

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

**("FS Arzneimittelindustrie"- Rules of
Procedure)**

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Introduction

The research, development, manufacture and marketing of pharmaceuticals are extremely important to human health and wellbeing. Research and development of effective pharmaceuticals presupposes close professional cooperation with doctors and other relevant members of specialist groups. The pharmaceuticals companies also have a duty to convey relevant and appropriate information in relation to pharmaceuticals that is necessary for the appropriate selection, dispensing and application of pharmaceuticals. In order to promote fair competition in advertising and cooperation with members of specialist groups, the Meeting of Members of the "Freiwillige Selbstkontrolle für die Arzneimittel-industrie e. V." has resolved the FSA- Code for the cooperation with healthcare professionals ("FSA Code Healthcare Professionals") as well as the "FSA-Code for cooperation with patient organisations" ("FSA Code Patient Organisations") (also referred to collectively as "Codes").

The members of the Association are aware that public confidence in the integrity of pharmaceuticals companies in relation to advertising and cooperation with members of specialist groups is fundamentally dependent on the effective supervision and enforcement of the rules of the Codes. In addition to effective and transparent penalties being imposed for breaches of the FSA Code Healthcare Professionals, this presupposes that everyone has the right to have complaints examined during a two-stage procedure, in which representatives of specialist groups, patient representatives and independent members are involved. With the aim of setting up such a procedure and thereby guaranteeing consistent implementation and enforcement of the Code, the Meeting of Members of the Association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V." has resolved the following

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

Section 1: General points

§ 1 Principles

- (1) The provisions of these Rules of Procedure serve to supervise adherence to and impose penalties in the event of breaches of the Codes by members of the FS Arzneimittelindustrie e.V. (hereinafter the "Association") and the undertakings associated with the members, who have agreed in writing to comply with the Statutes, these Rules of Procedure and the Codes ("bound companies").
- (2) The Chambers of First and Second Instance are appointed to perform the duties set out in § 1 (1). They are required to act in accordance with these Rules of Procedure and to impose penalties for breaches of the Code as described in these Rules of Procedure by members of the Association and by bound companies. They are bound neither by directions nor by any previous advisory of member companies by the Association.

- (3) In the case of a group, the affiliated undertaking shall primarily be pursued, inasmuch as it is itself a member of the Association or is a bound undertaking. For the rest, breaches by affiliated dependent companies, which are neither members of the Association nor bound companies, shall be attributed to the member which controls the undertaking in question. In the case of multi-level groups, the breach shall be attributed to the next highest controlling undertaking which is itself a member of the Association or is a bound undertaking.
- (4) For the rest, the provisions of these Rules of Procedure which apply to members shall be applicable to the bound companies.

Section 2: General rules of procedure

Subsection 1: Institution of proceedings

§ 2

Complaint entitlement

- (1) Anyone may file complaints with the Association, based on the allegation that a member, after accession to the Association, has breached the rules
 1. in Section 3 to 4 of the FSA Code Healthcare Professionals, with consideration to the interpretation principles laid down in Section 2 of this Code or
 2. in Section 3 of the FSA Code Patient Organisations with consideration the interpretation principles laid down in § 4 of this Code ("Code Breach") or
 3. in Section 2 of the FSA Transparency Code with consideration to the interpretation principles laid down in § 3 of this Code ("Code Breach").
- (2) According to § 2 subsection 1 no. 1, the right of companies to file complaints is restricted to breaches of the provisions of § 4 of the FSA Code Healthcare Professionals, with consideration to the valid principles in this respect. The provisions of the FSA Code Healthcare Professionals do not apply to non-prescription pharmaceuticals of members and their affiliated companies, unless the corresponding member company has voluntarily declared itself bound by the FSA Code Healthcare Professionals, also for non-prescription pharmaceuticals.

- (3) The Board of Management and the CEO may also institute complaint proceedings independently of one another against members of the Association. The same shall apply if the complaint proceedings instituted by the Board of Management or the CEO are based on an anonymous complaint (§ 4 (3)).
- (4) Complaints may only be made in relation to alleged breaches that have been committed after accession of the member or signature of the declaration of compliance.
- (5) The complaint is inadmissible if the member affected has already given a comprehensive declaration of discontinuance to the complainant at the time the complaint is filed, or if the complainant has been granted a court decision to this effect, or if court proceedings are pending but have not yet been finally and conclusively terminated. The prior delivery to third parties of declarations of discontinuance subject to criminal sanction does not however exclude the possibility of the member affected being obliged to deliver a declaration of discontinuance subject to criminal penalty in accordance with these Rules of Procedure.

§ 3

Further rights of the complainant

- (1) The complainant shall have the following rights of information and examination during the subsequent procedure:
 1. The complainant shall be informed of the outcome of the proceedings by being sent the operative part and the fundamental grounds of the decision (§ 11 (5) sentence 2). The complainant is referred to the procedural rights to which he is entitled.
 2. The Complainant shall have the right
 - a) to file an objection to decisions of the Chamber of First Instance, if a complaint does not lead to a finding of a breach of the Code (§ 25 (2));
 - b) in the event of failure to act on the part of the Chamber of First Instance, to call upon the Chamber of Second Instance, if the Chamber of First Instance fails to give a decision within 6 months of receipt of the complaint, and no declaration of discontinuance subject to criminal penalty in relation to the breach of the Code has been made by the undertaking affected (§ 25 (3)).

In such cases, the proceedings shall be continued before the Chamber of Second Instance.

- (2) Otherwise, the complainant shall not be involved in the proceedings.

§ 4

Content and form of the complaint

- (1) The complaint is to be directed in writing to the Managing Director of the Association and is to be supported. It should include substantiation of the complaints made, if possible by means of attachment of originals or copies of relevant documents (for example letters of invitation to specialist medical congresses and the like). The Managing Director shall forward the complaint to the appropriate Chamber of First Instance for consideration.
- (2) Complaints which relate to incidents more than one year previously shall not be dealt with.
- (3) Anonymous complaints relating to breaches of the provisions of the 3rd section of the FSA Code Healthcare Professionals, with the exception of § 2 (3), shall not be dealt with.

