the existence of grounds for recusal with regard to members of the Chamber of 2nd instance in the respective composition without the member concerned. In the event of a tie, the chairman of the Chamber of 2nd instance shall decide. If the request for recusal is directed against the chairperson of the Chamber of 2nd instance, the deputy chairperson shall decide in the event of a tie. Such a decision is not required if the rejected member considers the request for rejection to be justified.
- (4) If the chairperson of the Chamber of 2nd instance declares the application for recusal to the chairperson of the Chamber of 1st instance to be well-founded, the chairperson of the Chamber of 2nd instance shall decide on the objection as the Chamber of 1st instance, unless other Chambers of 1st instance have been established, whose jurisdiction in this case shall be based on the schedule of responsibilities for the Chambers of 1st instance (§ 18 (1) sentence 3). If the member concerned lodges an appeal against the decision of the chairman of the Chamber of 2nd instance as the Chamber of 1st instance, the chairman of the Chamber of 2nd instance shall not participate in the further proceedings. The deputy chairman of the Chamber of 2nd instance shall take his place. In such cases, the Chamber of 2nd instance shall decide in a composition of eight members.
- (5) If the chairperson does not participate in proceedings due to concerns of a conflict of interest, the Chamber of 2nd instance shall decide under the leadership of the deputy chairperson with a composition of eight persons. In the event of a tie, the objection shall be rejected as unfounded.
- (6) If a circumstance arises during the proceedings that could justify concern about a conflict of interest, the request for recusal must be submitted immediately before any further statements on the matter are made.
- (7) Appeals against the decision on a request for recusal are not admissible.

#### **§ 14 File management**

The office of the Association manages and administers the files of the adjudicating bodies.

#### **§ 15 Duty to provide information and reports on the work of the Chambers**

- (1) The Association publishes the Statutes of the Association, the Codes, the Rules of Procedure and the interpretation guidelines in accordance with § 6 (2) of the FSA Code of Conduct HCP HCO and § 5 of the FSA Code of Conduct Patient Organisations on the Internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)).
- (2) The Managing Director shall regularly inform the Executive Board, the members and the Advisory Board about the work of the Chambers and about the complaints dealt with by the Chambers of 1st and 2nd instance. In addition, at the end of February

of each new calendar year, the Managing Director submits a detailed public report on the work of the Chambers in the previous calendar year, which is also published on the Internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)). This report shall summarize the activities of the Chambers in all proceedings.

- (3) In cases in which a Code violation has been legally established, the legally binding decisions of the Chamber of 1st and 2nd instance shall be published on the Internet on an ongoing basis by posting the operative part and the main reasons for the decision ([www.fsa-pharma.de](http://www.fsa-pharma.de)). This also applies if proceedings have been terminated by a declaration to cease and desist within the meaning of § 20 (5) sentence 2. The reports and publications are made for all cease-and-desist declarations and for all justified complaint proceedings, stating the name of the member concerned. If complaints have not led to the assumption of a breach of the Code, publication will also take place if the respective ruling body approves publication in view of the significance of the decision, but without mentioning the name of the member concerned.
- (4) If the adjudicating body of the 2nd instance issues a public reprimand, § 24 (4) shall also apply. The names of employees of affected members or other persons involved or other companies, organizations, etc. must always be made anonymous.
- (5) The Chamber of 2nd instance shall be informed of all decisions of the Chamber of 1st instance and of any declarations of discontinuance issued. The members of the Chambers of 1st and 2nd instance shall regularly discuss the work of the Chambers. The chairman of the Chamber of 2nd instance shall have the right to submit proposals to the Board of the Association for amendments and additions to these Rules of Procedure or the Codes that the Chamber of 2nd instance deems appropriate with regard to the effective sanctioning of violations in advertising and cooperation with healthcare professionals or in cooperation with patient self-help organizations.

### **§ 16 Secrecy**

- (1) The members of the bodies of the Association, the members of committees and the employees of the Association, including the Managing Director, are obliged to maintain secrecy about their activities, the information obtained in the process and all processes that are confidential by nature or are expressly designated as such.
- (2) Insofar as persons other than those specified in § 16 (1) are involved in the work of the Association, they must be bound to secrecy before commencing their activities.

