FSA ANNUAL REPORT 2018

We promote ethical behaviour.
The FSA and its work in 2018.

FSA. Konsequent. Transparent.

Contents

Foreword by Peter Solberg

Peter Solberg
Chairman of the Management Board, FSA

Ladies and gentlemen,

In the year 2018, the work of FSA once again made a significant contribution towards fostering trust between the pharmaceutical industry, physicians and patients. Pharmaceutical self-regulation is considered across multiple industries as being a trademark of good cooperation; our Codes of Conduct create legal certainty for the companies in their interaction with healthcare professionals and in the implementation of internal structures. The work of our administrative office, our Arbitration Panel activity and the public disclosure of company names within the scope of the Codes are proof of this high standard.

In addition, for the third time, within the scope of the Transparency Code, FSA has made public the payments of the pharmaceutical industry to physicians and other healthcare professionals. Particularly pleasing to us is the normalisation of the public debate surrounding this disclosure. The "journalism of public shaming" of the early years has given way to nuanced reporting; this is a testimony to FSA's successful public relations work and ought to encourage physicians to opt for individual disclosure of their names within the scope of the Transparency Code.

Through their work, physicians are not only helping patients but also making a contribution towards advances in medicine. They are pioneers, and they can and should stand by this. Because only through consent to individual public disclosure can we – industry and healthcare professionals – collaboratively ensure transparency in our cooperation.

Finally, I would like to take this opportunity to thank Ulrike von Schmeling (Bayer AG), who after 10 years has stepped down from her position as member of the Management Board, for her tremendous commitment to FSA. Her work profoundly shaped the association. On behalf of the entire FSA Management Board, I wish her every success and all the best for the future.

Peter Solberg,
Chairman of the Management Board
Association of Voluntary Self-Regulation for the Pharmaceutical Industry
(Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V.)

Foreword by Holger Diener

Dr. Holger Diener
Managing Director of FSA

Ladies and gentlemen,

The Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA) can look back on an eventful year 2018. In the reporting period, the FSA received 36 complaints, of which 15 were by members, eight came through the Managing Director and 13 through anonymous third parties. All complaints were directed against member companies and were raised for violations of the FSA Code of Conduct Healthcare Professionals. You are receiving an overview of 2018 reporting in this Annual Report.

In the meantime, the FSA Codes of conduct have become established across multiple industries as a recognised trademark of good cooperation between the pharmaceutical industry and healthcare professionals; accordingly, there is high demand for advanced training and seminars. This demonstrates: There continues to be the necessity of providing information on-site in companies, as well as online, concerning the compliance-based interaction between pharmaceutical companies and healthcare professionals, above all physicians, as well as patient organisations. That is why the administrative office itself conducted two workshops in 2018, in addition to participating in some 20 additional events, including the staging of advanced training for members and at medical association functions.

Moreover, among other things, I had the opportunity in my capacity as FSA Managing Director to appear as a speaker on the topic of Compliance at the 30th German Pharmaceutical Law Convention in Frankfurt, as well as at the Global Compliance Congress for Life Sciences in London – proof of the international recognition of the guidelines created by the FSA.

In 2018, the FSA also began to step up the presentation of its work in the (media) public at large. After all, we know: The FSA can only foster trust in the collaboration of pharmaceutical companies and physicians if the association's activity is also noticed and understood.

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 201	10 July 2012	22 May 2014
29 May 2015	30 March 2017	10 January 2018

Start of Prosecution of Complaints
08 April 2004

Entry in the register of associations
29 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	15 November 2016	17 October 2017

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	30 October 2018

FSA Transparency Code

Adoption
27 November 2013

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

Modification of the Transparency Code

04 December 2014	30 October 2018

FSA Recommendations for Collaboration with Healthcare Partners

Adoption
01 December 2010

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

Headquarter
Berlin

Managing Director
Dr. Holger Diener

Chairman of the Management Board
Peter Solberg

Memberships and “Submissions” of affiliated companies

40 founding members (all members of the Association of Research-based Pharmaceutical Companies (vfa))
55 members, 11 companies submitted to the Code of Conduct (2018)

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

(From left to right:) Dr. Sebastian Guntrum, Dr. Kai Richter, Dr. Oliver Blattner, Peter Solberg, Dr. Manuel Steinhilber, Dr. Urte Kristina Wendt, Dr. Hannes Oswald-Brügel, Jörn Johannsen, Prof. Dr. W. Dieter Paar, Dr. Stefan Gehring, not shown: Kathrin Klär-Arlt

Peter Solberg	▸	Janssen-Cilag GmbH Chairman of the Management Board
Dr. Hannes Oswald-Brügel	▸	Roche Pharma AG / Roche Pharma AG Vice Chairman of the Management Board
Dr. Oliver Blattner	▸	Novartis Pharma GmbH
Dr. Stefan Gehring	▸	Bayer AG
Dr. Sebastian Guntrum	▸	Boehringer Ingelheim Pharma GmbH & Co.
Jörn Johannsen	▸	AbbVie Deutschland GmbH & Co. KG
Kathrin Klär-Arlt	▸	Pfizer Deutschland GmbH
Prof. Dr. med. W. Dieter Paar	▸	Sanofi-Aventis Deutschland GmbH
Dr. Kai Richter, MD	▸	AstraZeneca GmbH
Dr. Manuel Steinhilber	▸	Novo Nordisk Pharma GmbH
Dr. Urte Kristina Wendt	▸	Merck KGaA

Review of the Year 2018

"We promote ethical behaviour" – this principle stands for the FSA's goal of strengthening public confidence in the collaboration of pharmaceutical companies with healthcare professionals, patient organisations and other partners in the healthcare system. In establishing clear standards for ethically-sound collaboration of research-based pharmaceutical companies and healthcare professionals, the focus is always on patients; across multiple industries, the FSA Codes of conduct and guidelines are regarded as a recognised trademark of good cooperation.

A key element in this are the public disclosures within the scope of the Transparency Code. In 2018 as well – already the third time in succession – the member companies listed on their websites the full amount of payments made to physicians: To the extent that consent has been provided by physicians, the payments are designated by name. Where this is not legally possible, individual sums are added and listed as a total amount. There are legal reasons for the differentiated public disclosure: The companies are only allowed to list in connection with payments the names of physicians who have consented to such an individualised disclosure.

Declining percentage of consent in focus

According to estimates by FSA and vfa, in the year 2017 some 20 percent of the physicians opted for public disclosure – a declining number compared to the previous year. The fact that there is a declining number of physicians consenting to the individualised presentation of their collaboration with pharmaceutical companies within the scope of the Transparency Code is not the aim of the FSA and its members – quite the contrary. That is why in future public disclosures, the aim of all stakeholders once again ought to be an increase in the number of individual names published. Mentioning the physicians by name creates enhanced transparency and thus strengthens the long-term trust in necessary cooperation. For it is this collaboration in particular between healthcare professionals and the pharmaceutical industry that is met with opposition in the public at large.

The reason: Many people don't know for what services physicians are actually being remunerated. That foments prejudices. After all, being a physician means more than a profession. The public rightly places higher standards on physicians; trust is the basis of the relationship between physicians and patients. Only through

the consent of healthcare professionals to individually disclose names are the published figures truly meaningful.