§ 4a

Board of Management Guidelines

Through its Board of Management, the Association can decide upon binding guidelines for the interpretation of these Rules of Procedure. The Association shall publish these guidelines on the Internet (www.fsa-pharma.de).

Subsection 2: Principles and course of the proceedings

§ 5

Responsibilities

- (1) The Chamber of First Instance shall have responsibility at first instance for all complaints, inasmuch as the Chamber of Second Instance does not have jurisdiction (§ 4 (2)). In the event of admissible and well founded complaints by members, the Chamber of First Instance must demand a declaration of discontinuance protected by criminal sanction ("Regulatory proceedings", § 20). If the member refuses to give such a declaration of discontinuance, then the proceedings shall be continued before the Chamber of First Instance (§ 21). If the complaint should prove to be admissible and well founded during these proceedings, then the Chamber of First Instance shall issue a finding that there has been a Code breach.
- (2) The Chamber of Second Instance shall have jurisdiction both in the event of repeated breaches of the same kind (three breaches within two years), in accordance with § 20 (8) in conjunction with § 24 (1), and to decide on objections against decisions by the Chamber of First Instance, in accordance with § 25. In the case of appeals by the complainant for failure to act on the part of the Chamber of First Instance, the Chamber of Second Instance shall also have jurisdiction (§ 25 (3)).

§ 6
Course of the proceedings

- (1) If a complaint has not already been dealt with in the regulatory proceedings (§ 20), then the Chairman of the Chamber concerned shall set a date for a hearing.
- (2) In case there is a connection between several pending complaints before the Chairman of the respective instance, he may order that they be combined for the purpose of simultaneous proceedings and/or decision. The Chairman of the Chamber of the Second Instance has the authority to order the separation of combined proceedings.
- (3) The Chambers shall fundamentally sit at the registered office of the Association in Berlin. The complaint may be pursued further in written proceedings, following a resolution by the chairman of the Chamber concerned or in response to an application by the member affected, if the Chairman, at his own discretion, considers the setting of a date for a hearing to be unnecessary. If the member affected objects in writing within a week to the order for written proceedings by the chairman of the Chamber concerned, then the chairman must set a date for the hearing.
- (4) The chairman of the Chamber concerned shall arrange as necessary for further measures associated with the conduct of the proceedings and preparation for meetings (obtaining further information etc.).
- (5) The Chairman of the Chamber concerned may, at his own discretion, invite witnesses and if necessary expert witnesses. The members affected by the complaint (hereinafter "affected members") shall be required to allow company employees who are summoned to appear as witnesses or expert witnesses to attend the hearing, provided this is not opposed by grounds under employment law or other serious grounds.
- (6) The member affected and the members of the Chamber concerned shall furthermore at all events be invited to attend the hearing, and in the case of debates by the Chamber of Second Instance, the Chairman of the Chamber of First Instance who gave the decision as Chamber of First Instance shall also be invited to attend (hereinafter "participants in the proceedings"). In any case, the Managing Director may also participate in hearings of the Chamber of Second Instance. The remaining members of the Association shall not otherwise be granted access to the hearing.
- (7) Invitations shall be sent in writing by registered letter with advice of receipt. Invitations should be sent at the latest three weeks prior to the hearing. The invitation must additionally include the following information:
 1. details of the complaint, if applicable with documents attached, which enable the member affected to properly prepare for the hearing,
 2. place and time of the hearing,
 3. the names of the members of the Chamber concerned,

4. reference to the fact that members of the Chamber may be refused if there is concern that there may be a conflict of interests,
 5. reference to the fact that a decision may be taken even in the event that the member affected, or his representative, is absent without excuse,
 6. if applicable the names of invited witnesses,
 7. an indication to the member concerned, that it may arrange to be represented at every stage of the proceedings by an authorised member of staff and/or a lawyer.
- (8) If the proceedings are to be pursued in writing, then the chairman of the Chamber concerned shall take the necessary measures in relation to the conduct of the proceedings. § 6 (6) sentence 3 nos. 1, 3, 4 and 7 shall apply accordingly. The member affected shall have the opportunity to make observations. The chairman of the Chamber concerned may set time limits in this respect.

§ 7 Hearing

- (1) The chairman shall lead the hearing. After opening the hearing he shall state the names of the members of the Chamber and shall note who is present. He shall advise witnesses of their duty to tell the truth and shall release them until they are called for questioning. He shall subsequently question the member affected and the witnesses and shall designate and explain the other evidence. In special circumstances, witnesses may also be questioned in writing or in advance by the chairman or by a representative commissioned by him. The result of questioning is to be presented to the chairman during the hearing. There may also be telephone questioning during the hearing. The member affected shall have the right, up to the end of the hearing, to designate further witnesses. Inasmuch as they have not already been summoned to attend the hearing by the chairman of the Chamber concerned, witnesses must be present at the hearing.
- (2) The participants in the proceedings shall have the right to ask questions during the hearing. The representative of the member affected shall present a closing summary.
- (3) If the member fails to attend the hearing, without excuse, despite having been properly invited, and is also not effectively represented, then the Chamber shall give a decision based on the files. Otherwise the chairman of the Chamber concerned shall set a new date for the hearing. In the event of absence without excuse, the invited witnesses or expert witnesses shall only be questioned if the Chamber concerned deems it appropriate.

- (4) Minutes of the hearing are to be prepared, which shall reflect the principal content of the hearing. Any applications by participants in the proceedings and resolutions by the Chamber concerned are to be included in the minutes or else attached to these as an annex.
- (5) All participants in the proceedings may require individual statements to be minuted word for word.
- (6) The chairman shall sign the minutes and send them to the participants in the proceedings.

