

**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.*

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## **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 require close professional collaboration with physicians and other members of the healthcare community. At the same time, it is the responsibility of pharmaceutical companies to provide accurate and appropriate information about medicinal products that is necessary for the proper selection, dispensing, and use of such products. To promote fair competition in advertising and collaboration with healthcare professionals, the General Assembly of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V." (FSA) adopted the FSA Code for Healthcare Professionals, the FSA Code for Patient Organizations, and the FSA Transparency Code. To account for the growing importance of Digital Health Applications (DiGA) in patient care, the members of the Association have extended the scope of the FSA Codes and the Rules of Procedure on Medicines to include DiGA as well.

The members of the association are aware that public trust in the integrity of pharmaceutical companies regarding advertising and collaboration with healthcare professionals depends crucially on effective monitoring of compliance with and enforcement of the codes. In addition to effective and transparent sanctions for violations, this requires that any natural or legal person be able to file a complaint, which is reviewed in a two-stage procedure involving not only representatives of the member companies but also representatives of healthcare professionals, patient representatives, and the chairs of the first and second instances as independent members. With the aim of establishing such a procedure and thereby ensuring consistent compliance with the codes, the association's general meeting has adopted the following

### **Rules of Procedure for the Association's Members "Voluntary Self-Regulation for the Pharmaceutical Industry e. V."**

## **Section 1: General Provisions**

### **§ 1 Purpose and Scope**

- (1) The Rules of Procedure serve to monitor compliance with the codes and to pursue violations of the codes.
- (2) The adjudicating bodies of the first and second instances are responsible for fulfilling the tasks specified in § 1(1).
- (3) Members of the Association who have committed a violation of the Code are responsible for such violations. Affiliated companies are treated as members. In the case of a corporate group, the affiliated company that is itself a member of the Association or an affiliated company is primarily liable for violations of the Code. Furthermore, violations of the Code by affiliated subsidiaries that are neither members of the Association nor affiliated companies are attributed to the member that controls the company in question. In multi-tiered corporate groups, such violations are attributed to the next higher controlling company that is a member or an affiliated company.

### **§ 2 Definitions**

For the purposes of these Rules of Procedure, the following terms shall have the following meanings

1. " Interpretation Guidelines " the regulations issued pursuant to § 6(2) of the FSA Code for Expert Groups and § 5 of the FSA Code for Patient Organizations;
2. "Bias" means the existence of a reason that is likely to give rise to mistrust regarding the impartiality of a member or alternate of an adjudicatory body;
3. "substantiated complaint" a complaint based on an established violation of the Code;
4. "Complaint" means a request, accompanied by a statement to the Association, to pursue an alleged violation of the Code by a member;
5. "complaining member" means a complainant who is a member of the Association;
6. "complainant" means the person who files a complaint with the Association;
7. "Subject of the Complaint" means the specific violation of the Code in connection with the underlying facts from which the complainant derives his or her claim;
8. "Respondent" means the member accused of a violation of the Code in the complaint;
9. "Complaint Party" means the complaining member or the respondent;
10. "Complainant and Respondent" means the complaining member and the respondent;
11. "Third-party complainant" means the complainant who is not a member of the association;

12. "Fine" means a penalty imposed by an adjudicatory body for a member's established violation of the Code;
13. "FSA Code for Healthcare Professionals" means the FSA Code governing the pharmaceutical industry's cooperation with physicians, pharmacists, and other healthcare professionals;
14. "FSA Code for Patient Organizations" means the FSA Code governing the pharmaceutical industry's cooperation with patient organizations;
15. "FSA Transparency Code" means the FSA Code on transparency in cooperation with healthcare professionals and medical institutions;
16. "Code Violation" means a violation of the provisions listed in Section 7(1)(1) through (3),
17. "Codes": the FSA Code for Professional Groups, the FSA Code for Patient Organizations, and the FSA Transparency Code;
18. "Administrative fine" means a sanction for a violation of a cease-and-desist order issued by an adjudicatory body;
19. "Alternate" means a person appointed pursuant to Section 24(4) in the event of the incapacity or bias of a member of an adjudicatory body;
20. "Declaration of cessation subject to penalty" means a declaration within the meaning of Section 20(1), sentence 2;
21. "cease-and-desist obligation" means an obligation imposed by the adjudicating bodies within the meaning of Section 23(1), sentence 1, Section 25(1), or Section 25(2);
22. "submitted undertakings" means undertakings affiliated with members that have submitted in writing to the Articles of Association, these Rules of Procedure, and the Codes;
23. "Association" " " the association "Freiwillige Selbstkontrolle Arzneimittelindustrie e.V.";
24. "Parties to the proceedings" means the complainant, the respondent, the managing director of the Association, the members of the adjudicating body, and, in the event of a hearing before the adjudicating body of the second instance, also the chairperson of the adjudicating body of the first instance who rendered the decision as the adjudicating body of the first instance;
25. "Rules of Procedure" means these Rules of Procedure for the members of the Association;
26. "Contractual penalty" means a sanction for a breach of a cease-and-desist declaration with a penalty clause issued by the respondent;
27. "Video hearing" means an oral hearing in which at least one party to the proceedings or a representative within the meaning of § 13(1) participates via video and audio transmission; and
28. "Repeated violation of the same nature" means a violation occurring three times within two years that is either identical or, in its characteristic elements,

“essentially the same” as a violation that was already the subject of a substantiated complaint.

### **§ 3**

#### **Guidelines of the Executive Board**

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

### **Section 4**

#### **General Principles of Interpretation**

In addition to the provisions of these Rules of Procedure, procedural and substantive legal provisions may be applied to their interpretation, in particular those of the Federal Rules of Civil Procedure, the German Civil Code, and the Unfair Competition Act.

### **§ 5**

#### **Record Management and Right to Inspect Records**

- (1) The Association’s office maintains and manages the files of the adjudicating bodies.
- (2) The parties to the proceedings and the association’s board of directors have the right to inspect the files at any time. This does not apply to third-party complainants.