“Challenges in Implementing the Transparency Code”

Prof. Dr. Hans-Christoph Diener (left)
in a discussion with Dr. Holger Diener, the Managing Director of the FSA

In this sense, this year’s public disclosure of the payments has been increasingly flanked by the FSA on Twitter and YouTube, e.g. with the video debate “Diener and Diener”, a discussion between FSA Managing Director Dr. Holger Diener and Prof. Dr. Hans-Christoph Diener (no relation to the FSA Managing Director), Professor emeritus of the University of Duisburg-Essen Medical School. For years, the well-known neurologist has advocated individual disclosure by physicians, detailing the amount and company from which payments have been received from the pharmaceutical industry. Already at the beginning of public disclosures within the scope of the Transparency Code, he personally had consented to public disclosure of payments received by him from pharmaceutical companies – and was subject to critical media reports as a result. In a discussion, he explains in detail why he nonetheless continues to consent to the public disclosure of his name and why individual participation by the medical profession is so important: “It is important for the public to know what is behind these payments”, says Diener. For example, this includes the participation in studies or comprehensive further training activities, which enable the development or improvement of drugs towards the best possible therapy of patients. “In this, the service provided by the physicians must always be in a reasonable proportion to the remuneration. Thanks to the Transparency Code, everyone can comprehend that these payments are reasonable”, adds Diener.

Increased Objectivity in Reporting

As reporting on the transparency disclosures in the year 2018 demonstrated: the tone of reporting surrounding the public disclosures within the scope of the Transparency Code has changed: away from “media shaming”, moving towards a more objective debate. This demonstrates that the increased public relations work of the FSA on all aspects of the Transparency Code continues to yield further effectiveness and fosters a greater public understanding for the necessary cooperation between research-based pharmaceutical companies and healthcare professionals. By voluntarily creating comprehensive transparency, the companies enable an objective debate on the collaboration between the pharmaceutical industry and physicians on the basis of publicly known facts and figures. Thus, patients and the general public can more clearly understand the services that are necessary for in-depth exchange of knowledge between industry and physicians. This is indispensable for the development of new drugs, optimal pharmaceutical care and thus for the health of everyone.

Philosophy Professor from Princeton as a Guest

Helmut Laschet, Peter Solberg and Prof. Dr. Martin Hartmann
(From left to right:) at the 2018 General Meeting

The year was made complete by the General Meeting of the FSA at the end of October in Berlin. The presentation by a guest lecturer centred on questions of trust building. “Between trust and distrust. What transparency can do – and what it can’t”, was the title of a lecture by Prof. Dr. Martin Hartmann (Lucerne and Princeton) highlighting the current academic debate on the questions of transparency.

In the subsequent panel discussion with Peter Solberg, Chairman of the Management Board, FSA, moderated by journalist Helmut Laschet (Ärzte Zeitung), the expert for practical philosophy made references to legitimate reservations against transparency. “Transparency alone is no protection against the abuse of political and economic power”, said Hartmann. “It can also take a turn for the worse into social control, surveillance and restriction of privacy.” According to Solberg, the FSA Code of Conduct is designed to prevent these negative ramifications of transparency. “The Transparency Code regulates transparency, fosters trust and opens up opportunities for public debate – in the interest of companies and physicians alike.”

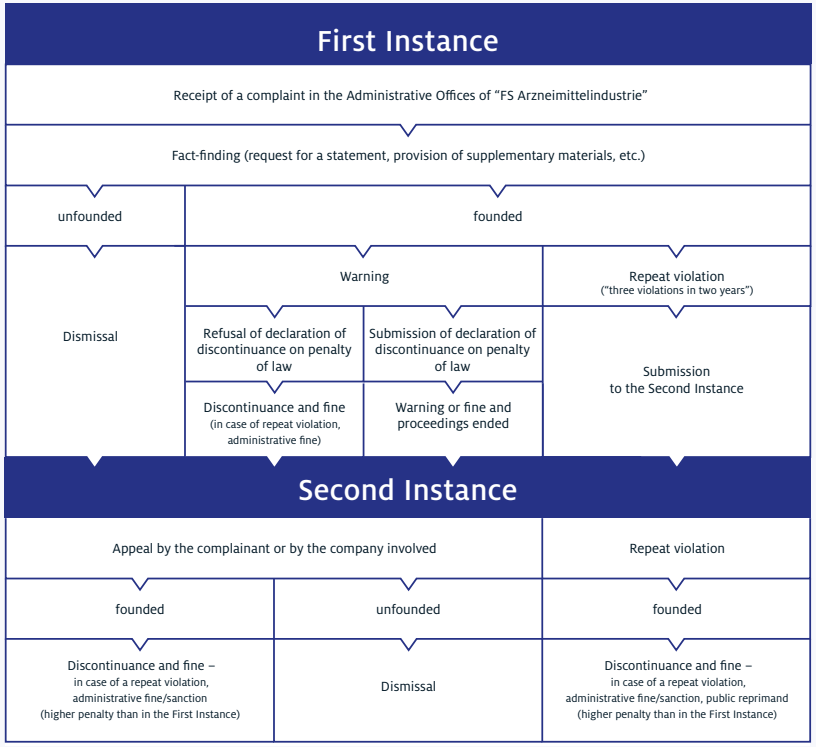
In 2018 as well, FSA’s work has proven the following: For FSA member companies, actively informing patients who are aware of their rights is more than mere lip service; it is put into practice and represents a long-term (personal) commitment. The work of the FSA enables the pharmaceutical industry to create transparency and to provide accountability in their business model – above and beyond what is required by law. To date, 55 member companies have committed to upholding our Codes of conduct; together, they represent roughly 75% of the German market for prescription drugs. It will continue to be the goal of the Management Board and all member companies to further position the FSA as a symbol of ethical behaviour by the pharmaceutical industry.

Do you have praise, suggestions or criticism?

Simply drop us a note:

h.diener@fsa-pharma.de

How Complaints are handled



As the definitive supervisory authority for ethical and transparent behaviour in the pharmaceutical industry, the FSA consistently sanctions violations of the codes. In doing so, as an entity policing unfair competition, it not only takes action against member companies but also against non-members. A complaint can be submitted to the FSA by anyone or any institution, e.g. by patients, physicians, companies, patient self-help organizations, health insurers or public agencies.

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 EUR 5,000 up to a maximum of EUR 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

Membership of the Arbitration Panel of the Second Instance

Chairman

Hermann Brüning

Vice Chairman

Dr. Veit Stoll
- MSD SHARP & DOHME GmbH

Members representing Industry

Katrin Becker
- Astellas Pharma GmbH

Dr. Ingo Beuttenmüller
- Bristol-Myers Squibb GmbH & Co. KGaA

Ina Heitmeier
- GlaxoSmithKline GmbH & Co. KG

Martina Ochel
- Sanofi-Aventis Deutschland GmbH

Thomas Olschewski
- Berlin-Chemie AG

Dr. Veit Stoll
- MSD SHARP & DOHME GmbH

Alternate Members representing Industry

Dr. Carola Dehmlow
- UCB Pharma GmbH

Nicola Fusch
- Lilly Pharma GmbH

Diana Engelhard
- Amgen GmbH

Andreas Lang
- Medigene AG

Susanne Weber-Mangal
- Vifor Pharma Deutschland GmbH

Members representing Physicians

Dr. med. Gottfried von Knoblauch zu Hatzbach
- President (ret.) of the State Medical Association of Hesse

Prof. Dr. med. Joachim Mössner
- Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e. V. – AWMF)

Dr. med. Theodor Windhorst
- President of the Medical Association of Westphalia-Lippe

Alternate Members representing Physicians

Dr. med. Roland Kaiser
- Medical Managing Director (ret.) 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
- Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e. V. – AWMF)

Patientenvertreter

Hannelore Loskill
- German self-help working group for people with disabilities or chronic diseases and their families (BAG SELBSTHILFE) e. V.

Ass. jur. 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.

Stellvertretende Patientenvertreter

Prof. Dr. Joachim Baltes
- German self-help working group for people with disabilities or chronic diseases and their families (BAG SELBSTHILFE) e. V.

Birgit Dembski
- 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.