§ 8

Representation of the member affected

- (1) The member affected may arrange to be represented at every stage in the proceedings by an authorised employee and/or a lawyer.
- (2) Irrespective of the outcome of the proceedings, the member affected shall bear the costs of its own representation or advice.
- (3) Authorised representatives of the member affected must, if asked to do so, confirm their capacity by means of a power of attorney to be submitted to the Chamber.

§ 9

Rights to inspect files

- (1) The member affected shall have the right to inspect files at any time.
- (2) In addition, the other participants in the proceedings and the Board of Management of the Association shall have the right to inspect files at any time. This shall not apply to the complainant.

§ 10

Time limits

- (1) The member affected shall be bound to adhere to time limits. All procedural acts by the member affected which are associated with time limits and are to be presented in writing, may be effected either by registered letter, fax, e-mail or by receipted delivery to the Association office. The member affected shall bear the onus of proof with respect to receipt of such declarations. If requested to do so, the Association office shall confirm to the member affected the receipt of declarations by fax or e-mail for the purposes of adherence to time limits.
- (2) In the event of failure to adhere to time limits, the member affected may upon request be restored to its former status if it was prevented without fault from adhering to the time limit. The application must be made in writing to the Chamber concerned, with respect to which the original time limit should have been adhered to, within a week of lapse of the obstacle.

**§ 11
Decisions**

- (1) If a complaint is not resolved through regulatory proceedings (§ 20), then the Chambers concerned shall give a decision, inasmuch as they are acting as a first instance. Inasmuch as the complaint is admissible and well founded, then a Code breach shall be found to have occurred and the complaint shall be allowed. If the complaint is inadmissible or unfounded, then the complaint proceedings shall be suspended. In addition, the Chambers acting at first instance may also suspend the complaint proceedings by means of a decision, if the circumstances cannot be clarified in a manner which allows a decision.
- (2) Inasmuch as the Chamber of Second Instance is examining the objection by an affected member or the complainant against a decision of the Chamber of First Instance, then the Chamber of Second Instance may confirm or override the contested decision. The Chamber of Second Instance may also give a decision according to which the decision of the Chamber is simply amended with respect to the penalties imposed.
- (3) As regards a resolution within the Chambers, the chairman of the Chamber of First Instance shall decide in the case of a resolution by this Chamber, and the majority of votes of the members of the Chamber of Second Instance shall apply in the case of a resolution by this Chamber. In the event of a tie, the objection shall be dismissed as unfounded.
- (4) Prior to a decision which precedes a hearing, the member affected shall be given the opportunity to make conclusive observations. The other participants in the proceedings (with the exception of the members of the Chamber concerned) shall additionally have authority to make conclusive observations. The Chambers may inform the member affected and the other participants in the proceedings of the decision and the fundamental reasoning on which it is based, immediately after the hearing and after conclusion of the consultation. The chairman of the Chamber concerned may also inform the participants that the decision will be transmitted in writing.
- (5) The chairman shall sign the conclusive written decision by the Chamber and shall serve this on the member affected, including written grounds, within two weeks following the hearing or following conclusion of the written proceedings. The complainant shall also provide written information on the outcome of the proceedings by sending the operative part of the decision and the fundamental grounds of the decision. The names of employees of the member affected or other persons involved, or companies, organisations etc., shall also be withheld as necessary.

Subsection 3: Other points

**§ 12
Unavailability**

- (1) In the event that a member of the Chamber of Second Instance is temporarily unavailable, the Chamber of Second Instance may decide

without the member in question, albeit with at least seven members, following a resolution by the chairman.

- (2) The business distribution plan to be drawn up by the Board of Management, within the meaning of § 24 (4) of the Statutes, provides further details.

§ 13 Conflicts of interest

- (1) Members of the Chamber concerned may be rejected by the member affected due to a concern that there is a conflict of interest, or if they themselves declare a conflict of interest, if a ground exists which is capable of engendering mistrust in relation to their impartiality. They shall themselves be declared to have a conflict of interests, if they are employees of the member affected or of the complainant, or were or are involved in the operation concerned.
- (2) If the member affected considers there to be a conflict of interest in relation to a member of the Chamber concerned, then the request for rejection is to be submitted and substantiated by the member affected to the Chamber concerned within a time limit of one week from receipt of the invitation. The member of the Chamber concerned who is affected should respond in relation to the rejection within a further week of receipt of the request for rejection. His observations are to be sent to the member affected.
- (3) If a member of the Chamber of First Instance is rejected by the member affected due to a conflict of interests, then the chairman of the Chamber of Second Instance shall decide on the existence of grounds for rejection. The member of the Chamber of Second Instance shall decide without the member affected whether grounds for rejection exist with respect to members of the Chamber of Second Instance. In the event of a tie, the chairman of the Chamber of Second Instance shall give a decision. If the request for rejection is directed against the chairman of the Chamber of Second Instance, then in the event of a tie, the deputy chairman shall give a decision. No such decision shall be necessary if the rejected member himself considers the request for rejection to be well founded.
- (4) If the chairman of the Chamber of Second Instance considers the rejection request against the chairman of the Chamber of First Instance to be well founded, then the chairman of Second Instance shall decide on the complaint as a Chamber of First Instance, inasmuch as no further Chambers of First Instance have been established, whose jurisdiction in this case shall be based on the business distribution plan for the Chambers of First Instance (§ 18 (1) sentence 3). If the member affected files an objection against the decision of the chairman of the Chamber of Second Instance acting as a Chamber of First Instance, then the chairman of the Chamber of Second Instance shall not participate in the remainder of the proceedings. He shall be replaced by the deputy chairman of the Chamber of Second Instance. In such cases, an eight member Chamber of Second Instance shall give a decision.

