

**Essential contents regarding the establishment
of the organization
“Voluntary Self-Regulation for the
Pharmaceutical Industry”
 (“Freiwillige Selbstkontrolle für die
Arzneimittelindustrie e. V.”)
on February 16, 2004, in Berlin**

Objectives and implementation:

1. The objective is the safeguarding of the necessary collaboration between the pharmaceutical industry and physicians as well as control of the observance of the existing legal conditions created for said collaboration. Furthermore, the communication of specialist knowledge according to scientific principles, which is required for the proper selection of pharmaceuticals, must also be ensured in the future. Without the technical exchange with the medical profession, the research and development of effective pharmaceuticals would not be possible. During such an exchange, the physicians' independence and free choice of therapy must be guaranteed.
2. This objective is implemented by establishing voluntary self-regulation for the pharmaceutical industry. For this purpose, a new organization was established on February 16, 2004, outside the existing association offices, which will be authorized to perform the required sanctioning and monitoring of the members and all companies that are subject to the corresponding rules of conduct. This is the only way to prove the establishment and implementation of effective, voluntary self-regulation in a credible manner.
3. Initially, the organization was established by the VFA member companies but will be open to all companies of the pharmaceutical industry.

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Advantages of voluntary self-regulation:

4. Such a system has a number of advantages:
 - With its objective, the chosen model is not restricted to the member companies of a single association but allows membership to Germany-based companies of the

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pharmaceutical industry. The organization will counter possible legal violations by companies that do not subject themselves to this voluntary self-regulation with written warnings and possibly action suits filed by the organization with the civil courts in charge. This is meant to create a "level playing field" for monitoring and sanctioning.

- Within the meaning of true self-regulation, rule violations shall remain within the responsibility of the industry. In this manner, possible misconduct can be eliminated in a timely and efficient manner through the creation of an unbureaucratic warning and sanctioning procedure. While the normal course of law remains basically in force against the decisions of the arbitrators at the first and second level of authority, which are incontestable pursuant to association law, the civil courts will only perform a limited verification of the content of such decisions. For the activities of self-regulation to be successful, the legal decisions of the organization must usually be accepted.
- The procedure facilitates an appropriate and practice-oriented development of behavioral standards in this area, which is superior to the prosecution of violations through government authorities (which is still possible) due to the concentration of proceedings and the special experience-based knowledge, and can lead to the development of generally mandatory standards. To this extent, effective self-regulation is also associated with the expectation that government control will be required to a lower degree.

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Organization:

5. The design of voluntary self-regulation as a model that enables all companies of the pharmaceutical industry to participate requires an organization of voluntary self-regulation that is independent of existing association structures. For this purpose, an independent organization "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V." (Voluntary Self-regulation for the Pharmaceutical Industry) (in short: "FS Arzneimittelindustrie") was established on February 16, 2004. This organization operates under its by-laws ("FS Arzneimittelindustrie" By-laws), procedural rules ("FS Arzneimittelindustrie" Procedural Rules) and code of conduct ("FS Arzneimittelindustrie" Code of Conduct), which stipulates the rules and requirements of conduct for all member companies. In principle, the content of the code of conduct is

based on the standards of conduct for the collaboration with physicians decided on by the German Association of Research-based Pharmaceutical Companies (VFA), the German Association of Pharmaceutical Manufacturers (BAH) and the German Association of the Pharmaceutical Industry (BPI) in July of 2003 and designed to be obligatory. The monitoring and sanctioning of the conduct requirements is the responsibility of the arbitrators at the first and second level of authority. The arbitrator at the first level of authority can impose fines from EUR 5,000.00 to EUR 50,000.00. The arbitration panel at the second level of authority can impose fines of EUR 5,000.00 to EUR 250,000.00 and a public reprimand.