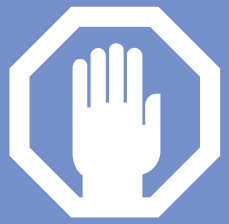
Overview of Arbitration Activity – 2018 Final Report

A) Number of Complaints (since 2004)	Total	2018
Total of complaints	**577**	**36**
submitted by members	225	15
submitted by third parties	303	13
Management Board Resolution	17	0
Management Resolution	32	8
against members	**496**	**36**
against non-members	81	0
number of cases adjudicated	**557**	**29**
against members	475	29
against non-members	82	0
involving Code of Conduct Patient Organisations	1	0
involving Transparency Code	1	0

B) Results of Cases Adjudicated (since 2004)	Total	2018
dismissed on formal grounds	56	1
dismissed on material grounds	302	23
Remedy / Warning	1	0
Warnings / Declarations of discontinuance	153	2
Rulings of the First Instance	19	2
Rulings of the Second Instance	26	1

C) Status of Proceedings for Pending Complaints	2018
Number of open cases	**20**
Number of open cases	0
Hearings	20
Declarations of discontinuance and commitment / Warnings / Rulings	0
Transfer to Second Instance / Civil proceedings	0
pending	0

D) Receipt of Complaints	2017	2018
January	0	0
February	4	0
March	1	2
April	4	1
May	0	0
June	2	2
July	0	7
August	2	2
September	1	2
October	1	2
November	10	4
December	2	14
Total	**27**	**36**



Report Code of Conduct violations:

www.fsa-pharma.de

Complaints in 2018

In the reporting period, the FSA received 36 complaints, of which 15 were by members, eight came through the Managing Director and 13 through anonymous third parties. All complaints were directed against member companies and were raised for violations of the FSA Code of Conduct Healthcare Professionals.

In the forefront of handling were questions concerning the selection of event venues of internal and external events.

On its website, the FSA provides regular information on all decisions of the First and Second Instances concerning violations of the Codes:

www.fsa-pharma.de/schiedsstelle/berichterstattung

In the annual report the general public is informed once annually about all the decisions of the past business year.

§ 22 Section 3 Sentence 3 et seq., § 29 Sentence 2 FSA Code of Procedure

On the calculation of the fine and the procedural fee for the submission of the statement of discontinuance subject to prosecution upon the first hearing

§ 7 FSA Code of Conduct Healthcare Professionals

Ref.: 2017.10-527

Principles

1. **If the company already submits a sufficient statement of discontinuance upon receiving the letter of formal notice by the Arbitration Panel, this can be taken into account in mitigating the fine.**

2. **In such a case, Arbitration Panel of the First Instance may reduce the procedural fee or waive it altogether.**

Facts of the case

The Arbitration Panel received the complaint from an Association of Statutory Health Insurance Physicians, claiming that the member company, Bayer Vital GmbH, was promoting its drug to healthcare professionals with a folder which represented the opportunity for commercial prescription of the drug in a scope that was misleading. The complainant extensively substantiated the allegation of misleading behaviour.

Supplementary to this, the Association of Statutory Health Insurance Physicians pointed out that already in April 2017, an employee of the company had already produced and submitted information material on the same topic, the misleading character of which had been acknowledged by the company at the time and the distribution of which had thus been stopped.

In responding to the letter of formal notice, the company issued a declaration of discontinuance subject to criminal prosecution without further discussion of the case subject to the complaint.

Outcome

The Arbitration Panel considered the complaint as founded, accepted the declaration of discontinuance and obliged Bayer Vital GmbH to pay a fine in the amount of EUR 10,000 to Save the Children Deutschland e. V. (Appeal for donations for Rohingya).

In the company's favour, the level of the fine took into account the fact that the complaint had been recent and was already resolved upon letter of formal notice, so that no further warning was required.

In application of § 29 Sentence 2 Code of Procedure, the FSA waived the procedural fee.

Berlin, December 2017

Wording FSA Rules of Procedure

§ 22 Penalties of the Chamber of First Instance

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

§ 29 Regulatory proceedings

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

Wording FSA Code of Conduct Healthcare Professionals

§ 7 Prohibition of misleading practices

(1) Misleading promotion is inadmissible, irrespective of whether it is misleading by distortion, exaggeration, undue emphasis, omission or in any other way.

§ 22 Section 3 Sentence 3 et seq., § 29 Sentence 2 FSA Code of Procedure

Concerning admissibility of the conference venue for external training events

Ref.: 2017.11-535-538

Principle

Due to the amendment of § 20 Section 5, the principles developed by the Arbitration Panel for the admissibility of internal training events are applied to external training events. The Arbitration Panel sees no reason to redefine this standard on the occasion of the new regulation.

Facts of the case

The Arbitration Panel received an anonymous complaint that five member companies had obliged to support an external training event. The complainant stated that the event was to take place in January 2018 in a conference venue, namely the HYATT Regency Hotel in Cologne, which was not compliant with the Code of Conduct.

The companies stated that they wanted to support the event with amounts of between EUR 1,500 and EUR 10,000. For this, they would be allowed a range of promotional opportunities, including an information stand, depending on the level of support. In their opinion, the event referred to in the subject maintained the framework provided by the Code of Conduct. The conference venue was said to have been selected solely on the basis of objective criteria.

Essential grounds for the decision

In the view of the Arbitration Panel, the selected conference venue also upheld the framework set by the FSA Code of Conduct Healthcare Professionals.

According to § 20 Section 5 as adopted on 1 January 2018, financial support for external training events is generally permissible; at the time of the decision, the version adopted by the General Assembly in autumn of 2016 was in force. The further amendment to the Code of Conduct adopted in the following year, in October 2017, had not yet entered into force due to pending approval by the Federal Cartel Office.

Accordingly, (among other things) the requirements of § 20 Section 3 applied to the selection of the conference venue; in particular, the selection of the conference venue had to be based solely on the basis of objective criteria. Companies should avoid conference venues that are known for their entertainment value or are considered extravagant.

Consistent with its rulings, the Arbitration Panel considers it possible in principle to hold an internal training event in a so-called "luxury hotel" if the program agenda of the training event does not convey a considerable incentive or the opportunity to take advantage of leisure activities or, for instance, the existing luxury features of the hotel (cf. proceedings on Ref. 2015.11-493 with further evidence). It repeatedly stated that such establishments can also be considered as event venues.

This framework is applied to external training events as a result of the amendment to the Code of Conduct that came into force on 1 January 2018. The Arbitration Panel saw no reason to redefine this standard on the occasion of the new regulation.

The event that was the subject of the complaint was intended to start out after registration with the welcoming remarks at 9:00 a.m., followed by four lectures ranging from 15 to 25 minutes, and after a break, three additional lectures of the same scope were to follow. After the lunch break, four additional lectures of 25 to 45 minutes were scheduled; this was to be followed by an outlook on the year 2019 and – until 4:00 p.m. – the farewell to the participants. This program was intended to be offered over a period of 7 hours, interrupted by a coffee break of 25 minutes and a lunch break of 60 minutes.

There were no indications that the program sequence did not meet the requirements prescribed by legal precedents for a tightly-scheduled, closely-sequenced program format, either from the complaint or from the other miscellaneous information submitted to the Arbitration Panel. The Arbitration Panel also saw no evidence that would suggest any significant incentive or possibility of using leisure activities or the hotel's existing luxury facilities. Therefore, whether the hotel that presents itself as a "luxury hotel", should actually be regarded as such, or as a "typical conference and business hotel", was left unresolved.

That the attractiveness of the hotel would have been so great that the participants would have been inclined to use the existing hotel facilities and to neglect participation in the event (cf. proceedings on Ref. 2007.11-211) was neither presented nor apparent.

The complaint was therefore unfounded. The proceedings were dismissed.