### **§ 6**

#### **Confidentiality and Disclosure Obligations Regarding the Work of the Adjudicatory Bodies**

- (1) The members of the association’s governing bodies, the members of committees, and the association’s employees, including the executive director, are obligated to maintain confidentiality regarding their activities, the information obtained in the course of such activities, and all matters that are confidential by nature or expressly designated as such.
- (2) To the extent that persons other than those specified in § 6(1) are involved in the association’s work, they must be bound to confidentiality before commencing their activities.
- (3) The Association publishes the Articles of Association, the Codes, the Rules of Procedure, and the Interpretation Guidelines on the Internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)).
- (4) The Executive Director shall regularly inform the Board of Directors, the members, and the Advisory Board about the work of the adjudicatory bodies and about the complaints handled by the adjudicatory bodies of the first and second instances. In addition, by the end of the first quarter of each new calendar year, the Executive Director shall submit a detailed public report on the work of the adjudicatory bodies in the preceding calendar year, which shall also be published on the Internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)). This report shall provide a summary of the activities of the adjudicatory bodies.

- (5) In cases where a violation of the Code has been established as final and binding, the
1. final decisions of the adjudicatory bodies of the first and second instances;
  2. submitted cease-and-desist declarations subject to penalties; and
  3. public reprimands within the meaning of Section 25(5)

published on the Internet by posting the operative part and the essential grounds for the decision ([www.fsa-pharma.de](http://www.fsa-pharma.de)).

- (6) The reports and publications shall be issued with the name of the respondent. If complaints do not result in a finding of a Code violation, a publication shall also be issued if the adjudicating body advocates publication in view of the significance of the decision. However, in this case, the name of the respondent shall not be disclosed.
- (7) The second-instance adjudicatory body shall be informed of all decisions of the first-instance adjudicatory body as well as of any cease-and-desist declarations submitted. The members of the first- and second-instance adjudicatory bodies shall regularly discuss the work of the adjudicatory bodies. The chairs of the first- and second-instance panels have the right to submit proposals to the association's board for amendments and additions to these rules of procedure or the codes that the second-instance panel deems appropriate for the effective sanctioning of code violations in advertising and collaboration with members of the professional community or in collaboration with patient self-help organizations.

## **Section 2: General Rules of Procedure**

### **Subsection 1: Initiation of Proceedings**

#### **§ 7 Right to File a Complaint**

- (1) Any natural or legal person may file a complaint with the association alleging that a member has violated the regulations
1. of Sections 3 and 4 of the FSA Code for Professional Groups, taking into account the principles of interpretation set forth in Section 2 of this Code,
  2. Section 3 of the FSA Code for Patient Organizations, taking into account the principles of interpretation set forth in § 4 of this Code, or
  3. Section 2 of the FSA Transparency Code, taking into account the principles of interpretation set forth in § 4 of this Code

The adjudicating bodies of the first and second instances are free in their legal assessment of the facts of the case in question and, in particular, are not bound or restricted by the complaint.

- (2) The right to file a complaint under Section 7(1)(1) is limited to members and other companies regarding violations of the provisions of Section 4 of the FSA Code for Professional Circles, taking into account the applicable principles. The provisions of the FSA Code for Healthcare Professionals do not apply to non-prescription medicines of members and their affiliated companies, unless the

member company has voluntarily agreed to comply with the FSA Code for Healthcare Professionals also for non-prescription medicines.

- (3) The Executive Board may initiate a complaint procedure against members of the Association on its own initiative. This also applies if the complaint procedure initiated by the Executive Board is based on an anonymous complaint (§ 9 (3)). Upon initiation of a complaint procedure, the Executive Board is not considered the complainant.
- (4) The complaint is inadmissible if, at the time the complaint is filed, the respondent has already issued a comprehensive cease-and-desist declaration to the complainant, or the complainant has obtained a corresponding court decision, or if court proceedings are pending in this regard that have not yet been legally concluded. However, the prior submission of cease-and-desist declarations to third parties does not preclude the respondent's obligation to submit a cease-and-desist declaration subject to a penalty under these Rules of Procedure.

## **§ 8**

### **Further Rights of the Complainant**

- (1) The complainant has the right to participate in the proceedings.
- (2) The third-party complainant has only the following rights to information and review in the proceedings:
  1. He shall be informed of the outcome of the proceedings by being sent the operative part of the decision and the essential grounds for the decision (Section 11(13), sentence 2) and shall be advised of the procedural rights available to him.
  2. He has the right to
    - a) to file an objection to decisions of the first-instance adjudicatory body, provided that his complaint does not result in a finding of a violation of the Code (Section 26(1));
    - b) in the event of inaction by the first-instance adjudicatory body to appeal to the second-instance adjudicatory body, provided that the first-instance adjudicatory body does not render a decision within 6 months of receiving the complaint and the respondent has not, within that period, issued a cease-and-desist declaration subject to a penalty in response to the complaint (§ 26(2)) .

## **§ 9**

### **Content and Form of the Appeal**

- (1) The complaint must be addressed to the Association's Executive Director by letter, email, or via the online complaint form ([www.fsa-pharma.de](http://www.fsa-pharma.de)) and must be substantiated. It should be supported, if possible, by the inclusion of relevant documentation. The Executive Director shall forward the complaint to the competent first-instance adjudicatory body for consideration.
- (2) The subject of the complaint may only be alleged violations of the Code that occurred after the respondent joined the association or signed the declaration of compliance and that took place no more than one year ago.

- (3) Anonymous complaints regarding violations of the provisions of Section 3 of the FSA Code for Professional Circles will not be considered, with the exception of § 7(3). Member companies are required to submit complaints by disclosing their identity. Other companies and individuals are encouraged to submit complaints openly as a general rule and to do so anonymously only if there is a specific need for anonymity.
- (4) If a third-party complainant is another company in the pharmaceutical industry or in the field of digital health applications (DiGA) as defined in Section 33a of the German Social Code, Book V (SGB V), the complaint is subject to prior express written consent to the cost-sharing provisions of Sections 30 through 35.