## **Section 3: Adjudicating bodies**

### **§ 17 Duration of the appointment of the members of the Chambers of 1st and 2nd instance**

- (1) The member or members of the Chamber of 1st instance shall be appointed for a period of two to five years. At the end of this period, a new appointment shall be made. Reappointment is permissible.
- (2) The members of the Chamber of 1st instance shall be appointed by the Board of Directors for a period of two years in accordance with § 23. At the end of this period, a new appointment shall be made. Reappointment is permissible.

- (3) Members of the Chambers of 1st and 2nd instance may only be dismissed by the Executive Board for good cause during the period of their appointment.

### **Subsection 1: Chamber of 1st instance**

#### **§ 18 Composition**

- (1) The Chamber of 1st instance may consist of the managing director, deputy managing directors or third parties. The appointment of the managing director, deputy managing directors or third parties shall be made by the Management Board. If, instead of or in addition to the managing director, individual deputy managing directors or third parties are entrusted by the Management Board with the task of acting as the Chamber of 1st instance, they shall each form their own Chamber of 1st instance. In this case, the Board of Directors shall issue a schedule of responsibilities from which the exact responsibilities are derived. The managing director and any deputy managing directors or third parties must be qualified to hold judicial office.
- (2) The Managing Director and his deputies or third parties are not subject to any substantive instructions from the Association with regard to their activities as the first-instance adjudicating body. In particular, they are not bound by the result of the Association's advice to individual members.
- (3) The Managing Director and his deputies or third parties may not work or become active for a member of the Association outside of their business activities for the Association in order to avoid a conflict of interest.

#### **§ 19 Tasks**

- (1) The Chamber of 1st instance is responsible for all objections in the first instance, unless the Chamber of 2nd instance is also responsible in the first instance (§ 5 (2)).
- (2) The Chamber of 1st instance shall examine the complaints received and prepare the proceedings by clarifying the facts of the case itself. Furthermore, the Chamber of 1st instance shall examine whether the Chamber of 2nd instance has jurisdiction. In such a case, the Chamber of 1st instance forwards the complaint and the result of the preliminary examination to the chairman of the Chamber of 2nd instance.

#### **§ 20 Standard proceedings before the Chamber of 1st instance**

- (1) For the purpose of clarifying the facts of the case, the Chamber of 1st instance may request the complainant to further substantiate his complaint, the member concerned to comment or to provide documents. The Chamber of 1st instance may also question witnesses or experts at any stage of the proceedings. The Chamber of 1st instance may schedule a hearing at any time to discuss the complaint with the complainant; it may also invite the complainant to this discussion.
- (2) If it is established on this basis that the objection is either manifestly inadmissible or manifestly unfounded, the objecting party shall be given the opportunity to substantiate its objection further within two weeks, with notification of the preliminary assessment. The Chamber of 1st instance then decides whether the proceedings are to be continued or discontinued. The discontinuation of the

proceedings may be contested by the complainant by way of an objection (§ 25 (2) sentence 2).