Berlin, January 2018

§ 20 Section 5 in connection with Section 3 FSA Code of Conduct Healthcare Professionals

Concerning the admissibility of a conference venue as a historically preserved monument for external training events

Ref.: 2017.11-530-532

Principles

1. **Due to the amendment of § 20 Section 5, the principles developed by the Arbitration Panel for the admissibility of internal training events are applied to external training events. The Arbitration Panel sees no reason to redefine this standard on the occasion of the new regulation.**

2. **Depending on the individual case, the principles may also be applied to conference venues housed in buildings preserved as historical monuments.**

Facts of the case

The Arbitration Panel received an anonymous complaint that three member companies had obliged to support an external training event. The complainant stated that the event was to take place in June 2018 in a conference venue, namely the Royal Spa House in Bad Reichenhall, which was not compliant with the Code of Conduct.

Two companies argued that they had not yet concluded a sponsorship agreement with the organiser of the event and that they had only received a request. The third company presented the agreement on which the sponsorship was based, in which the company obliged to support the event with a sum of EUR 9,100. For this purpose, the company afforded a number of promotional opportunities, including an information stand at an industry exhibition. The member company held the view that the event was within the scope of the Code of Conduct. The conference venue was said to have been selected solely on the basis of objective criteria.

The Royal Spa House in Bad Reichenhall has been used for this event since the 1960s.

Essential grounds for the decision

A breach of the Code of Conduct was ruled out in any case against the two companies that had not yet made a sponsorship commitment for the event; these proceedings were therefore to be discontinued for this reason alone.

As a result, it was decided that the company that had already made a sponsoring commitment had not violated the Code of Conduct either.

In the view of the Arbitration Panel, the selected conference venue also upholds the framework set by the FSA Code of Conduct Healthcare Professionals.

According to § 20 Section 5 FSA Code of Conduct as adopted by the FSA General Assembly on 17 October 2017 and approved by the Federal Cartel Office on 9 January 2018, financial support for external training events is generally permissible. The requirements for internal training events apply accordingly to the selection of the conference venue. Therefore, the choice of conference venue must be made solely on the basis of objective criteria. On the other hand, companies should avoid conference venues that are known for their entertainment value or are considered extravagant; additional explanations on this topic are found in Guidelines 11.2 and 12.2.

The conference venue in this case is a historically preserved building that was built in at around the turn of the 20th Century for spa operations, but since being taken over by the local spa guest centre in 1988, it has been used as a convention centre. The website indicates that the building – commensurate with the architectural era – is equipped in a very representative way: It features a grand, decorated staircase, a large hall with gallery, ceiling and wall elements decorated with stucco, elaborate stone and wooden floors, crystal chandeliers, large sashed windows decorated with draperies, etc. Compared to today's conference venues, this decor can give a certain special event quality to those who are receptive to historical buildings; conference guests, on the other hand, who are seeking a functional, modern setting, may instead consider it as no longer up-to-date. The pricing for the use of the conference rooms is aligned with the normal framework.

Consistent with its rulings, the Arbitration Panel considers it possible in principle to hold internal training events in so-called "luxury hotels" if the program agenda of the training event does not convey a considerable incentive or the opportunity to take advantage of leisure activities or, for instance, the existing luxury features of the hotel (cf. proceedings on Ref. 2015.11-493 with further evidence, 2017.11-535-538). This also applies to older, frequently historically preserved event venues, which due to their construction period and their history of use, conform to earlier building and furnishing styles, and tend to represent the exception in this form today (cf. Ref. 2009.3-255).

This framework is applied to external training events as a result of the amendment to the Code of Conduct that came into force in January 2018. The Arbitration Panel saw no reason to redefine this standard on the occasion of the new regulation.

The event, which is the subject of the complaint, is intended to start out the first day with the welcoming remarks at 9:00 a.m., followed by 12 lectures on topics predominantly from the field of pulmonology, each lasting 20 to 30 minutes, and a so-called "case conference". In total, roughly 2 hours are planned for breaks. At 6:45 p.m., a so-called "Come Together" is planned. The 2nd day is structured in a similar way and is scheduled to end at 5:15 p.m.

There were no indications that the program sequence did not meet the requirements prescribed by ruling precedence for a tightly-scheduled, closely-sequenced program format, either from the complaint or from the preliminary program submitted to the Arbitration Panel. The Arbitration Panel also saw no evidence that would suggest any significant incentive or opportunity to take advantage of leisure activities that Bad Reichenhall may have to offer.

The notion that the attractiveness of the spa location was so great so as to entice the participants to use the existing spa facilities and, in doing so, neglect participation in the event (cf. proceedings on Ref. 2007.11-211), was neither presented as an argument nor apparent.

The complaint was therefore unfounded. The proceedings were dismissed.

Berlin, January 2018

Wording FSA Code of Conduct Healthcare Professionals

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

(3) Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue as well as the invitation of healthcare professionals must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason. Further, the companies are to avoid conference locations which are known for their entertainment value or are considered extravagant.

(5) Within appropriate limits, financial support for the organisers of external further training events is permissible. Member companies supporting external further training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place. Moreover, when providing financial support to external further training events, for the selection of the conference venue and for hospitality, the provisions concerning internal further training events shall apply mutatis mutandis. The presence of the participants, as well as the agenda of the event is not to be documented.

§ 21 Section 1 FSA Code of Conduct Healthcare Professionals

Promotional materials towards patients that also provide the physician with an important secondary benefit

Ref.: FS II 1/17/2016.22-508

Principles

1. The prohibition of § 21 Section 1 FSA Code goes further than the statutory prohibition because it includes advertising that is not product-related and because with respect to exceptions, it does not mention § 7 Section 1 No. 1 Advertising in the Health Care System Act (HWG), but only § 7 Section 1 No. 2 – 5 Advertising in the Health Care System Act (HWG).

2. The principles which were developed from the Federal Court of Justice into § 7 Section 1 Advertising in the Health Care System Act (HWG), in particular in the decision "Das große Rätselheft"/The Big Puzzler Booklet (GRUR 2012, 1279), must be observed to the extent that these principles also apply to the regulation in § 21 FSA Code. "Payments in kind or promotional gifts" within the meaning of § 7 Section 1 Advertising in the Health Care System Act (HWG) are also "gifts" within the meaning of § 21 Section 1 FSA Code.

3. The term "gift", like the term "promotional gift", must be interpreted broadly and includes any benefit granted free of charge.

4. Promotional materials in which the focus is indeed on promotion aimed towards the patient, but which provide the physician with an important secondary benefit, should also be regarded as a gift to the physician. Such an advertising measure can easily foster or promote customer loyalty between the physician and the patient. Accordingly, the physician has an own promotional benefit.

5. Questions of ownership or the "power of disposal" of the promotional gift are not decisive.

6. Whether the promotional gift could individually unduly influence the decision of the physicians in prescribing the drug is irrelevant in the context of § 21 Section 1 FSA Code.

Facts of the case

The FSA received an anonymous complaint alleging that the member company, Boehringer Ingelheim Pharma GmbH & Co KG (hereinafter referred to as: the company) had supplied a pedometer in breach of the FSA Code of Conduct Healthcare Professionals (hereinafter referred to as: the FSA Code).

Among other products, the company manufactures drugs for the treatment of the respiratory illness, COPD. As part of the introduction of a new COPD drug, the company handed out a so-called "COPD Active Box" to physicians for distribution to patients. The text on the cover of the box was addressed to the patient. Inside, the box contained a letter to the patient, an information sheet on COPD therapy with the specific inhalation device, four "Don't forget" stickers, 15 pages of brochures on the disease and the inhalation device, and a basic pedometer, separately packed in a folding box bearing the company logo. In the box there was a field on which the physician could apply his practice stamp, beneath the notice "Presented by". There was a relevant notice on page 2 of the brochure on the inhalation device.

In an internal training document, "Discussion on the COPD Active Box" dated 13 October 2015, it is stated, among other things, that in the physician consultation, reference should be made to the "personalisation option" in connection with the stamp field where necessary.

