FSA.
Consequent.
Transparent.

Annual Report 2014

We promote ethical behaviour.
The FSA and its work in 2014.

Do you have praise, critique or suggestions?

Simply drop us a note:
h.diener@fsa-pharma.de

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Annual Report 2014

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Foreword by Kurt J. Arnold

Kurt J. Arnold
Chairman of the Management Board

Ladies and Gentlemen,

I have now held the position of FSA Chairman of the Management Board since April 2014. Although the tasks of the Management Board, of which I've been a member since 2008, and are very familiar to me, over the past few months, I have gained new impressions and learned new fields of activity. The defining topic of my first year as Chairman of the Management Board was, and continues to be, the successful implementation of the Transparency Code. With this, certainly charted new territory, indeed – and no other German industry does an obligation of this type exist. Nevertheless, the member companies of the FSA embraced the topic of transparency with major in-house time and effort, as they were convinced that the plausibility of all cooperation would lead to greater understanding and thus to more trust in this form of collaboration. With the Transparency Code, the FSA is once again setting a standard within the German pharmaceutical industry.

In addition to the adoption of the Code at the end of 2013, over the past reporting year, we have been able to surmount an additional hurdle along the path towards greater transparency – approval of the transparency rules by anti-trust authorities. Since May 2014, the Code is binding for member companies, who in turn is the beginning of last year have gone to great efforts to adapt their internal systems to the Code or also develop completely new ones. The correct recording of individual physician data requires good preparation for which the member companies invested lots of time over the past year. Since 1 January 2015, the companies now record payments made to members of the healthcare field.

Collaboration in the healthcare system is and will remain a sensitive topic, also for policymakers. The discussion concerning the criminal classification of statutory health insurance physicians and the move towards creating a class of offense for bribery and corruption in the healthcare profession also advanced in the year 2014.

Foreword by Kurt J. Arnold

While the German government announced during the course of the last reporting year that it would be putting forth a ministerial draft, the Bavarian Ministry of Justice presented its own draft bill. Bavaria Justice Department calls for making bribery and corruption in the healthcare field, subject to the criminal code with a fine or imprisonment. This is intended to apply to any member of the healthcare field who demands, allows himself to be promised or accepts a benefit linked to the procurement, prescription or dispensing of pharmaceuticals and medical products, or shows favouritism towards a third-party in an unethical manner or in a manner otherwise in breach of professional duties. The German government presented its draft in mid-2015.

The member companies of the FSA already resolved this issue in 2004 with the establishment of the Association. The established Code of Conduct Healthcare Professionals of voluntary self-regulation sets high ethical standards for the collaboration of the pharmaceutical industry with physicians. In doing so, the Code of Conduct does not differentiate between clinical physicians and physicians in private practice. The Code of Conduct guarantees that the collaboration will occur within reasonable and socially-acceptable bounds. With the Transparency Code, we have even gone a step further, making the conditions, under which the collaboration occurs, more logical for everyone.

Finally, I would like to use this opportunity to once again also thank all the departing Management Board members for their commitment over the past years and to extend a warm welcome our new members of the Management Board. Here's to good collaboration.

[Signature]

Kurt J. Arnold
Chairman of the Management Board
Association of Voluntary Self-Regulation for the Pharmaceutical Industry
(Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V.)

Foreword by Dr. Holger Diener

Dr. Holger Diener
Managing Director

Ladies and Gentlemen,

The past FSA year was marked by many events. The 10 year anniversary of the Association, the prohibition on gifts going into effect, and internal change in personnel, and naturally the anti-trust approval of the Transparency Code filled the agenda of FSA and its members in the year 2014. In this, the Transparency Code continued to be the focus of our Association's activity in the past reporting year. With the transparency initiative, we made an important step roughly 18 months ago towards fostering greater understanding for the collaboration of the pharmaceutical industry with members of the medical profession and thus further strengthening public trust. Now the idea is still to have all the stakeholders on board and to jointly lead the initiative to success.

In order for this to succeed, in my capacity as Managing Director over the past year, I have sought out and intensified the contact and dialog to physicians. At numerous physicians, symposiums, seminars and events of state medical associations, I explain the Transparency Code and the benefit for all stakeholders resulting from support of the initiative. The members of the healthcare profession and the pharmaceutical industry are pursuing the same goal – continuously improving the care of patients. For this reason, the collaboration in the healthcare field is particularly important and desirable. Through the disclosure of payments, we prevent even the appearance of conflicts of interest and demonstrate that all cooperation can take place within reasonable and socially-acceptable bounds.

The vast number of discussions I have undertaken with physicians, chamber representatives, journalists and other members of the healthcare field, clearly demonstrate that the Transparency Code and the objectives related to it are enjoying widespread acceptance. In the ongoing year, we will continue to depend on proper documentation of payments, preparation of initial disclosure and moving closer towards the goal of plausibility of cooperation. That is why a further area focus of my work in the last reporting year was dedicated to advising the FSA members. With in-house training seminars, and a variety of information materials, intensive preparations were made for the launch of documentation on 1 January 2015.

Foreword by Dr. Holger Diener

Finally, I would like to take this opportunity to once again thank Michael Klein for his outstanding commitment and is dedication throughout the past years: After more than 10 years at the helm of the FSA, he stepped down as Chairman of the Management Board in April of last year. The Association which he decisively shaped since the very beginning, however, will continue to have the benefit of his service as a member of the Management Board.

He was succeeded by Kurt J. Arnold. He also was involved in the establishment of the FSA and has already been a member of the FSA Management Board since 2008. With Kurt Arnold, we have gained a chairman who offers many years of experience in legal advisory of research, and manufacturing and distribution of pharmaceuticals. The FSA Codes of Conduct, and above all their compliance, always played a key role in this. The FSA wishes him continued success in this activity.

[Signature]

Dr. Holger Diener
Managing Director
Association of Voluntary Self-Regulation for the Pharmaceutical Industry
(Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V.).

Facts and Figures

FSA Code of Conduct
Constitutional Assembly / Adoption of the FSA Code of Conduct
16 February 2004

Code of Conduct Healthcare Professionals
Approval of the Code of Conduct Healthcare Professionals by anti-trust authorities
05 April 2004
13 March 2006
04 August 2008
23 March 2010
10 July 2012
08 May 2014

Start of Prosecution of Complaints
08 April 2004

Modification of the Code of Conduct Healthcare Professionals
02 December 2005
18 January 2008
27 November 2009
01 December 2011
20 November 2012
27 November 2013
04 December 2014

FSA Code of Conduct Patient Organisations
Adoption
13 June 2008

Approval of the Code of Conduct Patient Organisations by anti-trust authorities
13 October 2008
13 July 2012

Start of Prosecution of Complaints
17 October 2008

Modification of the Code of Conduct Patient Organisations
01 December 2011

FSA Transparency Code
Adoption
27 November 2013

Approval of the Transparency Code by anti-trust authorities
22 May 2014

Modification of the Transparency Code
04 December 2014

Facts and Figures

FSA Recommendations for Collaboration with Healthcare Partners
Adoption
01 December 2010

Modification of the Recommendations for Collaboration with Healthcare Partners
04 December 2014

Current as at: December 2014

Headquarter
Berlin

Managing Director
Dr. Holger Diener

Chairman of the Management Board
Kurt J. Arnold

Memberships and "Submissions" of affiliated companies
39 founding members (all members of the Association of Research-based Pharmaceutical Companies (vfa))
60 members, 26 companies submitted to the Code of Conduct (2014)

Purpose of the organisation:
To promote ethical behaviour in the collaboration between the pharmaceutical industry and physicians, healthcare professionals, healthcare institutions and healthcare policy, as well as patient self-help organisations, to prevent improper ethical influence and thus to ensure the best-possible medical care for patients.

Management Board

Kurt J. Arnold
Sanofi-Aventis Deutschland GmbH
(Chairman of the Management Board)

Ulrike von Schmeling
Bayer HealthCare AG
(Vice Chairwoman of the Management Board)

Dr. Uwe Fröhlich
Baxter Deutschland GmbH

Dr. Johann Huber
Boehringer Ingelheim Pharma GmbH & Co. KG

Michael Klein
Pfizer Deutschland GmbH

Dr. Andreas Kress
Novartis Pharma GmbH

Dr. Hannes Oswald-Brügel, LL.M.
Roche Pharma AG

Dr. Regine Pfeiff, PhD
Lilly Deutschland GmbH

Peter Solberg
JANSSEN-CILAG GmbH

Norbert Steinbach
AbbVie Deutschland GmbH & Co. KG

Dr. Manuel Steinhilber, LL.M.
Novo Nordisk Pharma GmbH

Current as at: December 2014

Front, from left to right: Ulrike von Schmeling, Dr. Regine Pfeiff, Dr. Johann Huber, Norbert Steinbach, Peter Solberg/Back row, from left to right: Dr. Hannes Oswald-Brügel, Dr. Manuel Steinhilber, Kurt J. Arnold, Dr. Uwe Fröhlich (not shown: Dr. Andreas Kress, Michael Klein)

Profile of FSA

FSA
Consistent.
Transparent.

Patients are the focus of the healthcare system – that is the credo on which the Association for Voluntary Self-Regulation of the Pharmaceutical Industry (FSA) was founded in 2004 upon an initiative by members of the German Association of Research-based Pharmaceutical Companies (vfa). It was the premise on which the Association adopted a Code of Conduct for the collaboration between the pharmaceutical industry and physicians and thus set an important signal. The FSA Code of Conduct Healthcare Professionals has been substantially revised and already expanded seven times, the last time in December 2014, in order to not only harmonize with international and European standards but also to reflect national developments and the fact that reliable compliance is a work in progress. Furthermore the members have submitted to the body of rules of the Code of Conduct Patient Organisations which since October 2008 has set new standards for transparency in collaboration between pharmaceutical companies and patient organisations and was supplemented by additional transparency requirements in December 2011. As a third standard of conduct, at the end of 2010 the FSA members established recommendations for the collaboration with institutions in the healthcare field, which are aligned with the basic principles of the Code of Conduct and modified in the year 2014. With its adoption of the FSA Transparency Code in November 2013, the Association is placing the collaboration of the pharmaceutical industry with members of the healthcare profession and organisations in the healthcare system on an even firmer footing in the future, as a supplement to the existing Codes of Conduct.

Our Concern
The goal of FSA is to promote ethical behaviour between the pharmaceutical industry and healthcare professionals as well as patient self-help organisations and to ensure fair competition of companies amongst themselves. The member companies, by recognizing the FSA Code of Conduct Healthcare Professionals, commit to not unethically influencing physicians' freedom of procurement, decision-making, and therapy, in order to ensure the best possible care of patients.

With the Transparency Code, the FSA member companies, starting in 2015, are bound to documenting all payments made to healthcare professionals and medical institutions and to disclose the data for the first time in the year 2016 – based on the year 2015.