- (3) If the member concerned fails to comply with a request to cooperate within a reasonable period of time, the complaint shall be assessed on the basis of the files or the available evidence. If the complainant submits a sufficiently substantiated objection, for example stating the specific circumstances of the time, place and nature of the alleged act, the adjudicating bodies may consider this factual submission to be admitted, unless the member concerned submits a substantiated counter-submission; in the context of a substantiated counter-submission, the member concerned must generally also submit available documents or provide suitable evidence due to its duty to promote the proceedings.
- (4) If the Chamber of 1st instance deems the complaint to be justified, it shall issue a warning to the member concerned and request it to submit a declaration to cease and desist within a period of two weeks in such a way that the infringement complained of is remedied for the future. The obligation to issue a cease-and-desist declaration subject to penalty shall in any case be combined with the obligation to pay a fine for a breach of the Code in accordance with § 22 (2) sentence 2. Such a cease-and-desist declaration with penalty clause must also contain the agreement to the stipulated fine. The fine is due for payment after the Chamber of 1st instance has accepted the declaration to cease and desist. § 22 (2) sentence 5 applies accordingly.
- (4a) By way of derogation from § 20 (4), the procedure shall end without further ado in the event of justified violations of the FSA Transparency Code, provided that
  1. the nature and extent of the infringement is not significant and
  2. the member concerned remedies the complaint within two weeks of being notified by the Chamber of 1st instance.The Executive Board of the Association shall issue binding guidelines in accordance with § 4a for the interpretation of the term "not significant in nature and scope" within the meaning of this provision. If no remedial action is taken, the provisions of these Rules of Procedure shall apply without restriction.
- (4b) By way of derogation from § 20 (4), the procedure may end in the event of justified violations by issuing a warning, provided this is accepted by the member concerned within 2 weeks. In such a case, the fine shall be waived. The other provisions of these Rules of Procedure apply without restriction.
- (5) This declaration to cease and desist is sufficiently punitive to eliminate the risk of repetition. The proceedings shall end upon submission of the cease-and-desist declaration by an authorized representative of the member concerned.
- (6) If the member concerned does not submit the required cease-and-desist declaration with penalty clause, the proceedings shall be continued (§ 21), unless the Chamber of 1st instance recognizes a cease-and-desist declaration by the member concerned that deviates from the required cease-and-desist declaration as a sufficient cease-and-desist declaration. A declaration to cease and desist issued at a later date shall not have the effect of terminating the proceedings, but shall only be taken into account when assessing any additional sanctions that may be imposed.
- (7) If the Chamber of 1st instance determines in the course of the initial examination that it is a repeated violation of the same type and that the member concerned has violated a cease-and-desist declaration or cease-and-desist obligation subject to penalty, the association shall assert the fine specified therein against the member concerned. The fine shall also be increased appropriately to eliminate the risk of repetition. In addition, in the event of a repeated violation, the Chamber of 1st

instance shall impose a fine in accordance with § 22 (2). This fine shall become due with the declaration of consent of the member concerned in accordance with § 20 (7), 2nd subparagraph, sentence 1. § 20 (4) sentence 5 and § 22 (2) sentence 4 apply accordingly. A repeated infringement of the same type shall be deemed to have occurred if the act complained of is either identical or "identical in its characteristic elements" to such an act that has already been the subject of a justified complaint in the past; a justified complaint shall be deemed to have been made if either a declaration to cease and desist has been issued by the member concerned or an obligation to cease and desist that is incontestable within the meaning of these Rules of Procedure has been issued by the first or second instance ruling bodies. If the member concerned agrees to pay the fine and its increase for future violations as well as the fine imposed (§ 20 (4) sentence 5), the proceedings shall end. If the member concerned does not agree to this, the proceedings shall be continued (§ 21). If it emerges in the further proceedings before the Chamber of 1st instance or, if applicable, Chamber of 2nd instance that the Chamber of 1st instance wrongly assumed a repeated infringement of the same type and a breach of a cease-and-desist declaration or an obligation to cease-and-desist in the course of the initial examination, the proceedings shall be continued. If the member concerned has offered the Chamber of 1st instance, together with its objection pursuant to § 20 (7) sentence 8, to issue a cease-and-desist declaration stating an appropriate fine with regard to a different, new violation, the proceedings shall end in accordance with § 20 (5).

- (8) In deviation from § 20 (7), the Chamber of 1st instance must transfer the proceedings directly to the Chamber of 2nd instance for a decision if the Chamber of 1st instance finds in the course of the initial examination of a complaint that the member concerned has either issued a cease-and-desist declaration for at least two violations of the same type within the last two years prior to the time of committing the violation complained of, or that the Chambers of 1st or 2nd instance has issued an incontestable cease-and-desist undertaking or Chamber of 2nd instance has issued an incontestable cease-and-desist order, i.e. the previous infringements are justified complaints within the meaning of § 20 (7) sentence 6. The submission of an alleged further infringement to the Chamber of 2nd instance can only be considered if the number of previous justified complaints required for a submission in the aforementioned sense is present and the Chamber of 1st instance comes to the conclusion that the further infringement complained of is not obviously inadmissible or unfounded (§ 20 (2)) and that it is a repeated infringement of the same type (§ 20 (7) sentence 6). In this case, the proceedings must be continued before the Chamber of 2nd instance as the Chamber of 1st instance. Otherwise, the proceedings shall be continued before the Chamber of 1st instance with regard to the complaint.