In August 2015, 75,000 copies of the "COPD Active Box" had been produced (unit price EUR 4.87). The box was provided to physicians for distribution to patients between September 2015 and approx. June 2016, thereafter only upon specific request, before the distribution was stopped due to the proceedings. At that time, the remaining stock amounted to approximately 27,000 units.

The company claimed this did not constitute a violation of § 21 Section 1 FSA Code. The COPD Active Box was said to be intended exclusively for COPD patients, as was apparent from its appearance. It was supposed to motivate patients to engage in more activity and sports despite their illness and to promote compliance.

Therefore, the Active Box with the pedometer was not said to be a promotional gift for the physician.

Due to the absence of a direct reference to the disease, COPD, the pedometer was also said not to be a prop used for training or demonstration to healthcare professionals according to § 15 a FSA Code but rather as information material solely for the patient.

The pedometer was said to be an item of trifling value for the patient. It is claimed to be only suitable as a kick-start for the initial steps, but not suitable for long-term use. Its purchase price was EUR 0.89.

Comparable pedometers were said to be available from Amazon from EUR 0.69.

In a letter dated February 21, 2017, the Arbitration Panel of the First Instance unsuccessfully warned the company for a violation of § 21 Section 1 FSA Code.

The company further argued that the distribution of the pedometer to physicians to be given out to patients does not violate § 21 Section 1 FSA Code; it was said to not be a gift to healthcare professionals. This was said to be aligned with case law on § 7 Advertising in the Health Care System Act (HWG). It said the "COPD Active Box" was clearly identified as gift item of the company. The physician was said to receive no material benefit. In passing it on, the physician was said to be merely a messenger between the company and the patient. Only the patient – not the physician at the same time – receives a gift intended for him without the physician receiving a secondary benefit, such as an indirect advantage in the form of his own advertising effect toward the patient, not even because of his stamp inside the box.

In its decision of 17 May 2017, the Arbitration Panel of the First Instance found a violation of § 21 Section 1 FSA Code of Conduct Healthcare Professionals and obliged the company to refrain in the future from offering or providing free pedometers to healthcare professionals directed to patients, be it within the scope of a so-called patient box or individually; in addition, the Arbitration Panel of the First Instance imposed a fine of EUR 24,000.

The company had appealed this decision within the deadline. It reiterated its arguments presented in the First Instance, in particular, concerning the absence of a direct economic benefit of the healthcare professionals.

Essential grounds for the decision

In according with the prohibition by the First Instance arising from § 21 Section 1 FSA Code, the subject of proceedings in the Second Instance was solely the distribution of the pedometer to healthcare professionals, but not the additional content of the Active Box as an independent subject of the dispute, which, however, was of significance for the interpretation within the scope of the subject of the "pedometer" dispute. The subject of the Second Instance proceedings was also not the distribution of the pedometer by the company – via the physician – to patients, which was not covered by § 21 Section 1 of the FSA Code.

The company's appeal was essentially unfounded. The Arbitration Panel of the Second Instance was also of the opinion that the company had violated § 21 Section 1 FSA Code.

According to § 21 Section 1 FSA Code, it is inadmissible in principle offer or grant gifts to healthcare professionals, independently of whether, as in this case, it involves product-related or non-product-related promotion.

The precondition for a prohibition was that the pedometer was to be regarded as a gift from the company to healthcare professionals. Therefore, it was not necessary to decide whether the pedometer – handed over by the physician – as a gift from the company to the patient violated § 7 Advertising in the Health Care System Act (HWG), which, as the Arbitration Panel of the Second Instance found, was indeed worth considering.

In the interpretation § 21 Section 1 FSA Code, the principles are to be observed which were developed concerning § 7 Section 1 Advertising in the Health Care System Act (HWG), in particular in the decision by the Federal Court of Justice in GRUR 2012, 1279, "Das große Rätselheft"/The Big Puzzler Booklet, to the extent that these principles also apply to the regulation in § 21 FSA Code. "Payments in kind or promotional gifts" within the meaning of § 7 Section 1 Advertising in the Health Care System Act (HWG) are also "gifts" within the meaning of § 21 Section 1 FSA Code. The term "gift", like the term "promotional gift", must be interpreted broadly and includes any benefit granted free of charge (see Federal Court of Justice (BGH) loc. cit. p. 1281).

The prohibition in § 7 Section 1 Advertising in the Health Care System Act (HWG), as well as the prohibition in § 21 Section 1 FSA Code, is intended to counter the abstract risk of an undue influence of the advertising target groups, in the present context, physicians. Such a danger does not exist if they do not regard the donation as a promotional gift (also) intended for them (see Federal Court of Justice (BGH) loc. cit.). Gifts within the meaning of § 21 Section 1 FSA Code and promotional gifts within the meaning of § 7 Section 1 Advertising in the Health Care System Act (HWG) must be distinguished from free promotional materials in which the focus is on promotion to patients and which, from the recipient's point of view, primarily serve the pharmaceutical company's own interests. But if they provide the physician an important secondary benefit that goes beyond promotion to the patient, the physician is also receiving a gift (see Federal Court of Justice (BGH) loc. cit.).

However, the active boxes with the pedometer were not a promotional gift intended for physicians (a). However, it not only served the promotion of the drug towards patients, but also offered physicians an extended secondary benefit (b). Therefore, there was a violation of § 21 Section 1 FSA Code without any additional condition being fulfilled (c). The Arbitration Panel of the Second Instance weighed in on this:

a) Physicians do not consider the Active Box with the pedometer as a promotional gift intended for them.

   The physicians receive the "COPD Active Box" including the pedometer subject to the complaint solely to hand it out to the patient, not for their own immediate use. The box is not intended to remain in their possession, but rather reach the patient.

   According to the entire appearance of the "COPD Active Box", it is clear for all those involved – physicians and patients – that only patients are were the target group. The pedometer is embedded in an advertising environment that leaves no doubt as to the fact that the entire Active Box and thus also the pedometer is intended for use by the patient alone, but not (also) by the physician. The value of the technically basic, cheap pedometer is thus not high enough that the physician would like to keep copies of the Active Box for himself and/or for his employees because of the pedometer and for this reason considers it a gift from the company to him personally. The Arbitration Panel of the Second Instance stated that the situation can be different with higher-value items.

b) According to the view of the Arbitration Panel, the company, however, granted the physicians an important secondary benefit that goes beyond the initial benefit (promotion of the company to the patients).

   Without incurring any costs themselves, the physicians who handed out the Active Box, including the pedometer, to patients appeared to them as gift-givers and, from their point of view, alongside the company. This afforded the physicians a considerable promotional advantage.

   The pedometer is indeed embedded in an advertising environment that was able to leave no doubt as to the fact that the entire Active Box and thus also the pedometer were intended for use by the patient alone. From the patients' point of view, however, it is not only the company but also the physician who appears as the gift giver to these patients. In any case, this follows from the relatively elaborate design of the Active Box, which also contains the pedometer. This gave the patient who received the box from the physician the obvious impression that it was also a gift from the physician

to him. This circumstance can easily foster or promote customer loyalty between the physician and the patient. Accordingly, the physician had an own promotional benefit.

The above-mentioned decision of the Federal Court of Justice had no impact on the facts of the case. Although the pharmacy had been clearly highlighted on the outside of the puzzle booklet, especially on the front with the reference "exclusively from your pharmacy"; furthermore, the inside of the booklet contained a multitude of puzzles to which only insignificant pharmaceutical advertising was added. Based on all the circumstances, the lower instance, with the approval of the Federal Court of Justice, felt compelled to assume that the pharmacist could present the puzzle booklet as his promotional gift without having to incur any own costs (loc. cit. p. 1281 et seq.). There was no comparable emphasis on the physician in the case of the 'COPD Active Box', which essentially contained – apart from the pedometer – objective information on the disease and the drug. However, in this case, the elaborate presentation of the box likewise led to the assumption that the physicians can act as gift givers towards the patients; thus, the physicians gained a secondary benefit.