With the FSA Code of Conduct Patient Organisations, they additionally commit to disclosing which self-help groups they support and in which manner. The objective of the FSA Code of Conduct Patient Organisations is to strengthen the neutrality and independence of self-help groups, in order to enable transparent and ethical collaboration with pharmaceutical companies.

In the year 2010 voluntary self-regulation was expanded and recommendations were devised for the collaboration of pharmaceutical companies with institutions in the healthcare field and their employees. These include, for example, health insurers, associations of statutory health insurance physicians and agencies. The recommendations are aligned with the basic principles of the Codes of Conduct – with the aim of establishing a transparent and trusting dialog and strengthening collaboration through clear-cut rules in this area as well.

Profile of FSA

Our Members

In the meantime, 60 pharmaceutical companies, including the largest operating in Germany, have joined the FSA and an additional 27 companies have submitted to the Code of Conduct. Together, they account for some 75 per cent of pharmaceutical market in Germany involving prescription drugs. Voluntary accession to FSA demonstrates a keen motivation on the part of the members to fine-tune, or if necessary, completely adapt their methodology to the ethically-based recommendations of the Association.

They have also subscribed to the basic premise that all measures used to communicate information and collaborate with physicians and patient organisations are to be kept within the bounds of what is ethically responsible. The FSA Codes of Conduct also apply to areas regulated by law but also sometimes contain stricter provisions than required by law, particularly with regard to creating transparency. Moreover, the recommendations on collaboration with healthcare institutions demonstrate that FSA pro-actively takes up additional fields of cooperation and applies the strict and proven standards of the Codes of Conduct to these areas.

Our Mission

In addition to our core mission of helping members apply the Codes of Conduct correctly, in order to thus prevent code violations beforehand, FSA also functions as a regulating body. For instance, it investigates complaints concerning violations of the Codes of Conduct by pharmaceutical companies and has the power to sanction misconduct. In cases where laws have been violated, it is also possible for the Association to assume the role of a fair-competition authority and to even take non-members to court. Additionally, FSA sees its mission as carrying out awareness training and staging informational with the aim of convincing both members and non-members to adhere to the set of rules.

Our Goal

Since the inception of the FSA's activities, there has been a noticeable change in behaviour among member companies and in the industry overall in ways consistent with the Code of Conduct Healthcare Professionals and the Code of Conduct Patient Organisations. Self-regulation indeed works. The Association has thus proved that its cause is justified and its work carries weight. FSA will continue to pursue this path consistently. It will remain FSA's goal in the future to further broaden the basis of this success.

Current as at: December 2014

Good health is mankind's greatest asset. Pharmaceuticals fundamentally contribute to the health and well-being of each individual. Research, development, manufacturing, and sales of pharmaceuticals place high demands on companies in the pharmaceutical industry. The patient is at the centre of all endeavours to prevent and cure illnesses and to ameliorate their effects with the help of potent pharmaceuticals.

The FSA in the Public Spotlight

"We promote ethical conduct" – this principle stands for the objective of FSA to create a more transparent and ethical basis for collaboration between pharmaceutical companies and healthcare professionals as well as patient organisations. In order to firmly instil this message in the public mind, among physicians, patients and policymakers, and to further foster awareness and acceptance for the transparency initiative, in 2014 the FSA also relied on continuous and broad-based communication of its mission. This helped to further solidify the positive public perception of voluntary self-regulation.

With the FSA and its members, the year 2014 was dedicated to the Transparency Initiative. After the **FSA Transparency Code** was approved in November 2013 by the members' General Assembly, the German anti-cartel authorities approved the transparency rules in May of the past reporting year as being compliant with anti-cartel competition rules, through which these became binding for FSA members. In 2014, the members undertook significant efforts to prepare the initial collection of data: Internal systems were adapted or completely newly developed in order to ensure that all the data was correctly documented and could be disclosed in 2016. The disclosure of specific sums enables the plausibility of cooperation between pharmaceutical companies and healthcare professionals – at the same time, however, it requires sensitivity for the accuracy of the individual data.

With the aim of using transparency to sustainably counteract unfounded allegations and to disprove even the appearance of conflicts of interest, the FSA and its member companies stood and constant dialog with physicians in 2014, in order to advocate for their support and to convince them of the common benefit of the transparency initiative. Moreover, FSA Managing Director Dr. Holger Diener was increasingly called upon during the last reporting year to explain the transparency initiative, the Code of Conduct and its background at numerous **physicians' symposiums** and **seminars.** Clinics and medical societies as well as state medical associations were informed, among other means, by a letter from the FSA, explaining the current developments.

Yet the topic of transparency was met with great interest in the year 2014 not only within the industry. The **media** also once again had the Transparency Code on their agenda last year. In this, the neutral to positive media response clearly indicates that the FSA is enjoying broad-based recognition, not only with regard to the aim of comprehensive transparency of cooperation. Also explaining the industry itself, along with current topics from the perspective of the FSA, were the contents of several media enquiries received by the FSA Managing Director. In numerous **journalist discussions** and **interviews**, Diener explained the aim of the FSA, to make the collaboration of the pharmaceutical industry with members of the healthcare field transparent, in order to foster greater public trust of the public in the work of voluntary self-regulation. The FSA enjoyed media coverage in the last reporting year above and beyond all relevant trade media. From the Süddeutsche Zeitung and Der Spiegel, through the Frankfurter Allgemeine Zeitung and taz, right down to physicians' journals and the German Pharmacist Journal (*Deutsche Apotheker Zeitung*), the Transparency Code as well as the prohibition on gifts, in effect since 1 July 2014, were the key topics. Other **special editions** were published on the Transparency Code in both the physicians' journals and the Medical Tribune.

The FSA in the Public Spotlight

A film illustrating the Transparency Code was produced in 2014. It explains in simple and illustrative terms the Code, its provisions and the background. The film is available on the website www.pharma-transparenz.de. The Website, launched at the end of 2013, underwent a facelift in September of this year and was expanded with various content.

1) Pharma Relations Online: "Anything but a fig leaf"
2) Physicians newspaper: "No more ballpoint pens from the field sales staff"
3) German Pharmacist Journal Online: "German anti-cartel office approves Transparency Code"

Screenshots of the websites:
www.pharma-transparenz.de
www.fsa-pharma.de

Moreover, the FSA designed **two flyers** explaining the Code of Conduct and its provisions, which can also be downloaded from the website. The flyer, "Information on the introduction of the FSA Transparency Code", shows the key information at a glance. The second flyer, "Information on publishing payments in kind according to the FSA Transparency Code", illuminates how the data collection will look in concrete terms. For this purpose, a standardized European-wide template was devised to assist the member companies in disclosing the payments. This is intended to ensure that the information provided by the companies can be easily understood by those seeking information.

The FSA in the Public Spotlight

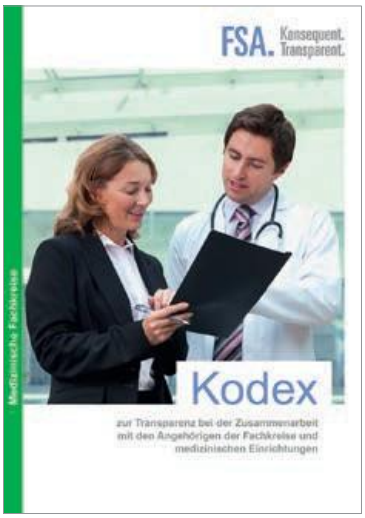
Right at the beginning of the second quarter in 2014, the FSA celebrated an anniversary – its 10 years of existence. Since 2004, the Association has stood for transparent and ethically-sound collaboration between pharmaceutical companies and healthcare professionals, patient organisations and further partners in the healthcare system. More on the celebration and the last 10 years of the Association can be found in a report by the then Chairman of the Management Board Michael Klein on page 19. Klein was Chairman of the FSA for 10 years before handing the baton over to Kurt J. Arnold in April 2014. Klein assumed additional tasks in his function as Vice President & Asst. General Counsel Central & Eastern Europe & DACH. But he is still serving the Association as a member of the Management Board. His successor, Arnold, Head of the Legal Department Commercial Operations at Sanofi-Aventis Deutschland GmbH, was also involved in the establishment of the FSA and has already been a member of the FSA Management Board since 2008.

On 1 July of the past reporting year, another decisive new provision went into effect: the complete prohibition on gifts according to the FSA Code of Conduct Healthcare Professionals. Since then, it is categorically forbidden for FSA member companies to promise, offer or provide gifts to healthcare professionals. This is independent of whether it involves product-related or non-product-related promotion. With this, now even the provision of inexpensive promotional items such as pens or notepads is forbidden. Also not allowed is the dispensing of general practice supplies such as syringes, bandages, needles or disinfectants, as well as reference books, medical periodicals or magazine subscriptions. It is still permissible to distribute scientific information if, firstly, the materials are inexpensive and secondly, they have a direct bearing on professional practice, as well as patient care.

In the fourth quarter of the past reporting year, the **appearance of the FSA** was given a fundamental facelift. Consistent in self-regulation and transparent in its actions: These main areas of focus at FSA are expressed by the new corporate design of the Association. After more than 10 years, the logo of FSA was replaced by a new design and the general colour scheme was slightly modified to reflect the dynamic approach, the FSA in all relevant topic areas. In this context, the **website** was redesigned from the ground up. The focus here was on a target group-oriented introduction into the various FSA topics and a well-organised structure of the website: For example, three interest groups (members of the healthcare profession, patient organisations and institutions in the healthcare system) are prominently featured with the colour scheme of the corresponding Code of Conduct/corresponding brochure. Overall, it is even easier for the visitors to the website to find relevant information. The URL was also modified to www.fsa-pharma.de. It briefly and concisely expresses all the key information.

The FSA in the Public Spotlight

FSA. Konsequent. Transparent.



New logo and Transparency Code Brochure

Information Flyer

The FSA can look back on an eventful and successful year 2014. In the past reporting year, with the approval of the Transparency Code by anti-trust authorities, the FSA surmounted an additional hurdle along the path towards greater transparency. FSA members are now taken the next major step with documentation of data: Since 1 January 2015, they are now recording all payments made to healthcare professionals and medical institutions. In 2016, this data will be available for public review. In order to guarantee successful implementation of additional milestones, it will in the year that has already begun to continue informing and enlightening healthcare professionals and medical institutions about the Transparency Code, its provisions and benefits. Transparency cannot succeed as a one-way street. That is why we need to enlist the support of all stakeholders in the healthcare system.

Ten Years of FSA

"Questioning the typical forms of collaboration and support provided by industry would jeopardize the role of Germany as a business and research location and ultimately also need to a stagnation in the care for patients. That is why the collaboration of physicians with the pharmaceutical industry and medical product manufacturers in particular, but also with other institutions in our healthcare system is unquestionably desirable, necessary and indispensable", remarked Professor Ingo Flenker, former President of the Westfalen Lippe Medical Association and Chairman of the Committee on the "Physicians' Code of Conduct" of the German Medical Association on 16 February 2004 at the founding of the "Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA) ".