## **§ 21**

### **Continuation of the proceedings before the Chamber of 1st instance**

- (1) If the proceedings are to be continued before the Chamber of 1st instance, the chairman of the Chamber of 1st instance shall set a date for an oral hearing or order the written procedure.
- (2) The oral hearing shall take place within four weeks of the expiry of the two-week period for submitting the cease-and-desist declaration.

## **§ 22**

### **Sanctions of the Chamber of 1st instance**

- (1) If the complaint has not already been terminated in the regular procedure (§ 20) and the complaint is admissible and justified, a Code violation must be determined by the adjudicating body of the 1st instance. This finding must be combined with an

obligation on the member to refrain from the conduct complained of in the future and to pay a fine for a repeated violation in an amount sufficient to eliminate the risk of repetition. If the proceedings are continued before the Chamber of 1st instance in accordance with § 20 (7) sentence 8, it must be determined whether the complaint is admissible and justified, whether it is a repeated violation of the same type and whether the member concerned has violated a cease-and-desist declaration or obligation to cease-and-desist with a penalty clause. If the Chamber of 1st instance affirms this, it shall issue a corresponding finding, which shall also include a decision on the increase of the fine in accordance with § 20 (7). After the decision within the meaning of § 25 (4) sentence 3 becomes final or after confirmation of the decision in accordance with § 24 (2) sentence 1, the association shall assert the fine stipulated in the cease-and-desist declaration or cease-and-desist obligation against the member concerned on the basis of the determination made. If, on the other hand, the Chamber of 1st instance comes to the conclusion that the member concerned has not violated a cease-and-desist declaration subject to penalty, but that the complaint is nevertheless admissible and justified, § 22 (1) sentences 1 and 2 shall apply, taking into account § 20 (7) sentence 9.

- (2) The administrative fine to be determined by the Chamber of 1st instance may not exceed an amount equal to 20 times the contribution of the member concerned for each case of infringement, up to a maximum of EUR 200,000.00. In addition, if a breach of the Code is established, the Chamber of 1st instance shall impose an additional fine of at least EUR 5,000.00 up to 20 times the contribution of the member concerned, but no more than EUR 200,000.00, in favor of a charitable organization. The charitable organization shall be determined by the Chamber of 1st instance after the due date. The fines imposed shall become due for payment when the respective decision becomes incontestable within the meaning of § 25 (4) sentence 3 or pursuant to § 20 (4) sentence 4. A fine that has already been paid shall remain unaffected by a reopening of the proceedings pursuant to § 27.
- (3) The sanctions listed in § 22 (1) and (2) are not exclusive. However, in the event of a repeat offence, a further fine shall only be imposed in addition to the fine if this is necessary and appropriate in view of the overall circumstances and the seriousness of the offence in order to punish it immediately, taking into account the fine initially imposed and now forfeited as well as the fine and procedural costs for the previous offence. The consequences for the member affected by the sanctions must be taken into account when assessing the sanction. Particular consideration must also be given to whether and to what extent the member concerned has taken organizational measures to counter violations of the Codes and whether the conduct complained of was merely a one-off misconduct. In addition, the internal sanctions and organizational measures taken and implemented or promised by the member concerned in response to the misconduct in general and in each individual case must be taken into account.
- (4) If the objection is inadmissible or unfounded, the objection procedure shall be discontinued. The same applies if the facts of the case cannot be clarified in a manner necessary for a decision.
- (5) Any 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) and is otherwise excluded. Liability for intentional acts remains unaffected.