## **Subsection 2: Principles and Procedure**

### **§ 10 Jurisdiction**

- (1) The first-instance adjudicatory body has jurisdiction in the first instance over all appeals, unless the second-instance adjudicatory body has jurisdiction (§ 10(2)).
- (2) The Second Instance Panel has jurisdiction as the initial instance in cases of repeated violations of the same nature (§ 21(1) in conjunction with § 25(1)) as well as in cases where the complainant alleges inaction (§ 26(2)). The second-instance panel is competent as the appellate body to decide on appeals against decisions of the first-instance panel (Section 26(1)).

### **§ 11 Procedural Flow**

- (1) A complaint that has been filed shall be served on the respondent.
- (2) Unless a complaint is already resolved in the warning procedure (§ 20), the chairperson of the adjudicating body shall set a date for an oral hearing.
- (3) If there is a connection between several complaints pending before the panel, the chairperson of the panel may order that they be joined. The chairperson of the second-instance panel may order the separation of joined proceedings.
- (4) The panels generally meet at the association's headquarters in Berlin. Upon a decision by the chairperson of the adjudicating body, the complaint may be pursued through written proceedings if, in the chairperson's discretion, scheduling an oral hearing is deemed unnecessary. The chairperson of the adjudicating body shall order this if it is proposed by one party to the complaint and the other party does not object within one week.
- (5) The chairperson of the adjudicating body may order procedural and preparatory measures (such as obtaining additional information, etc.).
- (6) The chairperson of the adjudicating body may summon witnesses and experts at any stage of the proceedings. The parties to the appeal are required to enable company employees who have been summoned as witnesses or experts to participate in the oral hearing, provided that this is not precluded by labor law or other compelling reasons.
- (7) The parties to the proceedings shall be invited to the oral hearing. The oral hearing is not open to the public.

- (8) The invitation shall be sent by registered mail with return receipt or by email to the parties to the proceedings. The invitation shall be sent no later than three weeks before the oral hearing. It must contain the following information:
1. The content of the complaint, accompanied, where appropriate, by documents that enable the parties to the complaint to properly prepare for the oral hearing,
  2. The place and time of the oral hearing,
  3. the names of the members and alternates of the panel,
  4. a notice that the members and alternates of the adjudicating body may be challenged on grounds of bias,
  5. a statement that a decision may be rendered in the absence of a party to the appeal or its representative,
  6. the names of invited witnesses and experts,
  7. a note that the parties to the appeal may be represented by an authorized employee and/or an attorney at any stage of the proceedings.
- (9) If the proceedings are conducted in writing, § 11(8), sentence 3, nos. 1, 3, 4, and 7, as well as paragraph 9, shall apply mutatis mutandis. The chairperson of the panel may set deadlines for the submission of statements.
- (10) The complainant may withdraw the complaint or an appeal at any stage of the proceedings. The Board of Directors or the Executive Board may decide within two weeks to continue the complaint proceedings. Otherwise, the complaint proceedings shall be discontinued depending on the stage of the proceedings. For §§ 30 through 35, withdrawal shall be deemed a defeat of the complainant.
- (11) Prior to a decision preceded by an oral hearing, the parties to the proceedings (with the exception of the members of the adjudicatory body) shall be given the opportunity to make closing statements. The respondent or their representative shall have the final word.
- (12) The adjudicating bodies may announce the decision and its essential reasoning to the parties to the proceedings immediately following the oral hearing and after the conclusion of deliberations.
- (13) The final, written decision of the panel shall be signed by the chairperson and served on the parties to the appeal, together with a written statement of reasons, within one month of the oral hearing or the conclusion of the written proceedings. Third-party appellants shall also be informed in writing of the outcome of the proceedings by means of the delivery of the operative part of the decision and the reasons for the decision. The names of employees of the respondent or other involved persons, companies, or organizations shall be anonymized where necessary.

- (14) Any decision by a first-instance adjudicatory body (§ 23) that adversely affects a party to the appeal or a third-party appellant must include instructions on the right to appeal. The instructions on the right to appeal shall
1. the type of appeal,
  2. the deadline for filing the appeal, and
  3. the authority to which the appeal must be filed,

## **§ 12 Oral Hearing**

- (1) The chairperson of the adjudicating body presides over the oral hearing. After opening the hearing, the chairperson announces the composition of the adjudicating body and verifies attendance. The chairperson questions the respondent and the witnesses and identifies and explains the other evidence. The chairperson of the adjudicating body may hear the other parties to the proceedings.
- (2) The chairperson of the adjudicating body shall instruct the witnesses to tell the truth and shall dismiss them until they are questioned. In special circumstances, witnesses and experts may be examined in writing or in advance by the chairperson or a representative appointed by him or her. The results of the examination shall be presented by the chairperson during the oral hearing. The chairperson of the panel may order that witnesses or experts be examined via video and audio transmission.  
The parties to the appeal may name additional witnesses until the end of the oral hearing. These witnesses must be present at the oral hearing, unless they have already been invited to the oral hearing by the chairperson of the adjudicating body.
- (3) The parties to the proceedings have the right to ask questions during the oral hearing.
- (4) If a party to the appeal fails to appear at the oral hearing despite having been duly summoned and is not validly represented, the panel may decide on the basis of the available evidence as reflected in the case file. In such a case, the chairperson of the panel may also set a new date for the oral hearing. If witnesses or experts have been summoned, the panel may question them.
- (5) Minutes shall be taken of the oral hearing, which shall reflect the essential content of the oral hearing. Any motions by parties to the proceedings and decisions of the adjudicating body shall be included in the minutes verbatim or attached to the minutes as an appendix.
- (6) All parties to the proceedings may request that individual statements be recorded verbatim.
- (7) The minutes shall be signed by the presiding judge and sent to the parties to the proceedings.
- (8) The chairperson of the adjudicating body may order that the oral hearing be conducted as a video hearing. The chairperson of the adjudicating body shall order this if it is requested by one party to the appeal and the other party to the appeal does not object within one week. The chairperson of the adjudicating body shall

generally conduct the video hearing from the association's headquarters. He may permit other members of the adjudicating body to participate in the oral hearing via video and audio transmission in the event of his absence or if there are compelling reasons to do so. The parties to the proceedings and third parties are prohibited from recording the video hearing or processing it using artificial intelligence systems. They must be informed of this at the beginning of the oral hearing.