Dr. Michael Klein greets the roughly 100 invited guests.

This statement makes the underlying purpose for creating the FSA very clear. The 39 founding members came together at the beginning of 2004, first to provide clear instructions for daily practice by setting concrete rules. Moreover, in safeguarding the trust relationship between physicians and patients, they consciously sought to provide rules that in certain areas go beyond what is allowed by law to sustainably protect this very same trust relationship.

That is why Michael Klein, Founding Chairman of the FSA, in his speech reviewing the Association's 10-year existence, made the start-up phase of the FSA the major focus of his remarks. He said that the industry very quickly and sustainably embraced this topic. To the extent that from certain sides, it was repeatedly alleged that the establishment of the Association was merely a reaction to the perceived threat of the then German government to set up an anti-corruption officer for the healthcare field, the activity of the FSA over the past ten years is substantial proof that this suspicion was surely unfounded. By mere virtue of what have now been seven revisions, i.e. the FSA Code of Conduct Healthcare Professionals has been expanded and made stricter since its first version, firmly underscores the fact that the FSA is more than serious about its self-proclaimed mission to change long-term behaviour. He stated that this can be proven with the example of a physician in private practice, who from day one has been covered by the FSA Code of Conduct Healthcare Professionals and how the collaboration with all other physicians is also subject to strict rules. Therefore, he says, the regulatory gap which the lawmakers now are seeking to close in the Penal Code, has never existed for the FSA members. This clear decision may perhaps have been a competitive disadvantage for the FSA members in 2004. Given the current discussion, however, the clear advantage of diligent self-regulation emerges, which is capable of quickly and effectively identifying problems, devising solutions and putting them into practice. He claims this is but one of the reasons why the FSA may be viewed as a successful model over the long-term.

Ten Years of FSA

With the FSA Transparency Code, the successful work is now being raised to a new level in that financial payments of member companies to physicians and other healthcare professionals will be published for anyone to see. To this extent, he says that there will probably be no lack of interesting topics and developments for FSA member companies over the upcoming 10 years.

FSA Managing Director Dr. Holger Diener speaks about the effectiveness of transparency.

Guest speaker Prof. Dr. Thomas Fischer welcomes the initiative of the FSA.

In his commemorative speech, Prof. Dr. Thomas Fischer, Chief Judge of the Federal Court for Criminal Matters, also touched on the relationship of the pharmaceutical industry to physicians. He spoke of the absolute necessity of close collaboration. In his speech, Prof. Fischer went on to discuss the significance and function of criminal law as the last resort compared to other prohibitions in a legal context. To this extent, he welcomed the fact that not every problem had to be solved by relying on the heavy hand of criminal law, instead clear regulations emerged in the precursor normative context. In this regard, he said that self-regulation of a branch of industry could make a significant, supplementary contribution. Compliance, he admonished, should not be understood as an end in itself, but rather had to also be sustainably implemented and become second nature in the companies.

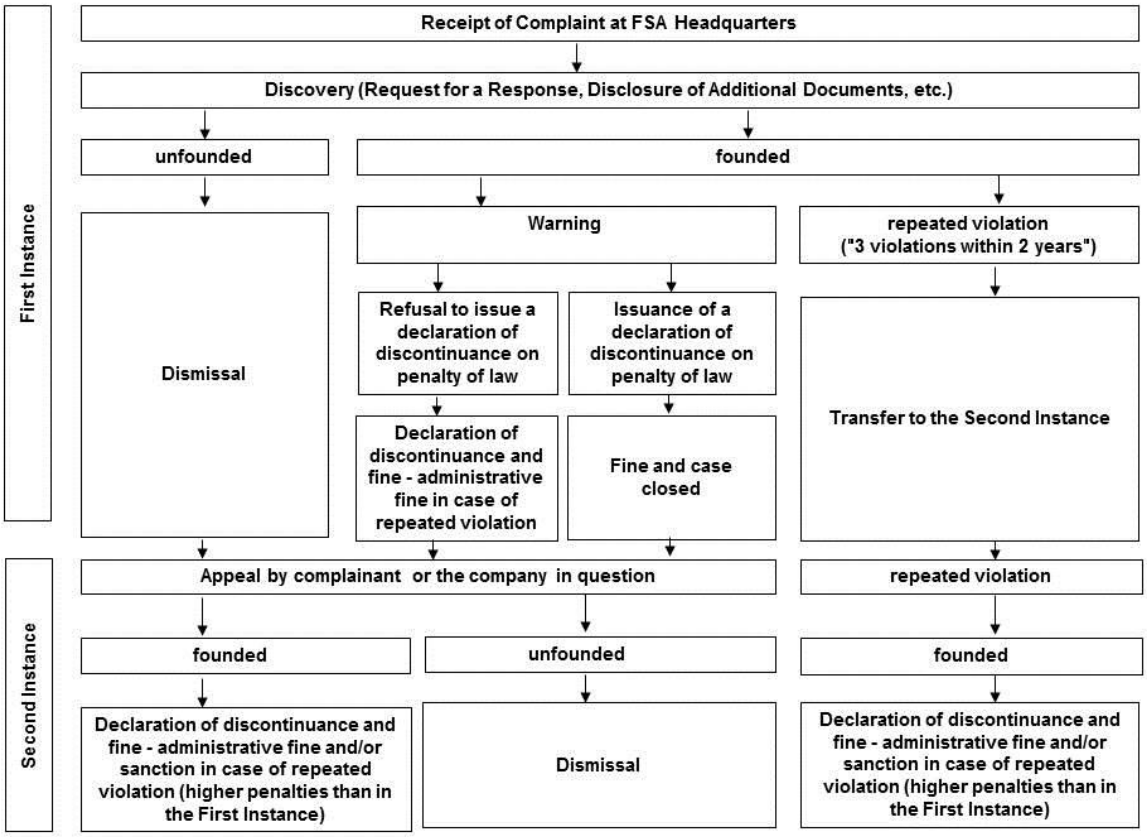
Ten Years of FSA

The celebration of FSA's 10-year existence ended with festivities and gave the attending guests from the member companies, policymakers and industry the opportunity to exchange views on various issues.

The FSA will also utilise the upcoming 10 years to play an active part in the discussion and through independent decisions to expand its function as a role model for collaboration between physicians, other healthcare professionals and patient organisations with industry.

Festive and friendly ending of the 10 year celebration.

Procedural overview – Monitoring and Sanctioning



Sanctions in the Case of a Violation

Declaration of discontinuance on penalty of law or prohibition order

Penalties for violations

First Instance: up to Euros 200,000
Second Instance: up to Euros 400,000

For declarations of discontinuance in standard proceedings and for violations of the Code of Conduct determined by the Arbitration Panel, a fine is specified of at least Euros 5,000 up to a maximum of Euros 400,000, payable to a charity organisation.

Transparency in case a Code of Conduct violation has been discovered:
Immediate disclosure of names

In case of repeated or particularly severe violations:
"Public reprimand" = judgmental statement mentioning the company by name

Guest speech by Dr. med. Gottfried von Knoblauch zu Hatzbach and Dr. med. Roland Kaiser

Dr. med. Gottfried
von Knoblauch zu Hatzbach
President of the State Medical Association of Hesse

Dr. med. Roland Kaiser
Medical Managing Director of the State Medical Association of Hesse

Ladies and Gentlemen,

The collaboration in the spirit of partnership between the pharmaceutical industry and physicians, not only in research but also in medical training, has a long tradition. Properly understood, it serves therapeutic progress and benefits above all the patients.

Naturally, in the process, all those involved are required to uphold certain rules of the road. The current political discussion concerning what the medical associations believe are completely unnecessary special criminal regulations concerning corruption in the healthcare field is evidence that today more than ever, among many groups in society, every form of cooperation between the pharmaceutical industry and physicians is considered suspect from the beginning. We need a proactive and credible strategy for dealing with this. Transparency and plausibility of all connections between industry and physicians are of extraordinary significance in this. This naturally pertains particularly to the support of medical advanced training through the pharmaceutical industry.

The medical associations are cognizant of their responsibility for objective and neutral ongoing advanced training of professional physicians, independent of business interests and dedicated to the current state of medical and scientific knowledge, and this is exactly what our citizens and patients expect of our organisations. That is why on 1 January 2015, the Hesse State Medical Association (as the first state medical association) established its own directive for dealing with sponsoring.

The research-based pharmaceutical industry has also long recognized this fact, subjecting itself to strict rules in the form of the FSA Codes of Conduct and further developing these rules over the past years also in dialog with physicians. Unfortunately, this regulatory instrument has direct reach only for the FSA member companies. Major parts of sponsoring of medical further training events through other players cannot be controlled by these means alone.

That is why with a view towards the common objective, the medical associations are also called upon to make their contribution. An ideologically exaggerated myth of complete freedom from economic interests is not very helpful in this regard. (A healthcare system that has in the meantime become geared through and through to the principle of the market and economic success is ultimately no longer totally free of economic interests.) Almost all further training events through which physicians can acquire points towards the proof of advanced professional training required by the Social Security Code V, are certified by the state medical associations. In this, the medical associations can and must consistently strive towards…

… promoting the most objective and neutral content and information possible, dedicated primarily to scientific accuracy and relevance, suitable for medical advanced training and independent of economic interests, and...

... the best possible transparency, as a safeguard against any potential economic interests and any unethical influence of the stakeholders....

Through the synergy of self-regulation of FSA companies and the certification practice of the medical associations, we should be successful in further narrowing existing 'grey areas' in the support of medical advanced training by companies in the medical industry.

[Signature]

Dr. med. Gottfried
von Knoblauch zu Hatzbach
President of the State Medical Association of Hesse

[Signature]

Dr. med. Roland Kaiser
Medical Managing Director of the State Medical Association of Hesse

Membership of the Arbitration Panel of the Second Instance

Chairman
Hermann Brüning

Vice Chairman
Dr. Veit Stoll, MSD SHARP & DOHME GmbH

Members representing Industry
Ina Heitmeier, GlaxoSmithKline GmbH & Co. KG
Dr. Gerhard Jäger, DAIICHI SANKYO Deutschland GmbH
Emil Messner, Eisai GmbH
Martina Ochel, Genzyme GmbH
Thomas Olschewski, Berlin-Chemie AG
Dr. Veit Stoll, MSD SHARP & DOHME GMBH

Alternate Members representing Industry
Kerstin Bode-Rau, Gilead Sciences GmbH
Dr. Carola Dehmlow, UCB Pharma GmbH
Dr. Frank Kessler, Biogen Idec GmbH
Dr. Gudula Petersen, Grünenthal Pharma GmbH & Co. KG
Manfred Melzer, Almirall Hermal GmbH

Members representing Physicians
Dr. med. Gottfried von Knoblauch zu Hatzbach, President of the State Medical Association of Hesse
Prof. Dr. med. Hans Reinauer, Association of the Scientific Medical Societies in Germany (AWMF)
Dr. med. Theodor Windhorst, President of the Medical Association of Westphalia-Lippe

Alternate Members representing Physicians
Dr. med. Roland Kaiser, Medical Managing Director of the State Medical Association of Hesse
Dr. med. Klaus Reinhardt, Chairman of the Hartmannbund – Association of Physicians in Germany (Verband der Ärzte Deutschlands e. V.)
Prof. Dr. med. Peter von Wichert, AWMF

Members representing Patients
Hannelore Loskill, German self-help working group for people with disabilities or chronic diseases and their families (BAG SELBSTHILFE) e. V.
Christoph Nachtigäller, ACHSE e. V.
Marion Rink, German self-help working group for people with disabilities or chronic diseases and their families (BAG SELBSTHILFE) e. V.