## **Subsection 2: Chamber of 2nd instance**

### **§ 23 Composition**

- (1) The Chamber of 2nd instance shall consist of the chairman and a minimum of eight and a maximum of 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 Chamber of 2nd instance and appoints the members of the Chamber of 2nd instance in accordance with the provisions of § 23 (1). The chairperson 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 (DiGA) within the meaning of § 33a SGB V (neutrality). The persons representing the medical profession must have a license to practice medicine. The appointment of doctors' representatives should be based on proposals from one or more doctors' organizations and the appointment of patient representatives should be based on the proposal of one or more patient organizations. The Board of Directors may only deviate from these proposals if there are reasonable doubts as to the impartiality of the persons proposed. If no proposals are submitted, the Board of Directors shall appoint the members of the Chamber of 2nd instance from among licensed physicians and patients at its own discretion.
- (3) The Chairman of the Chamber of 2nd instance and the representatives of the members of the Association shall be appointed by the Board of Directors without the need for a proposal from a third party.
- (4) In the event of a conflict of interest or incapacity of the members of the Chamber of 2nd instance, the Board of Directors may appoint one or more deputies for each member, whereby § 23 (1) to (3) shall apply accordingly to the selection and appointment of the deputies.
- (5) The Executive Board shall also appoint a member of the Chamber of 2nd instance as deputy chairman.
- (6) The Board of Directors shall determine a schedule of responsibilities which regulates the responsibilities of the representatives in the event of their being prevented or a conflict of interest.

### **§ 24 Sanctions of the Chamber of 2nd instance**

- (1) If the Chamber of 2nd instance acts as the Chamber of 1st instance by referral (§ 20 (8)), § 22 (1) shall apply accordingly. In this case, the administrative fine to be determined by the Chamber of 2nd instance may not exceed an amount equal to 20 times the contribution of the member concerned for each case of infringement, up to a maximum of EUR 400,000.00. If the adjudicating body of the 2nd instance comes to the conclusion that a levy pursuant to § 20 (8) was unjustly made because there is no violation of the same type within the meaning of § 20 (8) or otherwise the requirements for a direct levy to the adjudicating body of the 2nd instance are not met, the proceedings shall be continued before the adjudicating body of the 2nd instance; however, in this case the adjudicating body of the 2nd instance may only apply the sanctions applicable to the adjudicating body of the 1st instance (§ 22). § 20 (4) and (5) shall apply accordingly. If the adjudicatory body

acts as the Chamber of 1st instance due to an appeal due to inactivity of the adjudicatory body of first instance (§ 25 (3)), § 22 (1) and (2) shall apply accordingly.

- (2) If the Chamber of 2nd instance takes action in response to an objection by the member concerned against a decision of the Chamber of 1st instance (§ 25) and the objection is admissible and well-founded, it shall reject the objection and confirm the decision of the Chamber of 1st instance. The same applies if the Chamber of 2nd instance considers the objection to be inadmissible or unfounded following an objection by the complainant to a decision by the Chamber of 1st instance. If the Chamber of 2nd instance considers the finding of a violation of the Code by the decision of the Chamber of 1st instance to be admissible and justified, but the sanctions imposed by the Chamber of 1st instance (administrative fine or monetary penalty) to be inappropriate, the Chamber of 2nd instance may overturn the decision of the Chamber of 1st instance in this respect and amend the sanctions imposed. In doing so, the Chamber of 2nd instance may also impose more severe sanctions than the Chamber of 1st instance in accordance with § 24 (3) and (4) within the framework of the penalty range available to it (no prohibition of appeal). If the objection is directed against a decision of the Chamber of 1st instance pursuant to § 22 (1) sentence 4 and the Chamber of 2nd instance comes to the conclusion that the member concerned has not violated a cease-and-desist declaration or obligation to cease and desist that is subject to penalty, the proceedings shall be referred back to the Chamber of 1st instance for a further decision pursuant to § 22 (1) sentences 1 and 2, taking into account § 20 (7) sentence 9. If the Chamber of 2nd instance considers the complaint to be inadmissible or unfounded or if, in its opinion, the facts of the case cannot be clarified in a manner necessary for the decision, it must set aside the decision of the Chamber of 1st instance and discontinue the complaint proceedings.
- (3) In the event of a finding of a Code violation within the meaning of § 24 (1) or in the event of confirmation of the decision of the Chamber of 1st instance within the meaning of § 24 (2), the Chamber of 2nd instance shall impose 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, in favor of a charitable institution. If a decision of the Chamber of 1st instance is confirmed, the Chamber of 2nd instance shall only impose a higher fine if, in the opinion of the Chamber of 2nd instance, the sanctions imposed by the Chamber of 1st instance are not sufficient to adequately reflect the seriousness of the misconduct. The fines imposed shall fall due after the decision of the Chamber of 2nd instance has been served on the member concerned. A fine that has already been paid shall remain unaffected by a reopening of the proceedings in accordance with § 27.
- (4) The Chamber of 2nd instance may also issue a public reprimand in the event of particularly serious or repeated violations, taking into account § 28 (2). In this case, the association shall publish this reprimand in its full wording and naming the member concerned. The names of employees of the member concerned or other persons involved or other companies, organizations, etc. shall be anonymized if necessary. The reprimand shall be published on the Association's homepage on the Internet and in the Association's annual report and communicated to the association or associations to which the member also belongs.
- (5) The sanctions listed in § 24 (1) to (4) are not exclusive. Where applicable, the amount of any fine initially imposed on the member concerned and now forfeited as well as the costs of the proceedings shall be taken into account. The consequences for the member affected by the sanctions must be taken into account when assessing the sanctions. Particular consideration must also be given to whether and to what extent the member concerned has taken organizational measures to counter violations of the Codes and whether the conduct complained of was merely