Questions of ownership or the "power of disposal" of the Active Box, including the pedometer, referred to by the Arbitration Panel of the First Instance, was not decisive in the view of the Arbitration Panel of the Second Instance. Neither had any bearing on whether the physician, in handing out the item to his patients, had a secondary benefit or not. The sole factor for this was the promotional effect. The Federal Supreme Court (loc. cit.) had also not based its decision on the ownership of the puzzle books or on the "power of disposal" over them.

c) Therefore, there was a violation of § 21 Section 1 FSA Code without any additional condition being fulfilled (aa). Nor did any of the exceptions specified in § 21 Section 2 FSA Code apply (bb).

aa) According to the case law of the Federal Court of Justice (loc. cit. p. 1282), while the secondary benefit within the scope of § 7 Section 1 Advertising in the Health Care System Act (HWG) would have to be capable of unduly influencing the decision of physicians in their prescription of the drug based on economic interests. Yet the physician's individual susceptibility to influence does not matter in the context of § 21 Section 1 FSA Code.

The provision in § 21 Section 1 FSA Code is intentionally stricter than that in Section 7 Advertising in the Health Care System Act (HWG). The rule seeks to prohibit any gift unless it is subject to an exception under § 21 Section 2 FSA Code.

The prohibition of § 21 Section 1 FSA Code goes further than the statutory prohibition because it includes advertising that is not product-related and because with respect to exceptions, it does not mention § 7 Section 1 No. 1 Advertising in the Health Care System Act (HWG), but only § 7 Section 1 No. 2 – 5 Advertising in the Health Care System Act (HWG). It is precisely the prohibition of gifts which are to be regarded as inexpensive small items that demonstrates the fact that the FSA Code involves a comprehensive prohibition of gifts in this respect. This clear provision would be watered down again if it was required to examine in each individual case whether the above-mentioned suitability is present or not in the case of gifts, which would tend to be rejected except for inexpensive small items, contrary to the intended non-inclusion of § 7 Section 1 No. 1 Advertising in the Health Care System Act (HWG) in § 21 Section 2 FSA Code and accordingly would in fact lead to an unintended exception.

bb) In the present case, no exception to the prohibition of § 21 Section 1 FSA Code followed from § 21 Section 2 FSA Code.

§ 15 a FSA Code is not applicable to the pedometer from the outset.

Exceptions according to § 7 Section 1 No. 2 – 5 Advertising in the Health Care System Act (HWG) were not considered for the pedometer, as the Arbitration Panel of the First Instance had already correctly assumed.

Accordingly, the entire Active Box with the pedometer and because of the pedometer was to be considered a prohibited gift within the meaning of § 21 Section 1 FSA Code.

The decision of the First Instance was therefore upheld. The Arbitration Panel of the Second Instance thus adapted the prohibition to the concrete breach merely for clarification purposes. This includes the entire Active Box, including the forbidden pedometer. For the prohibition of the pedometer, this promotional environment is of importance.

By contrast, in the view of the Arbitration Panel of the Second Instance, the pronounced prohibition goes too far in this regard and is therefore not justified, to the extent that it also prohibits the handout of the pedometer individually. This constitutes an inadmissible generalisation which goes above and beyond the concrete form of breach, as it does not take into account the promotional environment on which the legal assessment depends. Irrespective of this, there is no risk of first-time violation for individual distribution of the pedometer by the company. Accordingly, the decision of the First Instance had to be overturned in this regard and the appeals proceedings dismissed.

Outcome

The company was therefore obliged in the future to refrain from offering or distributing free pedometers to healthcare professionals, aimed towards patients, as was done within the framework of the so-called "COPD Active Box".

In addition, the company paid a fine of EUR 24,000 to the Campaign against Hunger, Berlin, for the "Pledge Drive 'Help for Yemen'".

Berlin, December 2017

Wording FSA Code of Conduct Healthcare Professionals

§ 21 Gifts

(1) It is prohibited to promise, offer or grant gifts to healthcare professionals. This applies irrespective to product-related or non-product-related advertising.

§ 20 Sections 4 and 5 FSA Code of Conduct Healthcare Professionals

Extensive support of an external training event; exclusive promotional opportunities for the sponsor

Ref.: 2017.11-529

Principles

1. **If the form and content of an external training event is specified by a commercial organiser and the financing is secured to a large extent by participant fees, then normally it cannot be assumed that it involves a disguised own event of a company if it supports the event financially with a large sum of money.**

2. **If the organiser grants a sponsor exclusive promotional opportunities at an external training event, this does not contradict the Code of Conduct Healthcare Professionals as amended, not even if it excludes other market participants from a comparable presence at the event.**

1. Facts of the case

The FSA received an anonymous complaint alleging that a member company was promoting a training event of a commercial service provider in the field of rheumatism symptoms as a "premium sponsor". The complainant stated that this was in fact an event organised by the company, which was merely disguised as sponsoring; the organiser had been provided with the sum of EUR 240,000. The complainant considered this a violation of the Code of Conduct.

In the course of the hearing, the Board also resolved to take up an additional complaint, the admissibility of the conference venue, the Spa House in Wiesbaden.

The company stated that it had sponsored the event since 2006. The nature, content and conference venue of the event were said to be essentially unchanged; this also applied to the scientific directors and lecturers. That amount was said to be correct. The support was said to refer to the evening symposium on Thursday evening and the lecture event on the following two days.

In return, the company received a number of quid pro quo's, including two information stands of 12 square metres each, 30 free tickets for its employees, numerous mentions as sponsors, both prior to and after the event (e.g. in newsletters), participation in the evening working meal with the lecturers and in the follow-up discussion on the development of next year's program, etc. Apart from the company, no other pharmaceutical manufacturer was active as an industry sponsor; only the member company was entitled to maintain exhibit stands.

According to the company, the program organisation, selection of lecturers and format of lectures were not influenced; this was said to be exclusively a matter for the organiser and the scientific management. The company said it did not invite any physicians to the event, not even to catering after the event; the evening format, as well as travel and accommodation in Wiesbaden, were said to be the sole responsibility of the participants. They also had to pay a registration fee of between EUR 350 and EUR 640 to the organiser for the event. In return, the participants were provided with very comprehensive documentation (approx. 600 pages) complying with research requirements and access to the lecture slides.

The event was said to be well established among rheumatologists for many years, recognised for its high level of professional expertise and well attended; last year, more than 750 participants, i.e. approx. 75% of all rheumatologists working in Germany, were said to have attended the event.

Concerning the conference venue, the company stated that was compliant with the Code of Conduct; it was also in line with the event's tradition of many years. Moreover, in the current year, no comparable conference venue had been available at that location.

The Arbitration Panel obtained supplementary information on training events in the aforementioned indication area. It was noteworthy that the event is universally well known and held in high regard. The scientific quality of the lectures was underscored, as were the competent and meticulous presentation of the topics. The members of the public approached by the Arbitration Panel also assume that the participants attend the event throughout the run of the event and not only selectively.

Among the quid pro quo's offered by the sponsors, the decisive benefit was the option of the information stand, which, due to its size and exclusivity, offers ideal conditions for contact with the practitioners: In daily practice, the participants had only little spare time, could rarely be reached and then only for a short time. On the other hand, information stands at training events and conventions have the great

advantage that they create space for technical discussions outside of daily hectic, whether on individual therapies, new research topics, the preparation of clinical studies, the planning of local training events, etc. This is a great advantage for a company, especially if, as a result of the exclusivity granted, it has the undivided attention of the participants in the breaks.

2. Essential grounds for the decision

In consideration of the merits of the case, the Arbitration Panel assumes that the technical and scientific part of the event is not in doubt.