### **§ 13 Representation**

- (1) The parties to the appeal may be represented at any stage of the proceedings by an authorized employee and/or an attorney.
- (2) The costs of representation or legal counsel for the parties to the appeal shall be borne by them, regardless of the outcome of the proceedings.
- (3) Upon request, authorized representatives of the parties to the appeal must identify themselves by submitting a power of attorney to the adjudicating body.

### **§ 14 Time Limits**

- (1) The parties to the appeal must comply with the established deadlines. Statements that are subject to deadlines and must be submitted in writing must be sent either by certified mail or by email. The burden of proof for the receipt of such statements rests with the party to the appeal. Upon request, the Association's office will confirm receipt of timely statements via email.
- (2) If a deadline is missed, the parties to the appeal may, upon request, be granted reinstatement to the previous status if they were prevented from meeting the deadline through no fault of their own. The request must be submitted in writing within one week after the obstacle ceases to exist to the adjudicating body before which the original deadline would have had to be met. Reinstatement of the objection period pursuant to § 26(1) is not permitted.
- (3) The provisions of Sections 221 through 225 of the Code of Civil Procedure apply mutatis mutandis.

## **Section 3: Adjudicating Body**

### **§ 15 Cases of Incapacity**

In the event that a member of the second-instance adjudicating body is unable to attend, the second-instance adjudicating body shall, upon a decision by the presiding judge, replace the member of the adjudicating body with a substitute appointed pursuant to § 24(4). If the incapacity arises at short notice, the second-instance panel may, upon a decision by the chairperson, decide without the affected member of the panel, but in any case, notwithstanding § 24(1), with the chairperson and three other members of the panel. At least one representative of the company's employees, one representative of the medical profession, and one representative of the patients must be present. Section 12(8), sentence 4, remains unaffected by this.

**§ 16**  
**Disqualification**

- (1) Members or alternates of the adjudicating body may be challenged by the parties to the complaint on grounds of bias or may recuse themselves. They must recuse themselves if they are employees of a party to the complaint or were or are themselves involved in the matter in question.
- (2) If a party to the appeal considers a member or alternate of the adjudicating body to be biased, a motion to recuse must be filed with the adjudicating body within one week of receipt of the summons and must be substantiated. The affected members or alternates of the adjudicating body shall respond to the motion to recuse within one additional week of receiving the motion. The statement shall be forwarded to the parties to the complaint. The affected members or alternates are biased if they themselves consider the motion for recusal to be well-founded.
- (3) The second-instance panel, through its presiding judge acting as a sole judge, shall decide on the existence of grounds for recusal regarding members of the first-instance panel. If the presiding judge of the second-instance panel finds the motion for recusal against the presiding judge of the first-instance panel to be well-founded, the presiding judge of the second-instance as the first-instance panel shall decide on the appeal, unless additional first-instance panels have been established, in which case their jurisdiction shall be determined in accordance with the schedule of cases for the first-instance panels (§ 18, sentence 4). If the chairperson of the second-instance panel is recused for bias, the deputy chairperson of the second-instance panel shall decide as the first-instance panel; if the deputy chairperson is also recused for bias, a member of the second-instance panel designated by the association's executive board shall decide. If a party to the appeal files an objection to the decision of the chairperson of the second-instance adjudicatory body acting as the first-instance adjudicatory body, the chairperson of the second-instance adjudicatory body shall not participate in the further proceedings. The vice-chairperson of the second-instance adjudicatory body shall take his or her place.
- (4) The members of the second-instance adjudicatory body shall decide on the existence of grounds for recusal with respect to members or alternates of the second-instance adjudicatory body without the affected member of the adjudicatory body. A member of the second-instance adjudicatory body who has been recused due to bias shall be replaced by an alternate appointed pursuant to § 24(4). If the bias of a member of the second-instance adjudicatory body is determined shortly before the oral hearing, § 15, sentence 2, shall apply mutatis mutandis. If the presiding judge does not participate in proceedings due to concerns regarding bias, the second-instance adjudicatory body shall decide under the direction of the vice-chair.
- (5) If a circumstance arises during the proceedings that could justify a concern regarding bias, the challenge must be filed immediately before any further statements on the merits of the case are made.

### **Section 3: Panel**

#### **§ 17**

#### **Term of Office and Independence from Instructions of Members of the Adjudicating Bodies of the First and Second Instance**

- (1) The members of the adjudicating body of the first instance are appointed by the Executive Board for a term of two to five years. Upon expiration of this term, a new appointment is made. Reappointment is permitted.
- (2) The members of the second-instance adjudicatory body shall be appointed by the Executive Board for a term of two years in accordance with § 24. Upon expiration of this term, a new appointment shall be made. Reappointment is permitted.
- (3) The Executive Board may remove members of the first- and second-instance adjudication bodies during their term of appointment only for good cause.
- (4) The members and alternates of the first- and second-instance adjudication bodies are not subject to any instructions from the Association, the member companies, or third parties with regard to their activities, nor are they bound by any prior consultation of the member companies by the Association. To avoid a conflict of interest, members of the first-instance adjudication body may not work for or become employed by a member of the Association. The chairperson of the second-instance adjudicatory body may not work for a member of the Association or any other company in the pharmaceutical industry or in the field of digital health applications (DiGA) as defined in § 33a SGB V.