a one-off misconduct. In addition, the internal sanctions and organizational measures taken and implemented or promised by the member concerned in response to the misconduct in general and in each individual case must be taken into account.

- (6) § 22 (5) shall apply accordingly.

## **Section 4: Legal remedies**

### **Subsection 1: Appeals against decisions of the Chamber of 1st instance**

#### **§ 25**

#### **Objection / complaint due to inactivity**

- (1) The convicted member may appeal against the decisions of the Chamber of 1st instance within a period of two weeks after notification of the decision.
- (2) The same shall apply to the complainant if his complaint has not led to the submission of a cease-and-desist declaration with penalty clause by the member concerned or to the conviction of the member concerned by the Chamber of 1st instance or if the Chamber of 1st instance has dismissed the complaint as either manifestly inadmissible or manifestly unfounded pursuant to § 20 (2). If the objection of the complainant is directed against the discontinuation of the proceedings by the Chamber of 1st instance in accordance with § 20 (2), the proceedings shall be continued and decided in written proceedings by the Chamber of 2nd instance as the initial instance in accordance with § 24 (1) by its chairman as a single judge or by the entire Chamber of 2nd instance. The chairman may decide as a single judge if he considers the objection to be inadmissible or unfounded.
- (3) In addition, the complainant has the right to appeal to the Chamber of 2nd instance in the event that the Chamber of 1st instance fails to act, provided that the Chamber of 1st instance does not reach a decision within six months of receipt of the complaint and the company concerned has not issued a cease-and-desist declaration with penalty clause within this period due to the breach of the Code complained of. In this case, the Chamber of 2nd instance will act as the Chamber of 1st instance pursuant to § 24 (1).
- (4) The objection must be submitted in writing to the Chamber of 1st instance within the time limit specified in § 25 (1) and must state the grounds for the objection. The Chamber of 1st instance shall forward the objection to the chairman of the Chamber of 2nd instance without delay. If no objection is lodged within a period of two weeks after notification of the decision, the decision of the Chamber of 1st instance shall become incontestable within the meaning of these Rules of Procedure.
- (5) The complainant's objection may only be directed against the failure to establish a breach of the Code. An objection by the complainant against the failure to impose sanctions (administrative fines, financial penalties) or the amount of sanctions imposed is not admissible.
- (6) The member concerned may limit his/her appeal to the sanctions imposed (administrative fines, financial penalties).
- (7) A separate appeal by the member concerned or the complainant against procedural measures and decisions is not admissible. The decision is only subject to review to the extent that it is contested.

- (8) In the event of an objection by the company concerned, the review by the adjudicating body of the 2nd instance requires the prior payment of an advance on costs (§ 31 (1)). The same applies to the objecting party if the objecting party is a member or another company from the pharmaceutical industry or from the field of digital health applications (DiGA) within the meaning of § 33a SGB V (§ 31 (2)).
- (9) As part of this review, the Chamber of 2nd instance may also impose sanctions in accordance with § 24 (2) to (5) that go beyond the sanctions imposed by the Chamber of 1st instance.
- (10) Every decision of a Chamber of 1st instance (§ 22) that adversely affects the member concerned must contain information on the right of appeal. The information on legal remedies shall specify the type of legal remedy, the deadline for lodging the legal remedy and the office to which the legal remedy is to be lodged. If the information is missing or incomplete, the decision shall only become final after six weeks from service within the meaning of these Rules of Procedure. This applies accordingly to the notification of the objecting party (§ 3 (1) No. 1) in the event that the objection has not led to a declaration of discontinuance with penalty clause by the member concerned or to a conviction of the member concerned by the Chamber of 1st instance.
- (11) In the event of failure to observe the objection deadline pursuant to § 25 (1), reinstatement is not permitted.