Alternate Members representing Patients
Prof. Dr. Joachim Baltes, German self-help working group for people with disabilities or chronic diseases and their families (BAG SELBSTHILFE) e. V.
Barbara Kleinow, German self-help working group for people with disabilities or chronic diseases and their families (BAG SELBSTHILFE) e. V.
Volker Langguth-Wasem, German self-help working group for people with disabilities or chronic diseases and their families (BAG SELBSTHILFE) e. V.

Current as at: December 2014

Overview of Arbitration Activity – 2014 Final Report

A) Number of Complaints (since 2004)	**Total**	**2014**
Total of complaints	**460**	**82**
submitted by members	202	7
submitted by third parties	218	53
Management Board Resolution	17	3
Management Resolution	23	19
against members	**397**	**82**
against non-members	81	0
number of cases adjudicated	**438**	**75**
against members	*356*	*75*
thereof against non-members	*82*	*0*
involving Code of Conduct Patient Organisations	5	0

B) Results of Cases Adjudicated (since 2004)	**Total**	**2014**
dismissed on formal grounds	50	0
dismissed on material grounds	223	68
Warnings / Declarations of discontinuance	126	3
Rulings of the First Instance	15	1
Rulings of the Second Instance	24	3

C) Status of Proceedings for Pending Complaints	**Total**	**2014**
Number of open cases	**28**	**0**
Substantiation	0	0
Hearings	28	0
Declarations of discontinuance and commitment / Warnings / Rulings	0	0
Transfer to Second Instance / Civil proceedings	0	0
pending	0	0

Overview of Arbitration Activity – 2014 Final Report

D) Receipt of Complaints	**2013**	**2014**
January	0	0
February	17	3
March	0	9
April	1	21
May	3	0
June	0	0
July	0	19
August	2	3
September	3	6
October	3	11
November	0	6
December	10	4
Total	**39**	**82**

Current as at: December 2014

Complaints in 2014 – Overview

In the reporting period, 82 complaints were submitted to the FSA, including seven by members, and 53 by third parties. In addition, three complaints were initiated through Management Board resolution and 19 through the Management. All complaints were levelled against member companies. In all the cases, these were complaints due to alleged violations of the FSA Code of Conduct Healthcare Professionals.

As at 31 December 2014, 75 proceedings had been adjudicated. In three cases, warnings were issued with a subsequent declaration of discontinuance by the companies. The First Instance of the Arbitration Panel held proceedings in one case. The Second Instance held proceedings and three cases. In 68 cases, the proceedings were dismissed because the complaints were impermissible or unfounded.

As at 31 December 2014, 28 proceedings were still pending against members.

In terms of content, the proceedings essentially involved transparency duties in sponsoring and their concrete interpretation in practice. What's more, the Arbitration Panel was called upon to deal with the classification of treatment monitoring and the implementation of the new, comprehensive prohibition on gifts.

It is interesting to note the increase in enquiries by members, but also by third parties (agencies, conference organisers, etc.), in particular with individual questions on the staging of training events or drafting of agreements with physicians. This enabled the clarification of several questions of interpretation of Code of Conduct rules in advance, consistent with FSA's prevention and advisory concept, thus averting possible violations of the Code of Conduct.

On its website the FSA regularly publishes all the rulings of the First and Second Instance: www.fsa-pharma.de/schiedsstelle/berichterstattung [Arbitration Panels/Reporting].

In the annual report, in compliance with the Association's statutes, the public is informed once a year about all the rulings of the previous business year.

Report Code of Conduct violations:
www.fsa-pharma.de

Complaints in 2014 – Non-interventional studies

Wording of the relevant Code of Conduct Rules

FSA Code of Conduct Healthcare Professionals

§ 19: Non-interventional studies with authorised medicinal products

(1) Non-interventional studies, to which drug monitoring projects also belong, are prospective studies with the purpose of gaining new insights from the treatment of patients on the application of pharmaceuticals in accordance with the instructions laid down in the marketing authorisation (e.g. harmlessness or efficacy of pharmaceuticals). The principle of non-intervention applies to all therapeutic and diagnostic measures. The inclusion and treatment, including the diagnosis and supervision, do not therefore follow a previously laid down study plan, but solely the physician's medical practise. The decision to include a patient in a non-interventional study has to be clearly separated from the decision on the prescription of a medicinal product. The data obtained has to be evaluated by means of epidemiological methods.

(2) When planning, implementing and evaluating non-interventional studies, all applicable legal regulations and the recommendations and guidelines published by the German Federal Institute for Drugs and Medical Devices (BfArM) and the Paul-Ehrlich-Institute (PEI) must be observed. Irrespective of the foregoing, the planning, implementing and evaluating of non-interventional studies must in every case comply with the following conditions:

7. The remuneration agreed must be in an appropriate relationship to the services rendered. With regard to the amount remunerated, § 18 Section 1 No. 6 applies subject to the provision that said remuneration should be set in such a manner that it does not create an incentive to prescribe the pharmaceutical in question. The performance of the study is not allowed to be misused to influence therapy, prescription or procurement decisions.

Complaints in 2014 – Non-interventional studies

§ 19 Section 2 Subsection No. 7 (see Subsection 3) in association with § 19 Section 1 Subsection 2 and 3, Section 2 Subsection 1 FSA Code of Conduct Healthcare Professionals – Non-interventional studies with authorised medicinal products
Ref.: 2013.2-345 (1st Instance)

Principles
On the separation of prescription decisions and TM inclusion.

Statement of Case
Bencard Allergie GmbH (hereafter referred to as "company") financed as a sponsor a "treatment monitoring" entitled: "Patient compliance upon participation in recall systems in the application of TA (trees) Bäume top, TA ("grass") Gräser top or Pollinex Quattro Plus" (hereafter referred to as "TM" or "NIS" – as an abbreviation for non-interventional study). The pharmaceuticals belong to allergenic extracts, which are used for hyposensitization treatment of allergy sufferers within the scope of so-called specific immune therapy "SIT" over at least three years. The scientific management and study organisation was headed up by Dr. S., a dermatologist in private practice and an allergist in Baden-Wuerttemberg. The client is the company, which named several persons, including a project manager, contact persons for contractual matters and side effects. The study was announced to the Paul-Ehrlich Institute ("PEI"); Dr. S. received a vote of the ethics commission at the competent state medical association, which raised no objections to carrying out the TM.

The documents submitted by the company for the TM consist, among other things, of two brochures, a "physician's folder" and a "patient's folder". In the monitoring plan contained in the physician's folder, the objective of the NIS is stated as "examining compliance improvement for therapy with Pollinex Quattro Plus, TA Gräser top or TA Bäume top, depending upon a patient recall system." Additional (secondary) objectives are stated as "monitoring the efficacy and compatibility of the therapy under practice conditions in a large patient population". In the patient information, it says: "The purpose of this survey is to gain knowledge on how long an allergy vaccination lasts on average and what motivates the patients to continue or discontinue such therapy."

In a circular letter ("SIT/hyposensitization therapy"), Dr. S. sought to enlist physician colleagues to take part in the NIS. There it was mentioned that "in most studies" the participation of patients in the third year of hyposensitization was below 50%. As no sufficient therapeutic success could be achieved in this way, it was said to be absolutely essential for medical reasons to improve compliance: "It would be a tremendous success if we could achieve a rate of approx. 70% of patients and in the third year when performing hyposensitization therapy." The required recall system was described as follows: "The reminder for the injection should occur in the first week after the anticipated date of injection has been missed. That is why it is necessary for an employee of your practice (generally a medical technologist) to review the injection table of all the patients participating in the study and to filter out tardy patients in order to send them a text message or an email."

Complaints in 2014 – Non-interventional studies

The company emphasized that no TMs had been conducted in this field of therapy up to now, which involved a direct handling of the patient ("recall") by the treating physician; previous studies for improvement of compliance were said to have been conducted by the manufacturer directly with the patients and had only resulted in limited compliance improvement. The physicians participating in the TM were promised the following remuneration per patient by the company: A one-time amount of EUR 20 for an introductory examination, a one-time amount of EUR 20 for ask, postage, telephone costs, EUR 80 annually for documentation of the injections and the filling out of symptom questionnaires. Accordingly, the physicians were able to receive EUR 280 for a three-year therapy, and EUR 360 for a four-year therapy overall. It was intended to involve 3000 patients and 50 centres in the TM, exclusively in Baden-Wuerttemberg. The explanation of the remuneration to be achieved was followed by justifications why patients beginning with a hyposensitization therapy could only be included in the TM if they were treated with the appropriate pharmaceuticals of the company.

After he, Dr. S., had engaged in intensive discussions with various other manufacturers of allergy medicines, he claimed to have finally found a good contractual partner: "It is understandable that Bencard can only finance a treatment monitoring study that also uses its products." At the end of the letter, the following reference was made to the physician colleagues: "In case you've not been familiar up to now with the medications of the company Bencard, there is an opportunity for a field salesperson [of the company] to inform you personally in the very near future concerning the application of the [company's] medicines." The letter was accompanied by a pre-printed fax reply sheet with which interested physicians were able to register for participation in the NIS. In the form, respondents were requested to check the "yes" or "no" box: "I would like to request a visit in the very near future by a field salesperson from the company Bencard, in order to discuss the procedures for using hyposensitization solutions from the company Bencard."

On behalf of the Arbitration Panel of the First Instance an expert witness, who is a professor for medical information processing, biometrics and epidemiology at a German university, prepared an expert opinion on the question as to whether the study met the requirements for a non-interventional study. The expert witness came to the conclusion that the company's project could not be carried out as an NIS, because the examination of compliance improvement under the influence of a patient recall system violated the principle of non-intervention. The therapy monitoring through such a reminder system did not belong to normal medical practice in Germany. What's more, the design of the NIS was inadequate for gaining insights into its main objective. The question as to whether a recall system actually would lead to an improvement could only be answered if a control group were established. In addition, the expert opinion discovered several deficits in the monitoring plan.