The Arbitration Panel further assumes that among the sponsor advantages granted to the company, above all the exclusive presence with two large stands, is particularly relevant, supplemented by 30 free tickets, which provide the company's employees not only with the opportunity for professional further training, but also for direct contact with the participants in the auditorium. All in all, this gives the company access to a large number of practitioners working in rheumatology in a scope and in an environment that is ideal for fostering, strengthening and utilising contacts to prescribing physicians (cf. also the procedures for Ref. 2013.9-360/362 on the key word "access model").

2. a. Disguising an own event through exclusive sponsoring

§ 20 Section 4 et seq. Code of Conduct regulates the admissibility of third party training events, § 20 Section 1 et seq. the company's own training events. The Code of Conduct makes only an indirect distinction between the two events. From the terms "own" or "third party" it becomes clear, however, that an essential criterion for the distinction is who is acting as the organiser. It follows from the characteristic element of "support" that the company is fully responsible for its own event from a business point of view, whereas the third party training event is the responsibility of the third party and is supported by the company only to a greater or lesser extent; the remainder of the financing is the responsibility of the third party. In the case of own events, the rules of § 18 FSA Code of Conduct Healthcare Professionals must also be observed, whereas in the case of third-party events, this can at best be demanded by means of a contractual obligation on the part of the organiser in the sponsoring agreement; the organiser is not directly subject to the Code of Conduct.

In the present case, it was argued that the nature and content of the event were determined solely by the organiser. It was also apparent that the overall revenues of the organiser comprised approximately 50% each from sponsoring by the company and from the participant fees. There was no substantiated argument presented by

the complainant concerning the alleged "disguising" of an own event. The rough figures concerning the calculation of the event, which the organiser made available to the Arbitration Panel, confirmed that the event could only be partially financed by the support of the company; the organiser required additional revenues in a six-figure amount in order to ensure a balanced budget. Moreover, there were no indications that the framework conditions for collaboration with the scientific directors and the lecturers disregard the limits of § 18 Code of Conduct.

That is why in its overall assessment of the facts, the Arbitration Panel concluded that the event was to be considered as being organised by third parties within the meaning of § 20 Section 4 et seq. Code of Conduct. This assessment is supported in particular by the fact that the Arbitration Panel was unable to identify any indications that the company sought to influence the nature and content of the event. The essential advantage of the extensive sponsoring for the company is the undisturbed contact with a large number of all rheumatologists working in Germany.

That is why – in contrast to comparable events – the event provides not only for one but two exhibition stands, which in turn do not have the often customary 4–6 square metres of stand space, but rather 12 square metres each.

The existence of this contact opportunity, however, depends largely on the attractiveness of the event. Physicians will only attend the event in this number if the training provided is regarded as particularly valuable and there is no character of a company event. Therefore, it can only be in the company's interest to refrain from exerting influence that could cast doubt on the value of the event in terms of how it is viewed from the outside. This includes the fact that the company exerts no influence on the nature and content of the event.

This assessment is not contradicted by the fact that the company is allowed an insight into the formulation of the program, that is allowed to be present at discussions on the evening prior to the event and in follow-up discussions – at least this would seem consistent with life experience – and provide suggestions, because the determination of form and content of the event lies outside the sphere of the company.

However, this does not represent a significant disadvantage to the company. According to the lecturers' own account, 14 out of the 15 speakers (one of whom only at the symposium) declare a "conflict" (among other things) with the company. These "conflicts" are usually due to an earlier or still ongoing contractual cooperation between the respective speaker and the sponsor, who has been active in the field of rheumatology for many years. The Arbitration Panel considers it customary

for these speakers to be familiar with the company's positions and to take them into account – already with respect to their (possible) future cooperation with the company.

Therefore, these "conflicts" cannot be interpreted as evidence of influence, but rather they allow the assumption that the majority of speakers would appear to hold positions that are not detrimental to the sponsor.

In light of all these facts, the Arbitration Panel sees no evidence of a disguised own company event.

2. b. On the permissibility of exclusive sponsoring

The permissibility of exclusive sponsoring is not explicitly addressed in the Code of Conduct. According to § 20 Section 5 Sentence 2 Code of Conduct Healthcare Professionals, it is only necessary to ensure that the existence of support is disclosed, whereby the scope in the case of commercial organisers – unlike organisations within the meaning of § 2 Section 2 Transparency Code – remains non-transparent. (This does not apply here, as the amount of the support was disclosed by the organiser and was thus recognisable for each participant.)

As far as the Arbitration Panel could determine, exclusive sponsoring is evaluated differently in companies' normal practice. Due to their internal compliance regulations, some companies completely exclude the activity of exclusive sponsorship, others restrict it, others do not comment on it at all.

The Code of Conduct greatly advocates that the information made available to healthcare professionals must be accurate and objective, and that physicians are not allowed to be unduly influenced in their therapy decisions; this is spelled out within the framework of parts 3 and 4 of the Code of Conduct, but this does not include rules on exclusive sponsoring.

Nevertheless, it is normal to ask the question to what extent a training event which grants sponsor access to only one company can fully meet the standard of objective and neutral information from which the Code of Conduct originate and which healthcare professionals rightly expect. At least during the breaks, the participants do not have access to a variety of viewpoints in the form that would be guaranteed by various companies from the industry represented at stands.

Finally: In its introduction, the Code of Conduct also points out that fair competition should not be restricted and that unfair practices should be avoided. Whether the practice of exclusive sponsoring can be reconciled with this must remain unresolved in view of the facts in this case and the lack of corresponding regulations in the Code of Conduct.

Nevertheless, it stands to reason that exclusivity inevitably means that other market participants are excluded from a comparable presence at the event and could perceive this as a competitive disadvantage, which is objectively only conditionally compatible with the spirit of the Code of Conduct (see also Ref. 2013.9-360/362, Note 2).

Overall, however, in the present case and in the current status of the Code of Conduct, the issue of a violation by agreeing to exclusivity for sponsoring is not considered.

2. c. On the appropriateness of sponsoring

The Arbitration Panel has repeatedly stated that the amount of sponsorship is part of the adequacy review as defined by § 20 Section 5 Sentence 1 Code of Conduct.

According to the information made available by the organiser to the Arbitration Panel, it is to be assumed that the income generated is essentially used for the necessary and typical expenses associated with the event. The profit remaining for the organiser is within a similar framework as was determined and not challenged by the Arbitration Panel in earlier, and thus comparable proceedings (cf. Ref. 2013.9-360-362, 2015.4-470-475); the Arbitration Panel therefore sees no reason to challenge the reasonableness of the sponsoring in this case.

The total amount pledged corresponds to funding of approximately EUR 320 per participant. The Arbitration Panel considers this amount to be justifiable in view of the concrete promotional advantages associated with the funding at an event lasting just under 2 ½ days.

2. d. Admissibility of the conference venue

In the view of the Arbitration Panel, the selected conference venue also upholds the framework set by the FSA Code of Conduct Healthcare Professionals.

According to Section 20 Section 5 FSA Code of Conduct as adopted by the FSA General Assembly on 17 October 2017 and approved by the Federal Cartel Office on 9 January 2018, financial support for external training events is generally permissible.

The requirements for internal training events apply accordingly to the selection of the conference venue. Therefore, the choice of conference venue must be made solely on the basis of objective criteria. On the other hand, companies should avoid conference venues that are known for their entertainment value or are considered extravagant.

The conference venue in this case is a historically preserved building that was built in 1907 for spa operations. Today it is used for events of all kinds, including classical music concerts. Commensurate with the architectural era, the building is equipped in a very representative way.

The Arbitration Panel has already stated that, under the current Code of Conduct, it considers it possible in principle to hold internal and external training events at older, often historically preserved venues. This is also true even if these venues, as here, correspond to earlier building and furnishing styles due to their construction period and their history of use, tend to represent the exception in this form today (cf. Ref. 2017.11-530-532). The prerequisite for this, however, is that the program design of the training event does not provide a significant incentive or the possibility of using leisure activities or the hotel's luxury facilities, if any.