- (5) If the chairman does not participate in proceedings due to concern in relation to a conflict of interests, then an eight man Chamber of Second Instance shall give a decision under the leadership of the deputy chairman. In the event of a tie, the objection shall be dismissed as unfounded.
- (6) If circumstances arise during the proceedings which could justify the concern in relation to a conflict of interests, then the request for rejection shall immediately be given consideration prior to other statements.
- (7) No remedies shall be admissible against the decision in relation to a request for rejection.

§ 14 **File administration**

The Association office shall manage and administer the files of the Chambers of First and Second Instance.

§ 15 **Duties to inform and reports on the work of the Chambers**

- (1) The Association shall publish the Statutes, the Codes, the Rules of Procedure and the interpretation guidelines laid down in § 6 (2) of the FSA Code Healthcare Professionals and § 5 of the FSA Code Patient Organisations on the Internet (www.fsa-pharma.de).
- (2) The Managing Director shall regularly inform the Board of Management, the members and the Advisory Board of the work of the Chambers and on the complaints dealt with by the Chambers of First and Second Instance. In addition, at the end of February of each new calendar year, the Managing Director shall submit a detailed publicly-accessible report on the work of the Chambers during the previous calendar year, which shall also be published on the Internet (www.fs-arzneimittelindustrie.de). This report should provide a summary of the work of the Chambers in all proceedings.
- (3) In those cases in which a breach of the Code has been finally and conclusively determined, the final and conclusive decisions of the Chambers of First and Second Instance shall be regularly published on the Internet, by setting out the operative part and the fundamental grounds of the decision (www.fsa-pharma.de). This shall also apply if a case has been concluded with the delivery of a declaration of discontinuance within the meaning of § 20 (5) sentence 2.

The reports and announcements concerning declarations of discontinuance, along with all substantiated complaints, shall include the name of the member involved. If complaints do not lead to the assumption that the Code of Conduct has been violated, this too will be made public, to the extent that the Chamber involved approves of its disclosure, bearing in mind the significance of the decision, without releasing the name of the member involved, however.

- (4) If the Chamber of Second Instance declares a public reprimand, then § 24 (4) shall additionally apply. The names of employees of members affected,

or other persons involved, or other companies, organisations etc. must however also be withheld in all cases.

- (5) The Chamber of Second Instance must be informed of all decisions by the Chamber of First Instance and of declarations of discontinuance that have been given. The members of the Chambers of First and Second Instance shall discuss the work of the Chambers at regular intervals. The Chairman of the Chamber of Second Instance shall have the right to make proposals to the Board of Management of the Association in relation to amendments and supplements to these Rules of Procedure or to the Code, that the Chamber of Second Instance considers to be advisable with a view to effective penalties being imposed for breaches in relation to advertising and cooperation with members of specialist groups or in collaboration with patient self-help organisations.

§ 16 Confidentiality

- (1) The members of the Association's executive bodies, the members of committees and the staff of the Association, including the Managing Director, shall be obliged to observe discretion with respect to their work, the information obtained during their work and to all operations which are by their nature confidential, or which are explicitly designated thus.
- (2) Inasmuch as persons other than those designated in (1) should be involved, they shall accordingly be obliged to observe discretion before they take up their activity.

Section 3: Chambers of First and Second Instance

§ 17 Term of appointment of the members of the Chambers of First and Second Instance

- (1) The member(s) of the Chamber of First Instance shall (each) be appointed for a period of two to five years. A new appointment shall be made at the end of this period. They shall be eligible for re-election.
- (2) The members of the Chamber of Second Instance shall each be appointed by the Board of Management for a period of two years, in accordance with the provisions in § 23. A new appointment shall be made at the end of this period. They shall be eligible for re-election.
- (3) The Board of Management may only recall members of the Chambers of First and Second Instance from office during their term of appointment on a serious ground.

Subsection 1: Chamber of First Instance

**§ 18
Composition**

- (1) The Chamber of First Instance may comprise the Managing Director of the Association, Deputy Managing Directors or third parties. The Board of Management shall entrust this responsibility to the Managing Director, Deputy Managing Directors or third parties. In case the Board of Management entrusts individual Deputy Managing Directors or third parties with the duty of the Chamber of First Instance alongside or in lieu of the Managing Director, then they shall each form their own Chamber of First Instance. In this case the Board of Management shall issue a business distribution plan, which indicates the precise responsibilities. In this case the Board of Management shall issue a business distribution plan, which indicates the precise responsibilities. The Managing Director and any Deputy Managing Directors or third parties must be qualified as Judges.
- (2) In relation to their work as Chamber of First Instance, the Managing Director and his Deputies or third parties shall not be bound by any directions by the Association in relation to content. In particular, they are not bound by the outcome of advisory of member companies by the Association.
- (3) In order to avoid a conflict of interest, the Managing Director and his Deputies or third parties may not work or take up work for a member of the Association outside their business activity for the Association.

**§ 19
Duties**

- (1) The Chamber of First Instance shall have responsibility at first instance for all complaints, inasmuch as the Chamber of Second Instance does not also have jurisdiction at first instance (§ 5 (2)).
- (2) The Chamber of First Instance shall examine the complaints received and shall prepare the proceedings by means of clarification of the facts of the case itself. The Chamber of First Instance shall also examine whether the Chamber of Second Instance has jurisdiction. If this is the case, the Chamber of First Instance shall pass on the complaint and the result of the preliminary examination to the chairman of the Chamber of Second Instance.

**§ 20
Regulatory proceedings before the Chamber of First Instance**

- (1) For the purposes of clarifying the facts of a case, the Chamber of First Instance may invite the complainants to provide further substantiation of their complaint, or may invite the member affected to submit observations or to deliver documents. The Chamber of First Instance may also conduct the questioning of witnesses or expert witnesses at any stage in the proceedings.