Complaints in 2014 – Non-interventional studies

Essential grounds for the decision
The Arbitration Panel of the First Instance issued a warning to the company, because by financing the NIS, in particular through the promise and/or provision of payments or cost reimbursements for participating physicians would violate § 19 Section 2 Subsection 2 No. 7 (Subsection 3 there) in connection with § 19 Section 1, Subsections 2 and 3, Section 2 Subsection 1 FSA Code of Conduct Healthcare Professionals (hereafter referred to as "Code of Conduct"). With the stated primary question (" compliance improvement depending upon a patient recall system"), it was not considered possible to conduct the study as an NIS due to the resulting methodical prescription of a patient recall system, which is why the basis for the remuneration provided to the participating physicians no longer applied. Conducting an NIS with the premise that only patients can be included to whom the company's allergenic products are prescribed at the beginning of a treatment within the scope of the SIT represents unfair influence of physicians' decisions. The project cannot be carried out as a TM/NIS, as it violates the principle of non-intervention; this is further elaborated in reference to the findings of the expert opinion. The decision concerning the course of the therapy, it's monitoring and possible promotion of therapy loyalty by its patients lies solely within the therapeutic sovereignty of the treating physician. Because the project financed by the company is impermissible as a TM, due to a violation of the principle of non-intervention, there is no longer any basis for normal remuneration as compensation for the additional material and documentation time and effort of the physicians participating in a TM.

Additional proceedings
In response to the warning, the company did not sign a declaration of discontinuance, and it continued to put forth arguments in particular regarding the question of non-intervention. For this purpose, it relied on the expert opinion concerning the question of non-intervention by the diploma mathematician L., who runs an office for biometrics and statistics and had also prepared the statistical analysis plan for the TM on behalf of the company. This expert came to the conclusion that recall systems were indeed used within the scope of the SIT. Companies offered patients, where appropriate, with the involvement of the treating physician, such reminder aids for the continuation of the therapy.

The company argued that in the recall system it was offering (which foresees no compliance management of the above-mentioned type by the treating physician), currently more than 4,500 patients are "active". These types of recall systems merely served as "support" of the hyposensitization therapy to be carried out according to the guidelines. This did not constitute any intervention in the "diagnosis, therapy and monitoring of patients". The deficits of the design and of the monitoring plan cited in the expert opinion were contested by the company. In particular, a control group was said to be unnecessary for the NIS, as with respect to patient compliance without the use of a recall system, there were already comparison data available. The remuneration promised and/or paid to the physicians were said to be justified as a quid pro quo within the scope of other contractual collaboration pursuant to § 18 Section 1 Code of Conduct. Measures of physicians for promotion of therapy loyalty of their patients belong to the core activity of medical practice, primarily benefiting the patients. A "reminder service" to get the injections within the scope of the SIT is therefore not a professional activity for the company, as required according to § 18 Section 1 No. 2 Code of Conduct. Therefore, the company referred to the decision of the Arbitration Panel of the First Instance concerning case number 2011.12-315.

Complaints in 2014 – Non-interventional studies

Upon request of the company, verbal proceedings were conducted, in which the factual and legal circumstances were further discussed.

Outcome
Upon conclusion of the verbal proceedings, the company issued a declaration of discontinuance upon penalty of law, in which it agreed to cease and desist

1. from promoting or having third parties promote the treatment monitoring "Patient compliance upon participation in recall systems in the application of TA (trees) Bäume top, TA ("grass") Gräser top or Pollinex Quattro Plus" (hereafter referred to as "TM" or "NIS") with the statements

    a. "It is understandable that Bencard can only finance a treatment monitoring study that also uses its products."

and/or

    b. "In case you've not been familiar up to now with the medications of the company Bencard, there is an opportunity for a field salesperson of the company Bencard to inform you personally in the very near future concerning the application of Bencard medicines."

and/or

    c. with a pre-printed fax reply containing the text, "I would like to request a visit in the very near future by a field salesperson from the company Bencard, in order to discuss the procedures for using hyposensitization solutions from the company Bencard."

as occurred under No. 1 a., b. and c. in the letter from …

and/or for the TM patient compliance:

    d. to approach patients (or have others approach them), to whom a treatment with a Bencard medication has not yet been previously prescribed by their physician and on a separate occasion

and/or

    e. to select size of the patient population with more than 2,000 patients and/or to determine a regional limitation

and/or

    f. to offer or to pay physicians compensation and cost reimbursements for services, which (I) are not necessary for carrying out the patient compliance TM or those that the (II) physicians already owe their patients or (III) for which the physicians may request compensation from the health insurance of the patient

and/or

g. using the documents (or having third parties use the documents) that are subject to the complaint, in particular the invitation letter from ..., without ensuring that (I) the aforementioned items have been taken into consideration, (II) the delegation of responsibilities (sponsor, project manager, head of research, etc.) are clearly and unambiguously communicated and (III) the prospective reasonable compensation is only based on services that go above and beyond the practice routine and the medical treatment owed to the patient.

The FSA accepted the declaration of discontinuance, and the proceedings were thus concluded.

Berlin, in June 2014

Complaints in 2014 – Further training events

Wording of the relevant Code of Conduct Rules

FSA Code of Conduct Healthcare Professionals

§ 20 Invitation to job-related, science-oriented training events

(5) Within appropriate limits, financial support for the organisers of external training events is permissible. However, entertainment programs must neither be supported financially or in the form of donations nor organised. Member companies supporting external training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place.

§ 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals – Duty to work towards disclosure of the condition and scope of support
Ref.: 2013.2-367-370/372-375 (1st Instance)

Principles

1. The necessary effort required pursuant to § 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals must be structured in such a way that in the specific case, the financial support, including its condition and scope, be officially disclosed by the organiser when the event is announced and when it takes place.

2. The necessary effort does not constitute a contractual obligation of the organiser, the contractual form, however, is recommended based on reasons of traceability and proof; moreover, it allows explicit and concrete specifications in terms of content, type, form and scope of the disclosure.

Statement of Case

A series of companies concluded sponsor agreements with two clinics for the staging of two symposiums. The agreement in both cases contained an obligation of the contractual partner to name the company as a sponsor, along with the condition and scope of the sponsoring as part of the announcement, as well as at the staging of the event.

As a result, the symposiums were announced for the state medical association competent for the registered location of the clinic as "our nearest further training event". During the announcement, the sponsoring companies were mentioned by name, yet the condition and scope of support were not. At the beginning of the event at one of the symposiums, the sponsoring amounts were disclosed in the form of a PowerPoint slide, at the other in the form of an available list. Based on the documents submitted to the Arbitration Panel, it became evident that the organiser consciously and intentionally failed to disclose the scope of support during the announcement.

Essential grounds for the decision

As the sponsoring companies were able to demonstrate that they had required their contractual partner within the scope of the sponsoring agreement to disclose their sponsoring payment during the announcement and at the staging of the event, the Arbitration Panel considered the duty to work towards disclosure pursuant to § 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals as having been fulfilled. The companies were not made responsible for the fact that the state medical associations as organisers had sent out announcements indeed mentioning the companies as sponsors, yet without stating the amount of the support.

Outcome
As a result, the proceedings were dismissed.

The case, however, led the Arbitration Panel to the following observations:

1. The necessary effort to work towards disclosure does not constitute a contractual obligation, the contractual form, however, is recommended based on reasons of traceability and proof. Moreover, it allows explicit and concrete specifications in terms of content, type, form and scope of the disclosure. The effort towards disclosure shall occur in the manner that enables the disclosure to be made with sufficient probability.

2. If during the printing of the announcement materials the contractual agreement with the organiser has not yet been concluded, yet there is indeed already a basic agreement among the parties as to the type and scope of support, it may be expected of the company already at this juncture to not only be named as sponsor, but also to work towards disclosing the amount of anticipated support.

3. The company cannot immediately assume compliance with the contractual obligations by the contractual partner. In case the company is present with several employees at the event itself (i.e. for manning a booth etc.), it ought to be reasonable to check the type and scope of the disclosure on site. This also pertains to the question as to whether the contractual partner of the company actually appears as organiser or as a third-party. The Arbitration Panel considers problematic any tacit assignment of the contractual rights and duties of the contractual partner to a third-party, as appears to be the case here.

4. After the information presented to the Arbitration Panel within the scope of the hearing suggested that the organiser, at least part of the time, despite a contractual obligation, consciously failed to disclose the support during the announcement, companies entering in future contracts of this type with this contractual partner will have to explore additional means of working towards disclosure; the mere, somewhat subtle mention in the contract would appear to no longer suffice for this organiser.

Berlin, in April 2014

Complaints in 2014 – Further training events

Wording of the relevant Code of Conduct Rules

FSA Code of Conduct Healthcare Professionals

§ 20 Invitation to job-related, science-oriented training events

(5) Within appropriate limits, financial support for the organisers of external training events is permissible. However, entertainment programs must neither be supported financially or in the form of donations nor organised. Member companies supporting external training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place.

§ 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals – Duty to work towards disclosure of the condition and scope of support
Ref.: 2013.2-380-387 (1st Instance)

Principles

1. General regulations in contracts with which the organiser obliges to observe the FSA Code of Conduct do not suffice for the fulfilment of the duty to seek disclosure. The pharmaceutical company is obliged to make a specific reference to the organiser already in the contract or in a separate letter, specifying exactly what it is to do in order to guarantee the required transparency (see Arbitration Panel of the Second Instance FS II 1/14/2013.2-346, 349, 352).

2. The disclosure is to be placed clearly, unambiguously and in a prominent place at the beginning of the website with self-explanatory terms such as "sponsors" or "support by the pharmaceutical industry" etc.). The use of the term "FSA list" tends to be rather confusing.

3. On websites, links leading to the disclosing information are to be clearly identifiable and explicitly named.

Statement of Case

A series of companies concluded sponsor agreements with two conference organisers concerning a further training event in the therapy field of urology. The agreement in both cases contained a general and not further specified obligation of the contractual partner to name the company as a sponsor, along with the condition and scope of the sponsoring as part of the announcement, as well as at the staging of the event.

The organisers created a website consisting of several pages link to one another. The somewhat inconspicuous information "FSA list", not further specified as a link, yet active, was placed in small letters on the far left-hand side on the website of the event. Double-clicking on the term "FSA list" led to a new page with a list containing the explanation, "According to the guidelines of the FSA, here you will find below the details of the exhibitors and sponsors. Please note that the companies listed here are those that expressed the explicit wish for disclosure of their sponsorship support." This was followed by a table listing the companies, the sponsoring amounts and the "sponsoring services" (meaning the quid pro quo of the organiser).

Complaints in 2014 – Further training events

The web address containing the program of the event, merely listed the logos of the sponsoring companies, but included no further details as to the scope and condition of the support.

Essential grounds for the decision
As the sponsoring companies were able to demonstrate that they had required their contractual partner within the scope of the sponsoring agreement to disclose their sponsoring payment during the announcement and at the staging of the event, the Arbitration Panel considered the duty to work towards disclosure pursuant to § 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals as having been fulfilled. The companies were not made responsible for the fact that the depiction on the website at best allowed access involving a considerable searching effort.

Outcome
As a result, the proceedings were dismissed on 3 July 2014.