### **Subsection 1: Adjudication Panel of First Instance**

#### **§ 18**

#### **Composition**

The Executive Board may establish one or more first-instance adjudicatory bodies. Each of these shall be composed of a single judge. The managing directors of the Association shall not serve as single judges. If there are multiple first-instance adjudicatory bodies, the Executive Board shall issue a plan of division of duties setting forth the exact areas of responsibility. The members of the first-instance adjudicatory bodies must be qualified to serve as judges.

#### **§ 19**

#### **Preliminary Review**

- (1) The first-instance adjudicatory body reviews the complaints received and prepares the proceedings by conducting its own investigation of the facts. The first-instance panel shall examine whether the second-instance panel has jurisdiction pursuant to § 10(2). In such a case, the first-instance panel shall forward the complaint and the results of the preliminary review to the chairperson of the second-instance panel.
- (2) To investigate the facts, the first-instance panel may request the complainant to further substantiate their complaint, or the respondent to submit a statement or provide documents. The first-instance panel may schedule a hearing at any time to discuss the complaint with the respondent. It may also invite the complainant to attend this hearing.
- (3) If, on this basis, it appears that the appeal is either manifestly inadmissible or manifestly unfounded, the appellant shall be given the opportunity, upon

notification of the preliminary assessment, to further substantiate his appeal within two weeks. Thereafter, the first-instance panel shall decide whether to continue or dismiss the proceedings. The complainant may challenge the discontinuation of the proceedings within two weeks by filing an objection to the discontinuation. If, as a result of the objection to dismissal, the first-instance panel determines that the complaint is not manifestly inadmissible or manifestly unfounded, the proceedings before the first-instance panel shall continue. If the first-instance panel does not grant the objection to dismissal, an appeal against dismissal may be filed. The second-instance panel shall decide on the appeal against dismissal through its presiding judge acting as a single judge. If the presiding judge of the second-instance panel grants the appeal against dismissal, the proceedings before the second-instance panel shall continue; otherwise, the proceedings shall be dismissed.

- (4) If the respondent fails to comply with a request for cooperation made within a reasonable time limit, § 12(4) shall apply mutatis mutandis. In all other respects, the appeal shall be assessed based on the record or on the available evidence. If the appellant has filed a sufficiently substantiated appeal—for example, by specifying concrete factual circumstances regarding the time, place, and nature of the alleged act—the adjudicating body may deem this statement of facts to be admitted, provided the respondent does not submit a substantiated counter-statement. As part of a substantiated counter-statement, the respondent is generally also required to submit available documents or present suitable evidence in accordance with their duty to facilitate the proceedings.

## **§ 20**

### **Warning proceedings before the tribunal of first instance**

- (1) If the tribunal of first instance deems the complaint admissible and well-founded, it shall issue a warning to the respondent. The warning shall contain a notice of the violation of the Code and a request to the member to submit a written cease-and-desist declaration to the association within a period of two weeks, subject to a penalty, in which the member undertakes to
1. refrain from violating the Code in the future and to pay an appropriate contractual penalty for each instance of violation, as well as
  2. to pay an appropriate fine for the violation of the Code.

The amount of the contributions to be paid shall be determined by the adjudicating body of first instance in accordance with § 20 (2), (3).

- (2) The contractual penalty is appropriate if it is suitable for eliminating the risk of recurrence. The following circumstances must be taken into account when determining it:
1. the nature, extent, and consequences of the violation,
  2. the severity of the fault,
  3. The size, market strength, and competitiveness of the respondent, as well as
  4. the respondent's economic interest in the past and future violations.

In doing so, the limits set forth in Section 23(3), sentence 1, must be observed.

- (3) The fine is appropriate if it appears necessary to penalize the violation of the Code based on the overall circumstances, in particular the severity of the violation. In doing so, the limits set forth in Section 23(3), sentence 2, must be observed.
- (4) If the association accepts the cease-and-desist declaration subject to a penalty, the respondent's obligations take effect and the fine becomes due for payment upon demand. This concludes the proceedings.
- (5) Notwithstanding § 20(1), proceedings regarding substantiated complaints against the FSA Transparency Code shall automatically be terminated, provided that
  1. the violation is not significant in terms of its nature and scope, and
  2. the respondent remedies the violation within two weeks of being notified by the adjudicating body of the first instance.

If no remedy is provided, the provisions of these Rules of Procedure shall apply without restriction.

- (6) Notwithstanding § 20(1), proceedings involving substantiated complaints may be concluded by issuing a warning, provided that the respondent accepts it within two weeks. In such a case, the fine is waived. The remaining provisions of these Rules of Procedure apply without restriction.
- (7) If the respondent fails to submit the cease-and-desist declaration subject to a penalty as required under § 20(1), sentence 2, within the prescribed time limit, the proceedings shall continue (§ 22). A subsequent declaration of discontinuance subject to a penalty that deviates from the required declaration does not result in the termination of the proceedings, but may be taken into account by the trial panel of first instance when determining possible additional sanctions.

## **§ 21**

### **Repeated violations of the same nature**

- (1) If, during the preliminary review (Section 19), the first-instance panel during the preliminary review (§ 19) that a repeated violation of the same nature has occurred and that the respondent has violated a cease-and-desist declaration subject to a penalty pursuant to § 20(1), sentence 2, or a cease-and-desist obligation, the Association shall enforce the contractual penalty or administrative fine specified therein against the respondent.
- (2) The first-instance panel shall offer the respondent the opportunity to enter into a new cease-and-desist declaration subject to a penalty within the meaning of § 20(1), sentence 2. In this case, the contractual penalty and fine shall be appropriately increased to eliminate the continuing risk of recurrence.
- (3) If the respondent has agreed to pay the contractual penalty or the administrative fine pursuant to § 21(1) as well as to enter into the cease-and-desist declaration subject to a penalty pursuant to § 21(2), the proceedings under the German Act on the Protection of Competition ( ) shall be terminated and the fine or administrative fine shall become due. Otherwise, the proceedings shall continue (§ 22).
- (4) If, in the further proceedings before the adjudicating bodies, it becomes apparent that, during the preliminary review, the adjudicating body of first instance wrongly assumed a repeated violation of the same nature and that, therefore, a different, new violation exists, and if the respondent has offered the adjudicating body of first together with their objection, offered to submit a cease-and-desist declaration

subject to a penalty, specifying an appropriate contractual penalty with regard to a new, different violation that has been committed, the proceedings shall be terminated in accordance with § 20 (4).