- (2) If it should prove as a result that the complaint is either clearly inadmissible or clearly unfounded, then the complainant shall be informed of the provisional assessment of the matter and given the opportunity to further substantiate its complaint within two weeks. The Chamber of First Instance shall subsequently decide whether the proceedings are to be continued or suspended. The complainant may contest suspension of the proceedings by way of an objection (§ 25 (2) sentence 2).
- (3) If the member affected fails to comply with a request to become involved, to which a time limit is attached, then the objection shall be decided on the basis of the current status of the files or on the basis of the available evidence.
- (4) If the Chamber of First Instance considers the complaint to be well founded, then it shall give a written warning to the member affected, and shall require it to give a declaration of discontinuance, subject to a time limit of two weeks, stating that it will refrain in future from the breach to which the complaint relates. The obligation to give a declaration of discontinuance subject to criminal penalty must definitely be combined with an obligation to pay a fine for a breach of the Code, as specified in § 22 Section 2 sentence 2. This fine shall fall due for payment by the member affected at the same time as delivery of such a declaration of discontinuance subject to criminal penalty, which must also contain agreement to the fine set. § 22 (2) sentence 4 shall apply accordingly. The declaration of discontinuance is also to include acceptance of the fine imposed.
- (4a) In deviation from Sect. 4, proceedings shall end for substantiated breaches of the FSA Transparency Code without further action to the extent that
 1. it involves an inconsequential breach in terms of its nature and scope and
 2. the member remedies involved responds to the remark of the Chamber of the First Instance within two weeks.

For interpretation of the term, "inconsequential breach in terms of its nature and scope" as defined in this provision, the Association's Board of Management shall decide upon binding guidelines according to § 4a. To the extent that no response is forthcoming, the rules of these Rules of Procedure shall apply without restriction.

- (4b) In deviation from Section 4, in cases where breaches are founded, the proceedings may end through issuance of a warning, which the member affected shall accept within 2 weeks. In such a case, there would be no punitive fine. The other rules of this Rules of Procedure apply without limitation.
- (5) This declaration of discontinuance shall be protected by adequate criminal sanction to exclude the risk of repetition. The proceedings shall end when the declaration of discontinuance is given by a representative of the member affected who holds representative authority.

- (6) If the member affected fails to make the required declaration of discontinuance subject to criminal penalty, then the proceedings will be continued (§ 21), unless the Chamber of First Instance allows a declaration of discontinuance by the member affected that differs from the required declaration of discontinuance, as an adequate declaration of discontinuance. Any declaration of discontinuance that is in any event given at a later date shall not have the effect of ending the proceedings, but shall simply be taken into consideration when assessing any additional penalties that may be imposed.
- (7) If the Chamber of First Instance should find during the initial examination that a repeated breach of the same kind is involved, and the member affected has breached a declaration of discontinuance protected by criminal sanction, then the Association shall claim the fine laid down therein from the member affected. The regulatory fine must moreover be increased appropriately in order to remove the existing risk of repetition. In addition, the Chamber of First Instance sets a fine for a repeated breach as specified in § 22 (2). This fine shall fall due at the time of the declaration of agreement of the member affected, in accordance with (7) paragraph 2, sentence 1. (4) sentence 5 and § 22 (2) sentence 4 shall apply accordingly. A repeated breach of the same kind shall exist if the action to which the complaint relates is either identical or its characteristic elements are "fundamentally the same" as an action which has already been the subject of a well-founded complaint in the past; a well-founded complaint shall exist if either a declaration of discontinuance has been given by the member affected or the Chambers of First or Second Instance have declared a discontinuance obligation which is incontestable within the meaning of these Rules of Procedure.

If the member affected should declare its agreement to payment of a regulatory fine and the increase thereof in the event of future breaches as well as the fine set (§15 (4) sentence 5), then the proceedings shall end. If the member affected does not agree, then the proceedings shall be continued (§ 21). If it should prove during the further proceedings before the Chambers of First and if applicable Second Instance, that during the initial examination, the Chamber of First Instance incorrectly assumed a repeated breach of the same kind and a breach of the declaration of discontinuance or of a discontinuance obligation, so that in fact a different and new breach was involved, and the member affected offered the Chamber of First Instance, together with its opposition according to § 20 (7) sentence 8, to give a declaration of discontinuance subject to a reasonable fine with respect to a different and new breach committed, then the proceedings shall end in accordance with § 20 (5).

- (8) By way of variation from § 20 (7), the Chamber of First Instance must pass the proceedings directly to the Chamber of Second Instance for a decision, if a complaint should arise for the Chamber of First Instance during the initial examination, that during the last two years before committing the breach to which the complaint relates, the member affected either gave a declaration of discontinuance or else a incontestable discontinuance obligation was declared by the Chambers of First or Second Instance in relation to at least two breaches of the same kind, so that the prior breaches were well-founded complaints within the meaning of § 20 (7) sentence 6. Handing over an alleged further breach to the Chamber of

Second Instance shall only be considered if there are the requisite number of prior well-founded complaints therefor, as described above, and the Chamber of First Instance comes to the conclusion that the further breach to which the complaint relates is not clearly inadmissible or unfounded (§ 20 (2)) and it constitutes a repeated breach of the same kind (§ 20 (7) sentence 6). In this case the proceedings are to be continued before the Chamber of Second Instance as an initial instance. Otherwise the proceedings in relation to the complaint are to be continued before the Chamber of First Instance.

§ 21

Continuation of the proceedings before the Chamber of First Instance

- (1) If the proceedings are to be continued before the Chamber of First Instance, then the chairman of the Chamber of First Instance shall set a date for a hearing or shall order written proceedings.
- (2) The hearing should take place within four weeks after expiry of the two week time limit for delivery of the declaration of discontinuance.