The case, however, led the Arbitration Panel to the following observations that ought to be taken into consideration in structuring contracts in the future:

1. According to the most recent legal precedent of the Arbitration Panel of the Second Instance, general regulations in contracts with which the organiser obliges to observe the FSA Code of Conduct do not suffice for the fulfilment of the duty to seek disclosure. A contractual provision of this type does not release the pharmaceutical company from its own duty to make a specific written reference to the organiser already in the contract or in a separate letter, specifying exactly what it is to do in order to guarantee the required transparency.

2. The disclosure ought to be placed clearly, unambiguously and in a prominent place at the beginning of the website with self-explanatory terms such as "sponsors" or "support by the pharmaceutical industry" etc.). The use of the term "FSA list" tends to be rather confusing.

3. On websites, links leading to the disclosing information are to be clearly identifiable and explicitly named.

Berlin, in July 2014

Complaints in 2014 – Further training events

Wording of the relevant Code of Conduct Rules

FSA Code of Conduct Healthcare Professionals

§ 20 Invitation to job-related, science-oriented training events

(5) Within appropriate limits, financial support for the organisers of external training events is permissible. However, entertainment programs must neither be supported financially or in the form of donations nor organised. Member companies supporting external training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place.

§ 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals – Duty to work towards disclosure of the condition and scope of support
Ref.: 2014.4-388-390 (1st Instance)

Principle
The concrete references made by the company towards the organiser, in order to guarantee the required transparency (see Arbitration Panel of the Second Instance FS II 1/14/2013.2-346, 349, 352), ought to include a reference to the organiser that the disclosure, if a website is to be set up for the event, it is to remain generally available, even after conclusion of the event.

Statement of Case
A series of companies concluded sponsor agreements with a conference organiser concerning a further training event in the therapy field of andrology. The agreement in each cases contained a general obligation of the contractual partner to name the company as a sponsor, along with the condition and scope of the sponsoring as part of the announcement, as well as at the staging of the event; in addition, further reference was made to the organiser in a separate letter, pointing out the necessity of disclosure.

The disclosure occurred within the scope of printed documents, a slide shown during the event, and through information on the website. The website subject to the complaint contained information for disclosure, however, only prior to and during the event. After the end of the event, the information concerning the scope and condition of support was removed from the website.

Essential grounds for the decision
As the sponsoring companies were able to demonstrate that they had required their contractual partner within the scope of the sponsoring agreement to disclose their sponsoring payment during the announcement and at the staging of the event, the Arbitration Panel considered the duty to work towards disclosure pursuant to § 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals as having been fulfilled. The companies were not made responsible for the fact that information on the support provided was only made available prior to and during the event.

Complaints in 2014 – Further training events

Outcome
As a result, the proceedings were dismissed on 13 August 2014.

The case, however, led the Arbitration Panel to the following observations that ought to be taken into consideration in structuring contracts in the future:

1. According to the most recent legal precedent of the Arbitration Panel of the Second Instance, general regulations in contracts with which the organiser obliges to observe the FSA Code of Conduct do not suffice for the fulfilment of the duty to seek disclosure. . A contractual provision of this type does not release the pharmaceutical company from its own duty to make a specific written reference to the organiser already in the contract or in a separate letter, specifying exactly what it is to do in order to guarantee the required transparency.

2. The concrete references ought to contain a reference to the organiser that the disclosure, if a website is created for the event, is to remain generally available there, even after conclusion of the event.

Berlin, in August 2014

Complaints in 2014 – Further training events

Wording of the relevant Code of Conduct Rules

FSA Code of Conduct Healthcare Professionals

§ 20 Invitation to job-related, science-oriented training events

(5) Within appropriate limits, financial support for the organisers of external training events is permissible. However, entertainment programs must neither be supported financially or in the form of donations nor organised. Member companies supporting external training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place.

§ 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals – Duty to work towards disclosure of the condition and scope of support
Ref.: 2014.7-410-425 (1st Instance)

Principles

1. The pharmaceutical company is obliged to make a specific reference to the organiser already in the contract or in a separate letter, specifying exactly what it is to do in order to guarantee the required transparency (see Arbitration Panel of the Second Instance FS II 1/14/2013.2-346, 349, 352).

2. This concrete reference includes clarifications as to where the disclosure is made and how clearly, unambiguously and prominently it is to be featured; the principles developed by legal precedent concerning mandatory information in the Internet (Federal Court of Justice (BGH) from 6 June 2013, NJW (New Weekly Legal Review) 2014, 1012 = Leading Decision (GRUR) 2014, 94) may be applied here.

3. If the entire event is announced uniformly, yet from an organisational standpoint, it is divided up into a so-called scientific segment, and an industry showcase, efforts should be made towards disclosure of the support for the "scientific segment", also on the documents/the website; this also applies especially if industry events are announced and staged in the "scientific segment" and/or the registration materials for the industry event also prominently feature the logo of the scientific symposium.

4. Payments by the company to the organisers of external further training events, which are made for the purpose of staging symposiums, are subject to the same duty to seek disclosure in the same manner as for other financial payments of support.

Statement of Case
The FSA received an anonymous complaint admonishing the missing disclosure of sponsoring payments, in particular to the industrial symposium for a convention in the field of cancer therapy. The Arbitration Panel subsequently approached the society, which – according to the website – [organises] the convention as "one of Germany's largest and oldest ... professional symposiums, which over [...] days attract several thousands of visitors from Germany and abroad"; the society claims to "bring experts together and thus foster the interdisciplinary collaboration between the individual professional disciplines.

Complaints in 2014 – Further training events

[The professional symposium] offers a window onto the current state of research and the situation in ... [– Oncology –] in Germany." The society contracted with Company A to handle the event, organisation and staging of the conference and the forum.

Upon enquiry as to whether companies from the pharmaceutical industry had supported the conference financially, the Arbitration Panel received a note from the society that Company A was "the organisation that staged the industry showcase" and [which was] "not responsible for financing the conference". Upon further enquiry with Company A, the Arbitration Panel learned that companies from the pharmaceutical industry had not supported the conference.

On this statement of case, 16 member companies of the FSA were heard, whose symposiums were announced in the official program of the conference and which (– according to the website of the society –) were all members of the so-called "section C" of the company and therefore declared their willingness to promote the purpose of the society and, as members, to become involved in common causes.

The membership in the section C in turn offered advantages in the stand allocation; to the extent that it was stated in the "exhibition space" registration form:

Membership in Section C
The membership of the company in section C offers advantages in the exhibition stand allocation. Likewise, the support of a section C member is factored into the final positioning of the exhibition space. A membership application for section C – prior to the registration date for the … Forum – is possible on short notice.

The hearing yielded the following additional statement of case:

The contract for complete organisation of the convention was driven by a conscious separation between the so-called industry area and the scientific segment. While the scientific segment was featured within the scope of the convention announcement, the participation of industry in the so-called "… Forum" (Forum) was intended to be outsourced. An exception to the separation into the forum were in turn industry symposiums, which were described as an integral part of the official convention program. This was done on the rationale that these symposiums were based on "validated content". The placement of the symposiums by the president of the convention was also performed in coordination with the scientific convention secretariat.

Concerning the validation of symposium content by the president of the convention, there is nothing stated in the materials presented to support this; in addition, no information has been submitted to the Arbitration Panel as to the placement of the symposiums by the president of the convention and any coordination procedures with the scientific convention secretariat.

The placement of the symposiums is described as follows in the registration materials:

Symposiums prior to and after the plenary sessions
The symposiums prior to and after the plenary sessions are exclusive symposiums with respect to the topics of main indications. The placement according to your desired session cannot be guaranteed. The president of the … Convention 2014 decides on the final admission and placement of the symposiums in the program, in coordination with the scientific convention secretariat.

Complaints in 2014 – Further training events

Lunch, breakfast and afternoon symposiums
All other symposium types (lunch, breakfast and afternoon symposiums) may be booked independent of the thematic structure of the convention and without limitation of the number of participants. Here as well, the placement according to your desired session cannot be guaranteed.

Promotion of your symposium
Your symposium can be promoted throughout the entire run of the convention with posters on your exhibition space. Posters in front of and in your symposium meeting room are not permitted. These are allowed to be set up prior to the beginning of your symposium outside the all and during the run of your symposium inside the meeting room. For this purpose, please use the A1 easels, it is not permitted to affix materials to the walls of the exhibition grounds. All posters in front of and in the meeting rooms must be removed following the event. Promotion in the south entrance is provided by the organiser.

Please note: The promotion of your symposium events is exclusively permitted in the meeting facilities of the … Forum 2014 […].

For the participation in the event, A made comprehensive registration forms available, each of which were divided up for the reservation of exhibition space, symposiums, publications, sponsoring (Internet download of the presentations, Internet café, press conferences) and meeting rooms, and in the header prominently displayed the logos of the convention and of Company A side-by-side. Company A is also listed as the organiser in small type in each footer. These forms were used by numerous companies for registration, partially, however, internal contract documents were also used instead. In a series of cases, these contracts each stated at the beginning the convention as the subject of the contract, only to be subsequently corrected to the forum by Company A. In one part of the correspondence subject to the hearing, the companies even today referred to having supported the convention – but not the forum.

In the contracts, partly also in the accompanying correspondence, there are routine obligations for disclosure of the scope and condition for support.

Both of the convention and for the forum, independent websites were set up, each consisting of numerous page is linked to one another. Visitors to the website of the convention, if able to identify the structure, were able to leave the convention website via the buttons *("program", "… Forum"*) in order to reach the website of the forum. There, the visitor had the opportunity via the "exhibition" button in the lower section of the website linked for this purpose (through "scrolling") to find the downloads for the standard layout, the exhibitor directory and finally the "Disclosure of Sponsoring pursuant to the FSA Code of Conduct"; listed there is information on the sponsoring companies, the amounts and the contracted quid pro quos.

A clear and prominent link allowing the untrained user to quickly have access to disclosure information and to the relevant sources on the websites was missing not only on the website of the convention but also on that of the forum. In total, approx. 70 companies participated in the forum. In doing so, payments of approx. 24 companies were disclosed. The payments to Company A involved amounts ranging from EUR 8,500 up to EUR 201,100, resulting in a total amount of approximate EUR 1.8 million, essentially for the staging of symposiums and for the reservation of exhibition space. The total amount of sponsorship payments of all 70 companies is not apparent.

Complaints in 2014 – Further training events

According to the statement by the society, the industry exhibition of the forum did not serve to finance the convention. Whether the above-mentioned amounts remained totally with Company A or, as part of the contract granted to Company A, entirely or partly flowed back into the society, has not been presented.

Essential grounds for the decision
As the sponsoring companies were able to demonstrate that they had made efforts with Company A to disclose their sponsoring payment during the announcement and at the staging of the event, the Arbitration Panel considered the duty to work towards disclosure pursuant to § 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals as having been fulfilled. The companies were not made responsible for the fact that the depiction on the websites at best allowed access involving a considerable search effort.