- (5) Notwithstanding § 21(1), the first-instance adjudicatory body must immediately refer the proceedings to the second-instance adjudicatory body for a decision as the court of first instance if, during the initial review of an appeal, it becomes apparent to the first-instance adjudicatory body that
  1. in connection with a repeated violation of the same nature involving at least two violations of the Code, the respondent has either issued a cease-and-desist declaration subject to a penalty or a cease-and-desist order has been issued, and
  2. the first-instance panel concludes that the further appeal is not manifestly inadmissible or unfounded (Section 19(3)).

## **§ 22**

### **Continuation of proceedings before the trial court**

The oral hearing shall take place within four weeks after the expiration of the two-week period for submitting the declaration of discontinuance subject to a penalty.

## **§ 23**

### **Decisions of the first-instance tribunal**

- (1) If the complaint has not already been resolved in the warning procedure (§ 20) and if the complaint is admissible and well-founded, the first-instance panel shall find a violation of the Code punishable by a fine and issue a cease-and-desist order against the respondent, pursuant to which the respondent is obligated to refrain from the violation of the Code in the future and to pay an appropriate administrative fine for each instance of non-compliance. If the appeal is inadmissible or unfounded, or if the facts of the case cannot be clarified to the extent necessary for a decision, the appeal proceedings shall be discontinued.
- (2) If the proceedings before the first-instance adjudicatory body are continued pursuant to § 21(3), sentence 2, the body shall examine whether the appeal is admissible and well-founded and whether it concerns a repeated violation of the same nature. If these requirements are met, the body shall render a corresponding decision, which shall also include an increase in the administrative fine in accordance with § 21(2), sentence 2. Once the decision becomes final within the meaning of Section 27(1), the Association shall, on the basis of the findings made, assert against the respondent the contractual penalty specified in the cease-and-desist declaration or the administrative fine specified in the cease-and-desist undertaking. If, however, the trial court finds that the respondent has not violated a cease-and-desist declaration subject to a penalty ( ), but the complaint is nonetheless admissible and well-founded, § 23(1) sentence 1 shall apply, taking into account § 21(4).
- (3) The administrative fine to be determined by the trial court may not exceed, for each instance of the violation, an amount equal to 20 times the respondent's contribution, but in no case more than EUR 200,000.00. The fine to be determined by the trial court in favor of a charitable organization may not exceed an amount ranging from at least EUR 5,000.00 to twenty times the respondent's contribution, but not exceeding EUR 200,000.00. The charitable organization shall be designated by the trial panel after the fine becomes due. The imposed fine becomes due once the decision is final within the meaning of § 27(1).

- (4) In the event of a repeat offense, an additional fine shall be imposed in addition to the administrative fine only if, based on the overall circumstances and the severity of the violation, immediate punishment is necessary and appropriate, taking into account the administrative fine initially imposed and now payable, as well as the fine and the procedural costs for the previous violation.

In determining the sanction, the following factors, among others, shall be taken into account:

1. the consequences of the sanctions for the respondent,
  2. whether and to what extent the respondent has taken organizational measures to prevent violations of the codes and whether the alleged conduct was merely a one-time lapse, and
  3. what internal sanctions and organizational measures the respondent has taken and implemented, or at least promised to take, in response to the alleged misconduct in general as well as in the specific case.
- (5) Any liability of the association, its bodies, and members of its bodies shall be determined by the adjudicating body in accordance with § 839(2), (3) of the German Civil Code (BGB) as applied mutatis mutandis and is otherwise excluded. Liability for intentional acts remains unaffected.

## **Subsection 2: Adjudicatory Body of Second Instance**

### **§ 24 Composition**

- (1) The second-instance adjudicatory body shall consist of the chairperson and at least four and at most twelve additional persons. Of these additional persons, half must be employees of the association's members, one-quarter must be physician representatives, and another one-quarter must be patient representatives.
- (2) The Executive Board shall determine the number of members of the second-instance adjudicatory body and appoint the members of the second-instance adjudicatory body in accordance with the provisions of § 24(1). The chairperson of the second-instance adjudicatory body must be qualified to serve as a judge. The persons representing the medical profession must hold a medical license. The appointment of physician representatives shall be based on nominations from one or more medical organizations, and the appointment of patient representatives shall be based on nominations from patient organizations. The Executive Board may deviate from these proposals only if there are reasonable doubts regarding the impartiality of the proposed individuals. If no proposals are submitted, the Executive Board shall appoint the members of the second-instance adjudicatory body from among licensed physicians and patients at its discretion.
- (3) The persons who, as company employees, represent the members of the association, as well as the chairperson of the second-instance adjudicatory body, shall be appointed by the Executive Board at its discretion, without the need for a proposal from third parties.
- (4) The Executive Board shall draw up a list of alternates for the second-instance adjudicatory body. § 24(1) through (3) shall apply mutatis mutandis to the selection and appointment of the alternates. The Executive Board shall publish the list of alternates on the Internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)). In the event of a conflict

of interest or inability to serve on the part of a representative of the company employees, a representative of the medical profession, or a representative of the patients, all alternate members representing the company employees, the medical profession, or the patients, respectively, shall be contacted. The alternate member shall be appointed in the order in which the contacted alternate members respond.

- (5) The Executive Board shall also appoint a member of the second-instance adjudicatory body as vice-chairperson.