§ 22

Penalties of the Chamber of First Instance

- (1) If the complaint has not been ended during the regulatory proceedings (§ 20) and if the complaint is admissible and well-founded, then the Chamber of First Instance must find there to be a Code breach. This finding must be combined with the obligation on the member to refrain in the future from the behaviour to which the complaint relates and to pay a regulatory fine of a sufficient amount to avoid the risk of repetition in the event of a repeated breach. If the proceedings are continued before the Chamber of First Instance in accordance with § 20 (7) sentence 8, then a finding must be made on whether the complaint is admissible and well-founded, it constitutes a repeated breach of the same kind and the member affected has breached a declaration of discontinuance or discontinuance obligation protected by criminal sanction. If the Chamber of First Instance agrees, then it shall make a corresponding finding, which shall also cover the decision on increase of the fine as described in § 20 (7). After the decision becomes incontestable within the meaning of § 25 (4) sentence 3 or after confirmation of the decision according to § 24 (2) sentence 1, the Association shall claim the regulatory fine laid down in the discontinuance declaration or obligation from the member affected, on the basis of the finding made. If however the Chamber of First Instance finds that the member affected has not breached a discontinuance declaration protected by criminal sanction, but that the complaint is admissible and well-founded, then (1) sentence 1 and 2, with consideration to § 20 (7) sentence 9 shall apply.
- (2) The regulatory fine to be laid down by the Chamber of First Instance may in any case be 20 times as high as the contribution of the concerned member but may not exceed an amount of EUR 200,000.00, for every instance of contravention. In the event of a Code breach the Chamber of First Instance may additionally impose a fine of EUR 5,000.00 or up to 20 times the contribution of the member concerned, however not exceeding EUR 200,000.00, in favour of a non-profit institution. In the event of the

incontestability of the decision concerned, within the meaning of § 25 (4) sentence 3, the fines declared shall fall due. A fine already paid shall not be affected by the reopening of the proceedings in accordance with § 27.

- (3) The penalties listed in (1) and (2) shall not be mutually exclusive. However in the case of a repeat, an additional fine alongside the imposition of a regulatory fine shall only be recognised if this is deemed necessary and appropriate given the overall circumstances and the gravity of the breach, its immediate punishment, taking into account an initially specified and henceforth forfeited regulatory fine as well as the monetary fine and procedural costs for the prior breach.

When determining the penalties, the consequences for the member affected by the penalties must be taken into consideration. Special note must be taken of whether and to what extent the member affected has endeavoured in its organisation to counter breaches against the Codes, and the behaviour to which the complaint relates is simply a non-recurrent misdemeanour. Additional consideration must be given to what internal penalties and organisational measures the member affected has taken and implemented, or has in mind, as a reaction to the misdemeanour to which the complaint relates, both in general and in the individual case concerned.

- (4) If the complaint is inadmissible or unfounded, then the complaint proceedings shall be suspended. The same shall apply if the facts of the case cannot be clarified in a manner capable of allowing a decision.
- (5) Any liability of the Association, its executive bodies and members thereof shall be based on Sections 839 (2) (3) BGB in the event of decisions of the Chamber and shall otherwise be excluded. Liability for intentional action shall not be affected.

Subsection 2: Chamber of Second Instance

§ 23 Composition

- (1) The Chamber of Second Instance shall comprise the Chairman and a minimum of eight, and a maximum of twelve, additional persons. Of these additional persons, one half must be company employees of association members, one fourth must be representatives of the medical fraternity, and one fourth must be patient representatives.
- (2) The Board of Management shall determine the number of members of the Chamber of Second Instance and appoint the members of the Chamber of Second Instance in accordance with the provisions in § 23 (1). The chairman must be qualified as a Judge and may not work for a member of the Association or for another undertaking within the pharmaceuticals industry (neutrality). Those persons representing the medical fraternity must be licensed doctors. The appointment of the representatives of the medical fraternity shall be made on the basis of proposals by one or more medical organisations and that of the patient representatives shall be

made on the basis of the proposal by one or more patient organisations. The Board of Management may only vary from these proposals if well-founded doubts exist regarding the lack of impartiality of the persons proposed. If no proposals are made, then the Board of Management shall determine the members of the Chamber of Second Instance at its own discretion from amongst approved doctors and from patients.

- (3) The chairman of the Chamber of Second Instance and the representatives of the members of the Association shall be appointed by the Board of Management, without any proposal from a third party being required.
- (4) In the event that the members of the Chamber of Second Instance are subject to a conflict of interests or are unavailable, the Board of Management may appoint one or more deputies for each member, in which case (1) to (3) shall apply accordingly for the selection and appointment of the deputies.
- (5) The Board of Management shall additionally designate a member of the Chamber of Second Instance as deputy chairman.
- (6) The Board of Management shall lay down a business distribution plan, which shall regulate the responsibilities of the representatives in the event that they are unavailable or are subject to a conflict of interests.

§ 24

Penalties of the Chamber of Second Instance

- (1) If the Chamber of Second Instance acts on the basis of a referral as an initial instance (§ 20 (8)), then § 22 (1) shall apply accordingly. In this case the regulatory fine to be laid down by the Chamber of First Instance may be 20 times as high as the contribution of the concerned member but may not, where applicable, exceed an amount of EUR 400,000.00, for every instance of contravention. If the Chamber of Second Instance finds that a complaint was improperly passed on according to § 20 (8), because there has been no breach of the same kind within the meaning of § 20 (8) or the prerequisites for complaints to be directly passed on to the Chamber of Second Instance are otherwise not met, then the proceedings shall be continued before the Chamber of Second Instance; however in this case the Chamber of Second Instance may only apply the penalties applicable for the Chamber of First Instance (§ 22). § 20 (4) and (5) shall apply accordingly. If the Chamber acts as an initial instance, following an appeal for failure to act on the part of the Chamber of First Instance (§ 25 (3)), then § 22 (1) and (2) shall apply accordingly.
- (2) If the Chamber of Second Instance acts against a decision of the Chamber of First Instance, in response to an objection by the member affected (§ 25), and if the complaint is admissible and well-founded, then it shall reject the objection and confirm the decision of the Chamber of First Instance. The same shall apply if, following an objection by the complainant against a decision of the Chamber of First Instance, the Chamber of Second Instance holds the complaint to be inadmissible or unfounded. If the Chamber of Second Instance considers the finding of the Code breach by the decision of the Court of First Instance to be admissible and well-founded, but considers the penalties imposed by the Chamber of