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6. To ensure that companies that are not willing to become members in the new "FS Arzneimittelindustrie" or are excluded from it based on conduct harmful to the organization will not enjoy unfair competitive advantages, the organization will be given an additional task. It will also prosecute legal violations of such companies that are not involved in the voluntary self-regulation effort.
7. The organization shall have all the usual executive bodies, i.e. the general assembly (consisting of all affiliated companies of the pharmaceutical industry), the executive board, an advisory board and the arbitrators at the first and second levels of authority. In addition, the executive board will appoint an executive officer, who will head the executive office of the "FS Arzneimittelindustrie". The executive officer is the arbitrator at the first level of authority. Depending on the expected work load, the executive board can appoint additional individuals as deputies of the executive officer. These individuals will serve as independent arbitrators at the first level of authority.
8. All associations of the pharmaceutical industry that oblige their members in their by-laws to join the "FS Arzneimittelindustrie" will form an advisory board. This board will serve in a consulting function. In addition, the consent of the advisory board must be obtained for those cases in which the organization's by-laws, procedural rules or code of conduct with the corresponding behavioral standards are to be enacted or amended.

Procedural overview:

9. Control regarding the observance of the code of conduct and the required technical information in this respect are the responsibility

of the arbitrators at the first and second level of authority. The arbitrator at the first level of authority is the organization's executive officer.

10. The *course of procedures* is as follows:

- Each objection must be submitted to the organization's office in writing and with a statement of reasons. There is no restriction on the right to petition ("everybody"). The objection may not be submitted anonymously.

If, at the time the organization's proceedings are initiated, an investigation by the state prosecutor or criminal proceedings are pending in the same matter or such legal action is initiated while the organization's proceedings are under way, the arbitrators in charge will order the organization's proceedings to be suspended until any court proceedings are finalized and legally effective.

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- The arbitrator at the first level of authority will examine the received objection and prepare the proceedings by performing an investigation of the underlying facts (possibly asking the complaining party to further substantiate its objection, requesting a statement from the member company in question, requesting supplementary documents, inviting witnesses, etc.). If the member company does not meet the request for cooperation, a legal assessment is made based on files at hand or based on the available evidentiary materials (witnesses, experts, documents).
- If the arbitrator at the first level of authority believes that the accusations are justified, he or she can issue a warning to the company and demand a declaration of forbearance so that the reported violation will be stopped in the future ("regular proceedings"). A violation of this declaration of forbearance is punishable. The voluntary declaration of forbearance will usually bring the proceedings to an end. If the company does not make a declaration of forbearance, the proceedings will continue. A voluntary declaration of forbearance made at a later date will not end the proceedings but will be taken into account in the assessment of possible sanctions.
- If the proceedings continue due to the lack of a declaration of forbearance and if a violation of the code of conduct is ascertained over the further course of the proceedings, a pronouncement of the decision will be made in this respect. This pronouncement will be associated with the commitment

of the member company to cease the objected conduct and to pay a disciplinary fine for any recurring violation. Depending on the severity of the violation, additional sanctions (fines) may be necessary. The affected company may contest this decision. A final decision will be made by the second level of authority, which has greater power to impose sanctions than the first level of authority (see Article 13 ff., "Decision-making and sanctioning possibilities").

- For repeated violations of the same kind (three violations over a period of two years), the arbitrator at the first level of authority must immediately transfer the proceedings to the second level of authority. In these cases, the voluntary issue of a declaration of forbearance will only impact the degree of sanctions.
- The complaining party will be informed of the outcome of the proceedings (substance of the decision). In principle, the executive office of the organization, the members of the arbitration panels at the first and second level of authority, the members of the advisory board and the executive board are bound by confidentiality with regard to the content negotiated. This does not apply to the name of the accountable company, if a public reprimand is issued. In addition, the organization will regularly report on its activities.
- If the company makes a voluntary declaration of forbearance or if the final decision contains a pronouncement on the violation of the code of conduct, the company will incur the costs of the proceedings. The exact amount is based on a scaled rate system, i.e. the costs of the proceedings depend on the level of authority involved.
- A graphic representation of the organization's structure and a procedural overview that graphically outlines the course of the complaint proceedings are **attached** to this paper.