Within the scope of § 20 Section 5, the Arbitration Panel evaluates the staging of these types of symposiums, along with the reservation of exhibition booths (see reporting on Ref.: 2013.2-338; 2013.2-339; 2013.5-357), publications or other sponsoring (Internet download of the presentations, Internet café, press conferences, etc.) in the same manner as other support of external further training events. This also applies if these activities are formally outsourced into an accompanying event taking place at the same location (or in immediately adjacent space) and at the same time. The fact that the symposium is offered as part of the scientific convention program, the convention features the content validation of the symposiums in the convention documents, the admission and placement of the symposiums is subject to a decision by the convention president, and finally, that the membership in the convention society may lead to certain advantages in the stand assignment at the forum, supports the impression that within the scope of the overall assessment according to § 20 Section 5 Subsection 3, it involves a unified event, which equally includes the convention and the industry forum. Therefore, the disclosure of support in a prominent and unambiguous form on the website of the convention would have been warranted.

Otherwise, there would have been the overall risk that as a result of separating the sponsoring of a so-called industry showcase within the scope of § 20 Section 5 would not have required disclosure, as there the criterion characteristic of the external further training event could be dubious, and under circumstances the convention as an external further training event would not have fallen within the regulatory scope of § 20 Section 5 Subsection 3, as in that case, industry support requiring disclosure could be questionable.

Outcome
All of these proceedings were dismissed on 21 August 2014.

The case led the Arbitration Panel to the following observations that ought to be taken into consideration in structuring contracts in the future:

According to the more recent legal precedent of the Arbitration Panel of the Second Instance, general regulations in contracts with which the organiser obliges to observe the FSA Code of Conduct do not suffice for the fulfilment of the duty to seek disclosure. Therefore, a contractual provision does not release the pharmaceutical company from its own obligation to make a specific reference to the organiser already in the contract or in a separate letter, specifying exactly what it is to do in order to guarantee the required transparency (see Arbitration Panel of the Second Instance FS II 1/14/2013.2-346, 349, 352).

- This includes clarifications as to where the disclosure is made and how clearly, unambiguously and prominently it is to be featured; the principles developed by legal precedent concerning mandatory information in the Internet (Federal Court of Justice (BGH) from 6 June 2013, NJW (New Weekly Legal Review) 2014, 1012 = Leading Decision (GRUR) 2014, 94) may be applied here.

- If the organiser, as in the case at hand, announces the overall event uniformly and divides it up into a so-called "scientific segment" (here: the Convention) and an industry showcase (here: the Forum), yet announces and stages industry events in the "scientific segment", then efforts should be made there as well – on the documents/the website to the scientific segment – to disclose the support, if necessary, to make a clear and prominent link to the relevant sources on the websites; this also applies especially if the registration materials for the forum turns out to be featured prominently next to the logo of the event organisation of that of the convention.

- For symposiums that industrial firms offer within the scope of external further training events and for which they make payments to the organisers of these further training events, there is the duty to seek disclosure in the same manner as for other financial payments of support. The organiser, as defined by § 20 Section 5 FSA Code of Conduct is in fact the external organiser of the further training event, not the industrial firm that books the organisational setting for staging a symposium with this organiser.

Berlin, in August 2014

Complaints in 2014 – Further training events

Wording of the relevant Code of Conduct Rules

FSA Code of Conduct Healthcare Professionals

§ 20 Invitation to job-related, science-oriented training events

(5) Within appropriate limits, financial support for the organisers of external training events is permissible. However, entertainment programs must neither be supported financially or in the form of donations nor organised. Member companies supporting external training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place.

§ 20 Section 5 P. 3 FSA Code of Conduct Healthcare Professionals – Duty to work towards disclosure of the condition and scope of support
Ref.: 2014.8.-429-431 (1st Instance)

Principles

1. If a further training event is certified by the competent medical association, it will generally be considered as having the character of a further training event as defined by § 20 FSA Code of Conduct Healthcare Professionals.

2. Further training events as defined by § 20 FSA Code of Conduct Healthcare Professionals can also be events focused on academic medical research, to the extent that they have some bearing on the company and its products.

3. If the naming of sponsors is solely limited to featuring a logo used by numerous group subsidiaries simultaneously, it is recommended that efforts be made within the group to not only display the logo but also the full company name of the sponsor, whether it be in the prior text or in a footnote, etc.

Statement of Case

The FSA received notice admonishing the missing information concerning sponsoring remuneration for a convention on the topic of German academic medical research. The convention was certified with six points of category A by the competent medical association.

Therefore, the FSA Management Board initiated complaint proceedings pursuant to § 2 Section 3 of the FSA Code of Procedure.

As part of this statement of case, three member companies of the FSA were heard, whose logos were listed in the official program of the convention thanking them for their sponsorship activity; there was no further identification of the sponsors in the thank you note.

Complaints in 2014 – Further training events

The hearing yielded the following additional facts:

Two of the member companies were able to clarify that the event had not been financially supported by them but by group affiliates over which they had no control as defined by § 1, Section 3 P. 2 Code of Procedure.

The third member company was able to demonstrate that it had contractually obligated the organiser to make a disclosure and had additionally supported the organiser prior to the event with examples of the type of desired disclosure. Nonetheless, the disclosure did not occur, as the organiser in the meantime is of the opinion that events focused on the topics of academic medical research are not considered further training events as defined by the FSA Code of Conduct.

Essential grounds for the decision
To the extent that two member companies were able to demonstrate that the event was not staged by their company, but rather by group affiliates that sell medical products and diagnostics, and the prerequisite of control as defined by § 1 Section 3 P. 2 Code of Procedure was missing in both cases, it was determined that the rules of the FSA Code of Conduct Healthcare are not applicable.

The third member company was able to demonstrate that it had contractually obligated the organiser to make a disclosure and, in addition, had offered support prior to the event with examples as to the type of desired disclosure; as a result, the duty to seek disclosure was sufficiently fulfilled.

Outcome
All of these proceedings were dismissed on 22 September 2014.

The case led the Arbitration Panel to the following observations:

1. Further training events that have been expressly certified by the competent medical association will generally be considered further training events as defined by § 20 FSA Code of Conduct Healthcare Professionals.

2. Independent of this, overly strict criteria should not be applied when evaluating the content of further training events as defined by § 20. As now clarified in the guideline pursuant to § 6 Section 2 in connection with § 20 Section 1 for interpreting further training events, the exclusive or partial dissemination of healthcare policy information bearing relevance to the company and its products may also be the subject of such further training events; this applies to such further training events that focus on academic medical research, to the extent that there is a connection to the company and its products.

3. The naming of sponsors solely reduced to the reproduction of the logo, as is often practiced simultaneously by numerous group subsidiaries, only offers limited clarity on the identity of the sponsor. The Arbitration Panel therefore considers it advisable in comparable cases to reproduce the logo along with the complete name of the sponsor, either in the prior text or in a foot note. Group companies should make best efforts to do this.

Berlin, in September 2014

Complaints in 2014 – Further training events

Wording of the relevant Code of Conduct Rules

FSA Code of Conduct Healthcare Professionals

§ 20 Invitation to job-related, science-oriented training events

(4) The invitation of healthcare professionals to the job-related training events of any third party (external training events) may only include reasonable travel expenses, necessary accommodations (if necessary including hotel breakfast) and participation fees charged by said third party, if the scientific character of these events clearly takes centre stage and if the company has a relevant interest in such a participation. The company may only assume the costs, if the event provides a link to the member company's field of activities as well as a link to the expertise of the event participant. Member companies must not support directly or indirectly any entertainment programs by paying participation fees for healthcare professionals

(5) Within appropriate limits, financial support for the organisers of external training events is permissible. However, entertainment programs must neither be supported financially or in the form of donations nor organised. Member companies supporting external training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place.

§ 20 Section 5, Subsection 3 FSA Code of Conduct Healthcare Professionals – Financial support of job-related, science-oriented training events

§§ 20 Section 4 Subsection 2, 29 Code of Procedure – Prerequisite for an effective declaration of discontinuance and its cancellation
Ref.: 2014.9-434 (1st Instance)

1. The financial support of further training events is only allowed to be approved if the company has previously thoroughly examined the programme and the scope of the event.

2. If the reply company reply to a sponsorship request by the organiser of a further training event is negative, yet the organiser uses the company's logo anyway without permission (e.g. during ongoing negotiations), this is generally not to be attributed to the company.

3. For effective retroactive cancellation of the submission agreement, the repayment of a fine already paid is generally not considered.

Complaints in 2014 – Further training events

Statement of Case
The FSA received notice that a number of member companies and a company that had submitted to the Code of Conduct were sponsoring an event in Munich involving the therapeutic area of urology, the programme of which consisted predominantly of entertainment elements (visit to the Oktoberfest, etc.). In this, the programme of the event, bearing the file name "final" and displaying four pharmaceutical company logos on one page (Version 1), was made available to the FSA.

The complainant was of the view that the entertainment programme was clearly the main focus and the convention venue during the time of the Oktoberfest was to be considered inappropriate. It also refers to the fact that the Oktoberfest was the main attraction of the entertainment programme.

The hearing yielded the following additional facts:

The member companies were able to explain that whilst they had indeed received a request from the organiser for sponsoring, they had said no to it, however; they claimed that the organiser had used their logos independently without their consent.

The submitted company admitted the violation and added that it had only learned of the programme of the event through the hearing summons of the Arbitration Panel. It admitted to the violation and responded to the hearing with the submission of a declaration of discontinuance under penalty of law, which according to the reference of the Arbitration Panel to §§ 20 Section 4 Subsection 2, 29 Code of Procedure was supplemented by the obligation to pay a reduced administrative fee and a fine of EUR 5,000 to a charitable organisation. The FSA accepted the declaration of discontinuance, and the administrative fee and a fine were paid.

Simultaneously, the Arbitration Panel approached the organiser concerning the use of the logo without consent of the companies involved and received an additional version of the programme, also bearing the designation "final", in which however the page with the four company logos was missing (Version 2). The representative of the organiser explained that Version 1 was merely an internal preliminary document, which was not published anywhere, however. From the totality of the information submitted, however, the Arbitration Panel gained the impression that Version 1 had still been used three weeks prior to the beginning of the event to recruit sponsors. Whether Version 1 or Version 2 was actually made available to participating physicians could not be determined, especially because the organiser blocked its website through access restrictions.

Roughly eight weeks after submitting the declaration of discontinuance, the member company, to whose corporate group the submitted company belongs, announced to the FSA it would be ending the submission agreement by submitting the declaration of discontinuance and following its acceptance by the FSA. The important reason justifying the cancellation was said to be that now – contrary to the previous assumption – one had reached the conclusion that no sponsoring had occurred, as the company name had not been mentioned.