## **Subsection 2: Appeals against decisions of the Chamber of 2nd instance**

### **§ 26**

#### **Non-appealability of the decisions**

- (1) The decisions of the Chamber of 2nd instance are final within the meaning of these Rules of Procedure.
- (2) These decisions should contain a note that an appeal is not possible in this respect. The same applies to the notification of the complainant of the outcome of the proceedings before the Chamber of 2nd instance.

## **Subsection 3: Resumption of the proceedings**

### **§ 27**

#### **Reopening of the proceedings**

- (1) The reopening of a completed objection procedure before the Chambers of 1st and 2nd instance is only permissible if
  1. the member concerned so requests and
  2. new circumstances are proven which - applying the requirements of §§ 579 and 580 of the German Code of Civil Procedure (ZPO) mutatis mutandis - alone or in conjunction with the previous basis for the decision are capable of justifying a substantially different decision.
- (2) An application to reopen the proceedings must be submitted to the Chamber that issued the decision. The application may only be made within one month of the reason for the reopening becoming known, but no later than one year after the decision in question becomes final.

- (3) The decision to reopen the proceedings shall be final within the meaning of these Rules of Procedure.
- (4) If the member concerned has submitted a cease-and-desist declaration with a penalty clause in the regular proceedings, it is not possible to reopen the proceedings.

#### **Subsection 4: Suspension of the proceedings**

##### **§ 28 Suspension of the proceedings**

- (1) The adjudicating bodies may stay the proceedings for special reasons, in particular for the reasons set out in the following paragraphs.
- (2) If, at the time the proceedings before the Chambers are initiated, a public prosecutor's investigation or criminal court proceedings in the same matter are pending or are initiated in the course of the proceedings before the Chambers, the respective Chamber shall, at the request of the member concerned, order the suspension of the proceedings until the criminal proceedings have been finally settled. The member concerned shall immediately inform the Chambers of the final settlement of the respective proceedings and provide information on the current status of the criminal proceedings at the request of the Chambers.
- (3) If civil court proceedings have been initiated against a member in the same matter, a public reprimand may only be issued at the request of the member concerned after the final conclusion of the civil court proceedings. Such a statement should not be made if the outcome of the civil court proceedings gives cause to do so. Should the civil court proceedings be suspended for longer than 6 months within the meaning of § 251 ZPO at the instigation of the parties, the proceedings shall be continued before the Chamber of 2nd instance. The member concerned shall immediately inform the Chamber of 2nd instance of the final settlement of the respective civil court proceedings and provide information on the current status of the civil court proceedings at the request of the Chamber of 2nd instance.
- (4) If several comparable proceedings against different members are pending before the Arbitration Board in one set of facts and only some of the members concerned have issued the required cease-and-desist declaration with penalty clause following a warning, the Arbitration Board shall suspend these proceedings until all proceedings in the set of facts have been concluded by a cease-and-desist declaration or a decision by the Arbitration Board. The end of the suspension shall be determined by the Chamber of 1st instance. Within the scope of this determination and depending on the circumstances of the individual case, but in accordance with the fundamental assessment in the parallel proceedings, the Chamber of 2nd instance decides whether the arbitration board waives all or individual rights from a cease-and-desist declaration already issued or accepts it after a further hearing and asserts the rights. This determination regarding the end of the suspension is not subject to appeal.

#### **Section 5: Costs of the proceedings**

##### **§ 29 Standard procedure**

If the member concerned submits a cease-and-desist declaration with penalty clause to the Chamber of 1st instance in the standard proceedings (§ 20), the member concerned

shall pay a procedural fee of EUR 2,000.00 to the association. If the declaration to cease and desist with penalty clause is submitted after the first hearing, the Chamber of 1st instance may reduce the procedural fee referred to in sentence 1.