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Arbitrators:

11. The arbitrator at the first level of authority is identical with the executive officer. He or she has an appropriate number of employees. Depending on the actual amount of work to be expected, the executive board can appoint additional executives

("deputy executive officers"), who will each represent independent arbitrators at the first level of authority.

12. The arbitration panel at the second level of authority consists of nine (9) individuals (one neutral chairman with the authority to serve as a judge, four representatives from the pharmaceutical industry, three licensed physicians, one patient representative). The appointment of the members of the arbitration panel is made by the organization's executive board. The physicians and patient representatives are appointed based on suggestions by physicians' or patient organizations.

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Decision-making and sanctioning possibilities:

13. To tighten the proceedings and reach solutions that are acceptable for both parties in a timely fashion, the proceedings for violations on the first level of authority will usually be concluded through a declaration of forbearance made by the company in question.
14. If no voluntary declaration of forbearance to conclude the proceedings is made after the proceedings have been initiated, the first level of authority can ascertain and make a decision on a code violation and possibly also impose a fine to be paid to a non-profit institution. This pronouncement is combined with the commitment of the member company to cease this kind of conduct in the future and to pay a fine for any repeated violations. If the company contests this decision or if the first level of authority refers this case to the second level on the grounds of repeated violations, the proceedings are to be continued before the arbitration panel on the second level of authority. The possible scope of sanctions of the arbitration panel at the second level of authority is broader than that on the first level.
15. Apart from pronouncing a code violation and prohibiting any future violations (which is still a possibility), the second level of authority can also impose a public reprimand as an additional sanction for repeated and particularly severe violations. This reprimand must be published in an appropriate fashion (e.g. on the organization's Internet website or in the organization's annual report). If a civil lawsuit against the company has been initiated in the same matter, a public reprimand can only be published upon the effective conclusion of said civil action. The organization should refrain from such a pronouncement, if this is suggested by the outcome of the civil lawsuit.

In addition, the second level of authority may impose a fine to be paid to a non-profit institution. The scope of sanctions in this respect is greater than that of the first level of authority (see Art. 5).

16. If the conduct of individual companies is harmful to the organization and said companies are persistently in breach of their duties as stipulated in the organization's by-laws, the executive board may decide to withdraw or at least temporarily suspend the companies' membership rights. This particularly applies to permanent violations of a company's duties pursuant to the by-laws or violations of regulations under the "FS Arzneimittelindustrie" Code of Conduct. Such decisions will be published on the Internet and communicated to the "parent" pharmaceutical association of the company in question with the possibility or consequence of being excluded from the association or having the company's membership rights suspended.

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Financing and voting rights:

17. The organization will be financed through annual membership dues and procedural fees collected from the companies in question for substantiated violations. Additional charges can be levied to finance special projects or eliminate financial difficulties of the organization. The voting rights in the "FS Arzneimittelindustrie" organization are determined based on membership dues.

Note:

To become effective, the Code of Conduct passed by the general members' assembly on February 16, 2004, still requires the Federal Cartel Office's acknowledgment as competitive regulations pursuant to Section 26 of the German Restraints of Competition Act. An application has already been filed and a decision from the Federal Cartel Office is pending.

As of: March 02, 2004

Procedural overview – Monitoring and sanctioning

Receipt of a complaint at the “FS Arzneimittelindustrie” executive office / 1st level of authority

Investigation by the arbitrator at the 1st level of authority (request for a statement, supplementary documentation, etc.)

founded

unfounded

Issue of a warning/
declaration of forbearance

Issue of a warning /
declaration of forbearance
refused by the company

Repeated violation
 (“3 violations in 2 years”)

Discontinuation

Proceedings are concluded

Forbearance / disciplinary fine
for repeated violation/sanctions

Transfer to the 2nd
level of authority

Contestation by the condemned company or repeated violations / 2nd level of authority (predominantly independent members)

founded

unfounded

Forbearance/fine for repeated violations/sanctions (greater penalties than 1st level of authority)

Rejection