Complaints in 2014 – Further training events

This was claimed to be backed up by the statement of an employee of the organiser and the fact that the last programme submitted to the FSA entitled "final" (Version 2) did not mention the companies as sponsors.. Nor was any sponsorship invoice issued or even paid. Subsequently, the submitted company cancelled the submission agreement towards the FSA and moved that the proceedings be dismissed. The repayment of the administrative fee and the fine were expressly waived.

Afterwards, the sponsoring agreement between the companies and the organiser was retroactively rescinded, and the FSA was notified to this effect.

Essential grounds for the decision
To the extent that the member companies were able to demonstrate that they had not provided financial support to the event, the proceedings in November 2014 were to be dismissed.

The submitted company was able to demonstrate that it had rescinded the originally agreed sponsoring agreement and had not rendered any financial support. Which programme versions the organiser presented to the participating physicians could not be determined. Therefore, it was presumed in favour of the company that no sponsoring reference was published by the organiser.

Outcome
All of these proceedings were dismissed in December 2014.

The company had waived the repayment of the fine, so that no decision had to be made on that matter.

The case led the Arbitration Panel to the following observations:

1. The commitment of the company seeking to financially support an event requires that the company has carefully examined the programme and the scope of the event (venue, time, etc.) in advance with regard to § 20 FSA Code of Conduct Healthcare Professionals. For this purpose, it may be necessary to actively request this information from the organiser.

2. If the violation of the FSA Code of Conduct has already been admitted in response to the hearing summons of the Arbitration Panel and a declaration of discontinuance under penalty of law has already been submitted, this is required to contain the obligation to pay an administrative fee and an adequate fine to be set by the Arbitration Panel (§§ 20 Section 4 Subsection 2, 29 Code of Procedure).

3. Facts learned retroactively may justify cancellation of the submission agreement, which is substantiated by the declaration of discontinuance accepted by the FSA. This presupposes the obligation of the company, however, to adequately assist in clearing up the facts substantiating the alleged violation, prior to submission of the declaration of discontinuance.

4. If the submission agreement is effectively cancelled retroactively, a repayment of the fine is not generally considered. The Code of Procedure of the FSA does not provide for any repayment; claims based on contract law or unjust enrichment would not be expected to hold up.

Berlin, in December 2014

Complaints in 2014 – Gifts

Wording of the relevant Code of Conduct Rules

FSA Code of Conduct Healthcare Professionals

§ 21 Gifts

(1) It is categorically forbidden to promise, offer or provide gifts to healthcare professionals. The supplies, regardless of whether it involves product-related or non-product-related promotion.

§ 21 Section 1 (n. v.) FSA Code of Conduct Healthcare Professionals –
Prohibition on the offering and distribution of gifts
Ref.: 2014.7-426 (1st Instance)

Principles

1. At external further training events, it is prohibited to offer and distribute gifts such as pens or lanyards (key chains) to healthcare professionals due to § 21 Section 1 Code of Conduct Healthcare Professionals in the version that came into force since 1 July 2014.

2. The exceptions for "basic notepads and pens of low value" mentioned in guideline 3.9 of the FSA Management Board on § 6 Section 2 in association with § 15 a Section 1 No. 1 does not apply to other articles such as key chains.

3. If the company is unsure about the regulatory content of a prohibition in the FSA Code of Conduct Healthcare Professionals and receives a clarification on this matter from the FSA, a period of six calendar days is totally sufficient to take a clarification into consideration for company activities.

Statement of Case

In the period from 23 to 25 July 2014, the Annual Meeting of the Bavarian Surgeons took place in Bad Kissingen, which was flanked by an ancillary industry exhibition. Takeda Pharma Vertrieb GmbH & Co. KG participated in this industry exhibition, along with numerous other companies.

The FSA received an anonymous complaint, according to which the member company had displayed pens and lanyards (key chains) on this stand, bearing the company logo, as free giveaways.

The Arbitration Panel subsequently heard the company and made reference to 21 Section 1 Code of Conduct Healthcare Professionals in the version in force since 1 July 2014, which forbids offering and distributing these items. The company admitted that it had displayed and partially given away approx. 30 pens and lanyards (key chains) each bearing the company logo at the above-mentioned convention. It raised the question of uncertainty, however, that existed with respect to the in-house interpretation of the guideline 3.9 of the FSA Management Board pursuant to § 6 Section 2 in association with § 15 a Section 1 No. 1.

The company addressed this uncertainty in an inquiry to the FSA dated 11 July and received a reply from the FSA Managing Director, in an email dated 17 July 2014, stating that the exception arising from paragraph 3.9 of the binding guidelines of the FSA Management Board concerning basic notepads and pens of low value, only pertained to "in-house" events organised by the pharmaceutical company itself, yet for "external" third-party events organised by third parties, however, the general prohibition of § 21 Section 1 Code of Conduct Healthcare Professionals did apply.

Essential grounds for the decision
The member company violated § 21 Section 1 Code of Conduct Healthcare Professionals, because it put on display and partly also distributed approx. 30 pens and lanyards (key chains) bearing the company logo at the above-mentioned convention.

The company's stated uncertainty as to the regulatory content of the prohibition does not justify the impermissible nature of distributing such items. Regardless of the fact that the above-mentioned principal only makes exceptions for "basic notepads and pens of little value", yet does not mention key chains, this uncertainty was eliminated. No later than with the clarification by the Managing Director of the FSA in an email dated 17 July 2014. Because the event took place six calendar days later, the time period was totally sufficient to take the clarification into consideration at the stand of the above-mentioned convention and thus forgo offering and distributing these items.

Outcome
Following the warning, the company agreed to cease and desist from offering or providing healthcare professionals gifts such as pens and lanyards (key chains) at external further training events.

In addition, the company was issued a punitive fine of 5,000 Euros, to be paid to a charitable institution. The fine was paid.

Berlin, in September 2014

List of Members

Abbott Arzneimittel GmbH – Freundallee 9 a, 30173 Hannover, Telephone: +49 511 6750-0
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Actelion Pharmaceuticals Deutschland GmbH – Basler Straße 63-65, 79100 Freiburg,
Telephone: +49 761 4564-0
Aegerion Pharmaceuticals GmbH – An der Welle 4, 60322 Frankfurt am Main,
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Almirall Hermal GmbH – Scholtzstraße 3, 21465 Reinbek, Telephone: +49 40 727040
Amgen GmbH – Hanauer Straße 1, 80992 München, Telephone: +49 89 149096-0
Astellas Pharma GmbH – Georg-Brauchle-Ring 64-66, 80992 München, Telephone: +49 89 454406
AstraZeneca GmbH – Tinsdaler Weg 283, 22880 Wedel, Telephone: +49 4103/708-0

Baxter Deutschland GmbH – Edisonstraße 4, 85716 Unterschleißheim, Telephone: +49 89 31701-0
Bayer AG – Bayerwerk, 51368 Leverkusen, Telephone: +49 214 30-1
Bayer Pharma AG – Müllerstraße 178, 13353 Berlin, Telephone: +49 30 4681111
Berlin-Chemie AG – Glienicker Weg 125-127, 12489 Berlin, Telephone: 030 6707-0
bioCSL GmbH – Emil-von-Behring-Straße 76, 35041 Marburg, Telephone: +49 6421 3912
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Mundipharma GmbH – Mundipharma Straße 2, 65549 Limburg, Telephone: +49 6431 701-0

Novartis Pharma GmbH – Roonstraße 25, 90429 Nürnberg, Telephone: +49 911 273-0
Novartis Vaccines and Diagnostics GmbH – Emil-von-Behring-Straße 76, 35041 Marburg, Telephone: +49 6421 3915
Novo Nordisk Pharma GmbH – Brucknerstraße 1, 55127 Mainz, Telephone: +49 6131 903-0

Otsuka Pharma GmbH – Hochhaus am Park, Grüneburgweg 102, 60323 Frankfurt am Main, Telephone: +49 69 170086-0

Pfizer Deutschland GmbH – Linkstraße 10, 10785 Berlin, Telephone: +49 30 550055-01
Pfizer GmbH – Linkstraße 10, 10785 Berlin, Telephone: +49 30 550055-01
Pfizer Manufacturing Deutschland GmbH – Heinrich-Mack-Straße 35, 89257 Illertissen, Telephone: +49 7303 12-0
Pfizer Pharma GmbH – Linkstraße 10, 10785 Berlin, Telephone: +49 30 550055-01
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Vifor Pharma Deutschland GmbH – Baierbrunner Straße 29, 81379 München, Telephone: +49 89 324918600
ViiV Healthcare GmbH – Prinzregentenplatz 9, 81675 München
ViroPharma GmbH – Terminalstraße Mitte 18, 85356 München, Telephone: +49 89 21094816

Directory of Submitted Companies

AstraZeneca Arznei GmbH – Tinsdaler Weg 183, 22880 Wedel
AstraZeneca Distributions GmbH – Tinsdaler Weg 183, 22880 Wedel
AstraZeneca Med GmbH – Tinsdaler Weg 183, 22880 Wedel
AstraZeneca Pharma GmbH – Tinsdaler Weg 183, 22880 Wedel
AstraZeneca Vertriebs GmbH – Tinsdaler Weg 183, 22880 Wedel

Bayer HealthCare AG – Bayer AG Konzernzentrale, 51368 Leverkusen
Bayer Vital GmbH – Bayer AG Konzernzentrale, 51368 Leverkusen

Chibret Pharmazeutische GmbH – Lindenplatz 1, 85540 Haar

Dieckmann Arzneimittel GmbH – Lindenplatz 1, 85540 Haar

Essex Pharma GmbH – Thomas-Dehler-Straße 27, 81737 München
EuMeCom Medizin Information GmbH – Warburgstraße 4, 20354 Hamburg

Glaxo Wellcome GmbH & Co. – Industriestraße 32-36, 20354 Hamburg

Intendis GmbH – Max-Dohrn-Straße 10, 10589 Berlin

Jenapharm GmbH & Co. KG – Otto-Schott-Straße 15, 07745 Jena

MSD Chibropharm – Lindenplatz 1, 85540 Haar
MSD Regional Business Support Center GmbH – Richard-Reitzner-Allee 1, 85540 Haar
Mundipharma Vertriebsgesellschaft mbH & Co. KG – Mundipharma Straße 6, 65549 Limburg

Novartis Pharma Distributions GmbH – Roonstraße 25, 90429 Nürnberg
Novartis Pharma Arzneimittel GmbH – Roonstraße 25, 90429 Nürnberg
Novartis Pharma Marketing GmbH – Roonstraße 25, 90429 Nürnberg
Novartis Pharma Vertriebs GmbH – Roonstraße 25, 90429 Nürnberg

Organon GmbH – Mittenheimer Straße 62, 85764 Oberschleißheim

Sanol GmbH – Alfred-Nobel-Straße 10, 40789 Monheim
SmithKline Beecham Pharma GmbH & Co. KG – Prinzregentenplatz 9, 81675 München
Steigerwald Arzneimittelwerk GmbH – Havelstraße 5, 64213 Darmstadt

Varipharm Arzneimittel GmbH – Lindenplatz 1, 85540 Haar

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