First Instance (regulatory fine or fine) to be inappropriate, then the Chamber of Second Instance may reverse the decision of the Chamber of First Instance in this respect and amend the penalties imposed. In accordance with (3) and (4), the Chamber of Second Instance may also impose more severe penalties than those of the Chamber of First Instance, within the context of the penalties available to it (no ban on deterioration). If the objection is directed against a decision of the Chamber of First Instance in accordance with § 22 (1) sentence 4, and if the Chamber of Second Instance finds that the member affected did not breach a discontinuance declaration or obligation protected by criminal sanction, then the proceedings shall be referred back to the Chamber of First Instance for a further decision in accordance with § 22 (1) sentences 1 and 2, with consideration to § 20 (7) sentence 9. If the Chamber of Second Instance considers the objection to be inadmissible or unfounded, or if the facts of the case cannot in its view be clarified in a manner necessary for the decision, then it must reverse the decision of the Chamber of First Instance and suspend the complaint proceedings.

- (3) In case a Code breach as defined in (1) has been determined or a decision by the Chamber of First Instance as defined in (2) has been sustained, the Chamber of Second Instance may impose a fine of at least EUR 5,000.00 up to 20 times the contribution of the member in question, however not more than EUR 400,000.00, in favour of a non-profit institution. In the event of confirmation of a decision of the Chamber of First Instance, the Chamber of Second Instance may only impose a higher fine if the penalties imposed by the Chamber of First Instance are inadequate, in the view of the Chamber of Second Instance, to reflect the severity of the behavioural misdemeanour. The fines declared shall fall due after service of the decision of the Chamber of Second Instance on the member affected. A fine already paid shall not be affected by the reopening of the proceedings in accordance with § 27.
- (4) The Chamber of Second Instance may furthermore declare a public reprimand in the event of especially serious or repeated breaches, with consideration to § 28 (2). In this case the Association shall publish the full wording of this reprimand and shall designate by name the member affected. The names of employees of the member affected or other persons involved, or companies, organisations etc., shall be withheld as necessary. The reprimand shall be published on the Association's website and in its annual report, and shall be notified to the organisation(s) within the pharmaceutical industry to which the member also belongs.
- (5) The penalties listed in (1) to (4) shall not be mutually exclusive. The amount of a regulatory fine initially set and henceforth forfeited against the member affected, and the costs of the proceedings, must be taken into account as necessary.

When determining the penalties, the consequences for the member affected by the penalties must be taken into consideration. Special note must be taken of whether and to what extent the member affected has endeavoured in its organisation to counter breaches against the Codes, and the behaviour to which the complaint relates is simply a non-recurrent misdemeanour. Additional consideration must be given to what internal penalties and organisational measures the member affected has taken and

implemented, or has in mind, as a reaction to the misdemeanour to which the complaint relates, both in general and in the individual case concerned.

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

Section 4: Legal remedies

Subsection 1: Legal remedy against decisions of the Chamber of First Instance

§ 25

Objection / appeal for failure to act

- (1) The member against whom a finding is made may file an objection against the decisions of the Chamber of First Instance within a time limit of two weeks following service of the decision.
- (2) The same shall apply to the complainant, if its complaint has not led to the delivery of a declaration of discontinuance subject to criminal penalty by the member affected, or to a judgment against the member affected by the Chamber of First Instance, or if the Chamber of First Instance has suspended the complaint in accordance with § 20 (2) as either clearly inadmissible or clearly unfounded. If the complainant makes an objection against suspension of the proceedings by the Chamber of First Instance according to § 20 (2), the proceedings shall be continued by the Chamber of Second Instance as the initial instance in accordance with § 24 (1) and decided by its chairman acting as sole judge or by the entire Chamber of Second Instance in written proceedings. The chairman can decide as sole judge if he considers the complaint to be inadmissible or unfounded.
- (3) In addition, the complainant shall have the right, in the event of failure to act on the part of the Chamber of First Instance, to call upon the Chamber of Second Instance by way of an appeal, if the Chamber of First Instance fails to give a decision within 6 months of receipt of the complaint, and no declaration of discontinuance subject to criminal penalty in relation to the breach of the Code has been made by the undertaking affected. In this case, the Chamber of Second Instance shall act as an initial instance in accordance with § 24 (1).
- (4) The objection must be filed in writing with the Chamber of First Instance within the deadline in accordance with § 25 (1) and must be substantiated. The Chamber of First Instance shall immediately pass on the objection to the chairman of the Chamber of Second Instance. If no objection is filed within a time limit of two weeks after service of the decision, then the decision of the Chamber of First Instance shall be deemed to be incontestable within the meaning of these Rules of Procedure.
- (5) The objection by the complainant may only be directed against the failure to establish a breach of Code. An objection by the complainant against the failure to impose penalties (regulatory or other fines) or the level of penalties is not permissible.

Subsection 3: Re-opening the proceedings

**§ 27
Re-opening the proceedings**

- (1) Re-opening concluded complaint proceedings before the Chambers of First and Second Instance shall only be admissible where
 1. the member affected applies for this and
 2. new facts are proven which, by application accordingly of the prerequisites of Sections 579, 580 ZPO [*Code of Civil Procedure*], are capable of substantiating a significantly different decision, alone or in conjunction with the earlier decision bases.
- (2) An application for re-opening the proceedings is to be made to the Chamber which gave the decision. The application may only be made within one month on which the ground for re-opening becomes known, and at most one year after the decision concerned becomes incontestable.
- (3) The decision on re-opening the proceedings shall be incontestable within the meaning of these Rules of Procedure.
- (4) If the member affected has made a declaration of discontinuance protected by criminal sanction during the regulatory proceedings, then the proceedings may not be re-opened.