### **§ 30**

#### **Costs for continuation of the proceedings before the Chamber of 1st instance**

If, in the course of the continuation of the proceedings (§ 21f.), the adjudicating body of the 1st instance determines in its decision that the member concerned has violated the Code, the procedural fee to be paid by the member concerned to the Association shall be EUR 5,000.00. The procedural fees for the continuation of the proceedings within the meaning of § 22f. shall not be payable if the adjudicating body of the 2nd instance sets aside the decision of the adjudicating body of the 1st instance as inadmissible or unfounded following an objection by the member concerned. If proceedings are combined, the office of the Association may reduce the procedural fee to be paid at its reasonable discretion.

### **§ 31**

#### **Proceedings before the Chamber of 2nd instance**

- (1) The conduct of proceedings before the Chamber of 2nd instance on the appeal of the company concerned against a decision of the Chamber of 1st instance requires the prior payment of an advance on costs in the amount of EUR 10,000.00, which must be paid within 14 days of receipt of a corresponding request for payment from the Association's office. In the event that proceedings are combined, the office may reduce the advance on costs to be paid at its reasonable discretion. If this advance on costs has not been received in an account of the association within this period, the proceedings before the Chamber of 2nd instance will not be conducted. If the Chamber of 2nd instance determines that the member concerned has violated the Code within the meaning of § 24 (1), the advance on costs shall be forfeited in favor of the association. The same applies if the adjudicating body of the 2nd instance rejects the appeal of the member concerned against a decision of the adjudicating body of the 1st instance within the meaning of § 24 (2); if, on the other hand, the adjudicating body of the 2nd instance merely mitigates the sanctions imposed by the adjudicating body of the 1st instance, the advance on costs shall only be forfeited to the extent that the member wins or loses. § 30 remains unaffected. Otherwise, the advance on costs shall be repaid to the company concerned after the conclusion of the proceedings within the meaning of § 26 (1).
- (2) The filing of an objection and an appeal due to inactivity of the Chamber of 1st instance is generally free of charge for the complainant. This does not apply to an appeal by a complainant who is a member or another company of the pharmaceutical industry or from the field of digital health applications (DiGA) within the meaning of § 33a SGB V. In this case, the proceedings before the Chamber of 2nd instance require the payment of a prior advance on costs in the amount of EUR 10,000.00, which must be paid within a period of 14 days after receipt of a corresponding request for payment from the Association's office, whereby § 31 (1) sentence 2 applies accordingly. The advance on costs shall be forfeited in favor of the association if the objection of the complainant before the Chamber of 2nd instance does not result in a finding of a violation of the Code. Otherwise, the advance on costs shall be repaid to the complainant after the conclusion of the proceedings within the meaning of § 26 (1). If the offending company is not a member of the Association, the proceedings before the Chamber of 2nd instance are also dependent on a prior express written declaration of consent to the cost-bearing provision of § 31 (2) sentences 2 and 3.

**§ 32**  
**Necessary expenses**

If the respective adjudicating bodies determine that the member concerned has violated the Code, the member must pay not only the procedural fees but also the reasonable expenses for travel and accommodation of any witnesses or experts invited. The same applies to reasonable remuneration for the work of experts.

**§ 33**  
**Due date for procedural fees and necessary expenses / VAT**

- (1) The procedural fees and necessary expenses are determined by the association's office and are due upon the decision of the respective adjudicating body becoming final.
- (2) The procedural fees specified in §§ 29 to 31 and the necessary expenses pursuant to § 32 shall be subject to the applicable statutory value added tax.

**§ 34**  
**Reopening of the proceedings**

- (1) If the respective Chambers rejects an application to reopen a completed objection procedure, the procedural fee for the decision on this application shall be based on the fee for the completed objection procedure.
- (2) If the respective Chamber grants an application to reopen the proceedings and the reopening of the proceedings leads to the original decision being set aside, any procedural fees and expenses already paid for the original proceedings shall remain unaffected. If the reopening of the proceedings leads to a partial annulment of the original decision, the registry shall set a procedural fee for the member concerned. The amount of the procedural fee is at the discretion of the registry and should take into account the ratio of the original penalty to the new penalty determined as a result of the retrial. It may not exceed the fee that would have been owed if the application for retrial within the meaning of § 34 (1) had been rejected.