## **§ 25**

### **Decisions of the Second-Instance Adjudication Body**

- (1) If the Second Instance Panel acts as the court of first instance by referral (§ 21(5)), § 23(1) shall apply mutatis mutandis. The administrative fine to be imposed by the Second Instance Panel may not exceed, for each instance of the violation, an amount equal to 20 times the respondent's contribution, but in no case more than EUR 400,000.00. If the second-instance panel determines that a referral pursuant to § 21(5) was made in error, the proceedings before the second-instance panel shall continue. However, in this case, the second-instance panel may impose only the sanctions applicable to the first-instance panel (§ 23). The provision of § 20(4) applies mutatis mutandis. If the second-instance tribunal acts as the court of first instance on the basis of a complaint of inaction (§ 26(2)), § 23 applies mutatis mutandis.
- (2) If the second-instance adjudicating body acts upon an appeal against a decision of the first-instance adjudicating body (§ 26), it may, within the scope of § 26(4), affirm the contested decision, set it aside, or modify the sanctions imposed by the first-instance adjudicating body. In doing so, the second-instance adjudicating body may, pursuant to § 25(4) through (6), impose sanctions within the range of penalties available to it that are more severe than those imposed by the first-instance adjudicating body (no prohibition on increasing the severity of the penalty).
- (3) The second-instance panel shall decide by a majority vote of its members. In the event of a tie, the decision shall be deemed not to have been made; in the case of a decision on the appeal, it shall be dismissed as inadmissible or unfounded.
- (4) If a violation of the Code within the meaning of § 25(1) is found, or if the decision of the first-instance panel is upheld, the second-instance panel within the meaning of § 25(2), a fine of at least EUR 5,000.00 up to 20 times the respondent's contribution, but not exceeding EUR 400,000.00, in favor of a charitable organization. In the event of confirmation of a decision by the first-instance adjudicatory body, the second-instance adjudicatory body shall impose a higher fine only if, in the opinion of the second-instance adjudicatory body, the sanctions imposed by the first-instance adjudicatory body are insufficient to adequately reflect the severity of the violation. The fines imposed shall become due upon service of the decision of the second-instance panel on the respondent.
- (5) The second-instance panel may also issue a public reprimand in cases of particularly serious or repeated violations, taking into account § 29(3). In this case, the Association shall publish this reprimand in its entirety, naming the respondent. The names of the respondent's employees or other involved persons or other companies and organizations must be anonymized. The reprimand shall be published on the Internet ([www.fsa-pharma.de](http://www.fsa-pharma.de)) as well as in the Association's annual report and communicated to the pharmaceutical industry association or associations to which the respondent also belongs.

- (6) The sanctions listed in § 25 (1) through (5) are not mutually exclusive. § 23 (4) applies mutatis mutandis to the determination of sanctions.
- (7) The provision of § 23(5) applies mutatis mutandis.

## **Section 4: Appeals**

### **Subsection 1: Appeals against Decisions of the Adjudicating Body of First Instance**

#### **Section 26 Objection and Complaint of Inaction**

- (1) The parties to the dispute may file an objection with the first-instance tribunal against its decisions within two weeks of the decision's service. The first-instance tribunal shall forward the objection without delay to the chairperson of the second-instance tribunal.
- (2) Furthermore, in the event of inaction by the first-instance tribunal, the complainant has the right to appeal to the second-instance tribunal by way of a complaint of inaction, provided that the first-instance tribunal has not rendered a decision within 6 months of receiving the complaint and the respondent has not, within that period, issued a cease-and-desist declaration subject to a penalty for the alleged violation of the Code. In this case, the second-instance panel shall act as the court of first instance pursuant to § 25(1).
- (3) The complainant's objection may only be directed against the failure to find a violation of the Code. An objection by the complainant against the failure to impose sanctions or the amount of sanctions imposed is not admissible.
- (4) The objection may be based only on the grounds that the decision is based on a violation of law or that the underlying facts justify a different decision. A violation of law occurs when a legal norm or a provision of the Codes has not been applied or has not been applied correctly. The second-instance adjudicating body must base its decision on all facts available up to that point.

### **Subsection 2: Appeals against Decisions and Procedural Acts**

#### **§ 27 Finality of Decisions**

- (1) The decisions of the first-instance tribunal are final unless an appeal is filed within the time limit specified in § 26(1). If the notice required under § 11(14) is missing or incomplete, the decision becomes final only after six weeks have elapsed from the date of service. The decisions of the second-instance tribunal are final.
- (2) The decisions of the second-instance tribunal shall include a note stating that no appeal is possible in this regard.
- (3) Appeals against decisions and other procedural actions are admissible only to the extent expressly provided for.

### **Subsection 3: Reopening of Proceedings**

#### **§ 28 Reopening of Proceedings**

- (1) The reopening of a concluded appeal proceeding before the adjudicating bodies of the first and second instance is permissible only if
  1. the respondent requests it and
  2. new facts are proven which—in accordance with the requirements of §§ 579, 580 of the Code of Civil Procedure—are capable, either alone or in conjunction with the grounds for the earlier decision, of justifying a substantially different decision.
- (2) An application for the reopening of proceedings must be filed with the panel that rendered the decision. The application may be filed only within one month of becoming aware of the grounds for reopening, but no later than one year after the decision in question became final.
- (3) If the respondent has issued a cease-and-desist declaration subject to a penalty, a reopening of the proceedings is not possible.