Subsection 4: Suspension of the proceedings

**§ 28
Suspension of the proceedings**

- (1) If preliminary proceedings by a public prosecution authority or criminal proceedings on the same matter are pending at the time the proceedings before the Chambers are instituted, or are instituted in the course of the proceedings before the Chambers, then on the application of the member affected, the Chamber concerned shall order suspension of the proceedings until a final ruling is given in the criminal proceedings. The member affected shall immediately inform the Chambers of the final ruling in the proceedings concerned and shall provide information at the request of the Chambers on the current status of the criminal proceedings.
- (2) If civil proceedings have been instituted against a member on the same matter, then a public reprimand may if necessary be made, at the application of the member affected, only after the definitive conclusion of the civil proceedings. A statement of this kind should be refrained from if this is appropriate on the basis of the outcome of the civil proceedings. If the civil proceedings are suspended for more than 6 months within the meaning of Section 251 ZPO, on the instigation of the parties, then the proceedings before the Chamber of Second Instance shall be continued. The member affected shall immediately inform the Chamber of Second Instance of the final ruling in the civil proceedings concerned and shall

provide information at the request of the Chamber of Second Instance on the current status of the civil proceedings.

Section 5: Costs of the proceedings

§ 29 Regulatory proceedings

If the member affected makes a declaration of discontinuance protected by criminal sanction to the Chamber of First Instance in the regulatory proceedings (§ 20), then the member affected must pay the Association a procedural fee in the amount of EUR 2,000.00. If a declaration of discontinuance under penalty of law is already submitted on the basis of the first hearing, the Chamber of the First Instance may reduce the procedural fee referred to in the first sentence.

§ 30 Costs of continuation of the proceedings before the Chamber of First Instance

If the Chamber of First Instance finds in its decision that there has been a Code breach by the member affected during continuation of the proceedings (§ 21 f), then the procedural fee payable to the Association by the member affected shall be EUR 5,000.00. The procedural fees for continuing the proceedings within the meaning of § 22 f shall not be payable if the Chamber of Second Instance reverses the decision of the Chamber of First Instance as inadmissible or unfounded, in response to an objection by the member affected. In case of multiple proceedings, the administrative offices of the Association may reduce the procedural fees at reasonable discretion.

§ 31 Proceedings before the Chamber of Second Instance

- (1) The conduct of proceedings before the Chamber of Second Instance in response to an objection by the undertaking affected against a decision by the Chamber of First Instance presupposes the prior deposit of an advance on costs of EUR 10,000.00, that is to be deposited within 14 days of receipt of a corresponding payment request by the office of the Association. In case of multiple proceedings, the administrative offices may reduce the advance at reasonable discretion. If this advance on costs is not received in an account of the Association within this time limit, then no proceedings will be conducted before the Chamber of Second Instance. If the Chamber of Second Instance finds there to have been a Code breach by the member affected, within the meaning of § 24 (1), then the advance on costs shall lapse in favour of the Association. The same shall apply if the Chamber of Second Instance dismisses the objection by the member affected against a decision of the Chamber of First Instance, within the meaning of § 24 (2); if however the Chamber of Second Instance simply attenuates the penalties imposed by the Chamber of First Instances, then the advance on costs shall simply lapse in the ratio in which the case is won and lost.

§ 30 shall not be affected. Otherwise, the advance on costs must be repaid to the undertaking affected upon conclusion of the proceedings within the meaning of § 26 (1).

- (2) The complainant shall essentially incur no costs through filing an objection or an appeal for failure to act on the part of the Chamber of First Instance. This shall not apply to an objection by a complainant who is a member or another undertaking in the pharmaceuticals industry. In this case, the proceedings before the Chamber of Second Instance shall presuppose deposit of a prior advance on costs in the amount of EUR 10,000.00 that must be deposited within 14 days of receipt of a corresponding payment request by the office of the Association. The advance on costs shall lapse in favour of the Association if no Code breach is found following the objection by the complainant before the Chamber of Second Instance. Otherwise, the advance on costs must be repaid to the complainant upon conclusion of the proceedings within the meaning of § 26 (1). If the complainant undertaking is not a member of the Association, then the proceedings before the Chamber of Second Instance shall also depend on a prior explicit written declaration of agreement with the provision on costs set out in § 2 sentences 2 and 3.

§ 32 Necessary disbursements

If the Chambers concerned find there to have been a Code breach by the member affected, then the latter must also pay the reasonable disbursements for travelling and accommodation of any witnesses or expert witnesses called, in addition to the procedural fees. The same shall apply for reasonable remuneration for the work of experts.

§ 33 Maturity of the procedural fees and necessary disbursements / value added tax

- (1) The procedural fees and necessary disbursements shall be determined by the Association office and shall fall due when the decision of the Chambers concerned becomes incontestable.
- (2) Value added tax at the statutory rate shall additionally be levied on the procedural fees laid down in § 29 to 31 and on the necessary disbursements according to § 32.

§ 34 Re-opening the proceedings

- (1) If the Chamber concerned bases an application to re-open concluded complaint proceedings, then the procedural fee for the decision on this application shall be based on the fee for the concluded complaint proceedings.
- (2) If the Chamber concerned allows an application to re-open the proceedings, and if re-opening the proceedings brings about reversal of the original decision, then procedural fees and disbursements already paid for the original proceedings shall not be affected. If re-opening the

proceedings leads to partial reversal of the original decision, then the office must levy a fee from the member affected. The amount of the procedural fee shall be at the discretion of the office, and should take account of the ratio of the original penalty and the new penalty set on the basis of the re-opened proceedings. It may not exceed the fee owed in the event of refusal of the re-opening application within the meaning of (1).