### **Subsection 4: Suspension of Proceedings**

#### **§ 29 Suspension of Proceedings**

- (1) The adjudicating bodies may suspend the proceedings for special reasons, in particular for the reasons set forth in the following paragraphs.
- (2) If, at the time proceedings are initiated before the adjudicating bodies, a prosecutorial investigation or criminal court proceedings are pending in the same matter, or if such proceedings are initiated during the course of the proceedings before the adjudicating bodies, the adjudicating body shall, upon request by the respondent, order the suspension of the proceedings until the criminal proceedings have been finally resolved. The respondent shall immediately notify the adjudicating bodies of the final disposition of the proceedings and, upon request by the adjudicating bodies, provide information on the current status of the criminal proceedings.
- (3) If civil court proceedings have been initiated against a member in the same matter, a public reprimand may be issued at the respondent's request only after the civil court proceedings have been finally concluded. Such a reprimand shall be withheld if the outcome of the civil court proceedings gives cause to do so. Should the civil court proceedings be suspended for more than 6 months at the request of the parties within the meaning of § 251 of the Code of Civil Procedure, the proceedings before the appellate court shall be continued. The respondent shall immediately notify the appellate court of the final disposition of the civil court proceedings and, upon request by the appellate court, provide information on the current status of the civil court proceedings.
- (4) If, within a single set of facts, several comparable proceedings against different members are pending before the Arbitration Board and only some of the respondents have submitted the required cease-and-desist declaration subject to a penalty following a warning, the Arbitration Board shall stay these proceedings until all proceedings within the complex of facts have been concluded by a cease-and-desist declaration subject to a penalty or a decision of the Arbitration Board.

The end of the stay shall be determined by the Panel of First Instance. The panel of first instance shall decide, 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, whether the Arbitration Board waives all or individual rights arising from a previously submitted, penalty-backed cease-and-desist declaration or accepts it after a further hearing and asserts the rights.

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

### **§ 30**

#### **Preliminary Review and Warning Procedure**

- (1) The filing of a complaint and the continuation of the proceedings before the first-instance tribunal (§ 31) are free of charge for the complainant and the third-party complainant.
- (2) Upon submission of a cease-and-desist declaration subject to a penalty clause to the Association in the warning procedure (§ 20), a procedural fee of EUR 3,000.00 shall be payable by the respondent to the Association. If the declaration of discontinuance subject to a penalty is submitted upon receipt of the complaint by the respondent, the tribunal of first instance may reduce this procedural fee.

### **§ 31**

#### **Costs in the Event of Continuation of Proceedings Before the Adjudicating Body of First Instance**

- (1) Upon the decision of the first-instance adjudicating body following the continuation of the proceedings (Sections 20, 22), a procedural fee of EUR 7,500.00 shall be payable to the Association. In the event of a joinder of proceedings, the Association's office may reduce the procedural fee payable at its discretion.
- (2) The procedural fee for the decision of the first-instance adjudicatory body shall be borne by the unsuccessful respondent. If the respondent is partially successful and partially unsuccessful, the procedural fee shall be borne proportionately.
- (3) If an objection is filed, the respondent shall bear the procedural fee for the decision of the first-instance adjudicatory body in the proportion in which the respondent prevails and loses, respectively, following the decision of the second-instance adjudicatory body in the appeal proceedings.

### **§ 32**

#### **Proceedings before the Second Instance Panel**

- (1) If the second-instance tribunal acts as the court of first instance by referral pursuant to § 21(5) or § 26(2), § 31 shall apply mutatis mutandis.
- (2) Upon filing the appeal, a procedural fee of EUR 12,500 shall be payable to the Association. In the event of a joinder of proceedings, the Association's office may reduce the procedural fee to be paid at its discretion.
- (3) The conduct of an opposition proceeding is contingent upon the prior payment of an advance on costs in the amount of the procedural fee for the opposition by the party filing the opposition within 14 days of receipt of a corresponding request for payment from the Association's office. If this advance on costs has not been received in an account of the Association within this period, the opposition

proceeding before the appellate panel of the second instance shall not be conducted.

- (4) The procedural fee for the opposition shall be borne by the opposing party that loses the opposition. If the opposing parties are partially successful and partially unsuccessful in the opposition, the procedural fee shall be divided proportionally between them. § 31 remains unaffected. An advance payment of costs made pursuant to § 32(3) shall be refunded to the extent of the success.
- (5) Notwithstanding § 32(3), a third-party appellant who is not another company in the pharmaceutical industry or in the field of digital health applications (DiGA) within the meaning of § 33a SGB V shall not be required to pay an advance on costs. In addition to § 32(4), a third-party complainant that is another company in the pharmaceutical industry or in the field of digital health applications (DiGA) within the meaning of § 33a SGB V shall contribute to the costs accordingly.

### **§ 33 Reopening of Proceedings**

- (1) Upon filing the motion for reinstatement, a procedural fee in the amount of the second-instance procedural fee becomes due to the Association. In the event of a joinder of proceedings, the Association's registry may reduce the procedural fee to be paid at its discretion.
- (2) If the adjudicating body rejects an application for the reopening of a concluded appeal proceeding, the party filing the application shall bear the procedural fee.
- (3) If the adjudicating body grants an application for the reopening of proceedings and the reopening of proceedings leads to a modification of the original decisions, any procedural fees and expenses already paid for the original proceedings shall remain unaffected. The procedural fee for the application for reopening shall be borne by the parties to the appeal in proportion to the extent to which the application for reopening is successful.
- (4) The provision of § 32(5), sentence 2, applies mutatis mutandis.

### **§ 34 Necessary Expenses**

In addition to the procedural fees, the respondent in the first instance and the appellants in the second instance shall also bear the reasonable expenses for travel and accommodation of summoned witnesses or experts, as well as reasonable compensation for the services of experts, in the same proportion as they are required to bear the procedural fees for that instance. Section 32(5), sentence 2, applies mutatis mutandis to necessary expenses in opposition proceedings.

### **§ 35 Due Date, Value-Added Tax, and Other Remedies**

- (1) The procedural fees and necessary expenses shall be determined by the Association's office and shall become due upon the decision of the adjudicating body becoming final.
- (2) The applicable statutory value-added tax shall be levied in addition to the procedural fees specified in §§ 30 through 33 and the necessary expenses under § 34.

- (3) No procedural fees shall be incurred for other legal remedies or procedural acts.

**§ 36**  
**Entry into Force**

The Rules of Procedure, as adopted by the General Assembly on March 19, 2026, shall enter into force on the same day. They shall apply to appeal proceedings initiated on or after March 19, 2026. For appeal proceedings initiated before March 19, 2026, the Rules of Procedure in the version dated March 20, 2024, shall remain applicable until their conclusion.