There were no indications, based on the complaint or the program, that the program sequence did not comply with the requirements in terms of an intensive, tightly-scheduled program agenda required by case law. [This is dealt with in detail.] The Arbitration Panel also saw no evidence that would suggest any significant incentive or opportunity to take advantage of leisure activities that Wiesbaden has to offer in the immediate vicinity of the event venue. In case individual participants on their own initiative and at their own expense happened to visit nearby gourmet restaurants or entertainment venues following the official program, this is attributable to neither the organiser nor to the sponsor; they neither refer to it nor invite them to do so.

The notion that the attractiveness of the spa location was so great so as to entice the participants to use the existing spa facilities and, in doing so, neglect participation in the event (cf. proceedings under Ref. 2007.11-211) was neither presented as an argument nor apparent. On the contrary: The practitioners interviewed by the Arbitration Panel confirm that the participants generally attend the event without limitation due to its quality.

Outcome

The Arbitration Panel dismissed the proceedings and closed to file.

Berlin, April 2018

Wording 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 further training events is permissible. Member companies supporting external further training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place. Moreover, when providing financial support to external further training events, for the selection of the conference venue and for hospitality, the provisions concerning internal further training events shall apply mutatis mutandis. The presence of the participants, as well as the agenda of the event is not to be documented.

§ 25 Section 4 Code of Procedure

On the extension of the deadline for filing briefs substantiating an appeal

Ref.: FS II 2 - 17 - /2017.6-522 (Second Instance)

Principles

1. **In exceptional cases, an extension of the deadline for filing briefs substantiating an appeal may be considered by way of supplementary interpretation and relevant application of § 520 Section 2 Sentence 2 Code of Civil Procedure (ZPO) by the Chairman of the Arbitration Panel of the Second Instance.**

2. **In the special, objective constellation at the turn of the year may be considered as good cause for an extension; strictly personal reasons such as vacation periods, on the other hand, are not relevant.**

Facts of the case

The FSA received an anonymous complaint concerning the organisation of an internal event. The Arbitration Panel of the First Instance unsuccessfully issued a warning to the company for a violation of § 20 Section 3 FSA Code of Conduct Healthcare Professionals. After a verbal hearing on 14 December 2017, the Arbitration Panel of the First Instance, in its decision of 19 December 2017, determined a violation of § 20 Section 3 FSA Code of Conduct Healthcare Professionals.

The company announced its intention to appeal this decision by e-mail on the same day and, at the same time, requested an extension of the deadline for filing briefs substantiating the appeal by 2 weeks to January 16, 2018 in light of the "the forthcoming Christmas holidays and the subsequent vacation (...)".

The Arbitration Panel of the First Instance informed the company by e-mail on December 20, 2017 that an extension would not be possible. § 25 Section 4 Sentence 1 Code of Procedure states that the appeal and briefs substantiating the appeal must be submitted within the two-week deadline. In the proceedings on FS II 6/07/2007.7-190, the Arbitration Panel of the Second Instance had already clarified that this period was intentionally relatively short in order to expedite appellant proceedings. Although this decision was pronounced for the receipt of payment, it was

held that it was to be assumed that the brief substantiating the appeal would also have to be filed by this deadline.

In a letter dated 22 December, the company filed an appeal and at the same time cited a breach of procedure. The rejection of the requested extension of the deadline constituted a violation of the entitlement to a hearing in accordance with law, which was constitutionally safeguarded pursuant to Art. 103 (I) of the Basic Law; this was further elaborated. This letter was then submitted on the same day to the Chairman of the Arbitration Panel of the Second Instance.

Statement

The Chairman of the Arbitration Panel of the Second Instance considers it necessary in the present exceptional case to extend the deadline for filing a brief, contrary to the wording of the FS Code of Procedure, substantiating the appeal that had already been filed – without substantiating briefs.

According to § 25 Section 4 Sentence 1 Code of Procedure, the opposition must be "filed and substantiated" within the appeal deadline. The Code of Procedure does not provide for a (separate) possibility of extending the time limit for filing a brief substantiating an appeal. This is intended to expedite the appeal procedure. Likewise, under § 25 Section 11 Code of Procedure, a reinstatement is not permissible if the appeal deadline is missed.

Although the wording of the Code of Procedure excludes any extension of the deadline for filing briefs substantiating the appeal, the situation is quite exceptionally different in the present case, which is of a special nature. The fundamental procedural principle, which also applies in the context of the Code of Procedure, is the entitlement to a fair hearing under the law. Without an extension, the appellant's counsel for the proceedings would not have a reasonable period of time to examine with due diligence the decision of the First Instance, to properly substantiate appeal, in consultation with the party. This could easily constitute an infringement of the principle of the entitlement to a fair hearing under the law and – depending upon the course and outcome of the proceedings – as a material procedural error, lead to a successful challenge of the decision by the Second Instance before an ordinary court. Such a situation can only be avoided by extending the deadline for submitting briefs substantiating the appeal.

The decision of the First Instance was served immediately prior to Christmas; the two-week deadline therefore expires shortly after New Year's Eve. As proper preparation between Christmas and New Year is practically impossible or only possible in

an unreasonable manner, the counsel of the appellant has only a few days to properly prepare, and these are in fact interrupted by the Christmas time. This would not provide a sufficient right to a fair hearing.

The Code of Procedure does not provide for such a special exception. By way of supplementary interpretation, only the way remains to apply by way of exception § 520 Section 2 Sentence 2 Code of Civil Procedure (ZPO), which allows an extension of the deadline for filing briefs substantiating an appeal, specifically by the Chairman (of the Second Instance).

In the view of the Chairman, there is a substantial reason for an extension under the circumstances specified above. This is seen in the special, objective constellation at the turn of the year, whereas strictly personal reasons such as vacation periods are not relevant. In addition, any delay in the proceedings is ruled out. The earliest date for as verbal hearing is 10 April 2018.

It is appropriate to extend the deadline until 16 January 2018 so that two weeks are available for proper preparation from 2 January 2018. The Chairman deemed a shorter period – due to the few working days before Christmas and after New Year – as inappropriate in light of the long period until a verbal hearing on 10 April 2018.

Outcome

The deadline for filing the objection was extended by two weeks, calculated from the end of the public holidays at the turn of the year.

Wording FSA Rules of Procedure

§ 25 Objection / appeal for failure to act

(4) The objection must be filed in writing with the Chamber of First Instance within the deadline in accordance with § 25 (1) and must be substantiated. The Chamber of First Instance shall immediately pass on the objection to the chairman of the Chamber of Second Instance. If no objection is filed within a time limit of two weeks after service of the decision, then the decision of the Chamber of First Instance shall be deemed to be incontestable within the meaning of these Rules of Procedure.

§ 20 Section 3 Sentence 2 FSA Code of Conduct Healthcare Professionals

Incentive effect of a conference venue, here: Prien am Chiemsee. Weighing the incentive effect with objective criteria; ex-ante consideration

Ref.: FS II 2/17/2017.6-522 (Second Instance)

Principles

1. **Prien am Chiemsee has an attractive location for physicians from more outlying areas and has a significant recreational value. This results in an additional, inappropriate incentive for these physicians to participate in a training event.**

2. **The choice of venue must be made solely on the basis of objective criteria. In this, however, objective reasons must be included in the overall assessment and weighed against – any existing – incentives that are not inappropriate.**

3. **When evaluating a conference venue, an ex-ante assessment, i.e. at the time of the original planning, is required, not on ex-post assessment.**

Facts of the case

The FSA received an anonymous complaint, alleging, among other things, that a colloquium organised by Berlin-Chemie AG (hereinafter: the company) had taken place in a hotel with a predominantly leisure character.

The company hosted the event in June 2017 (Friday/Saturday) at the 4-star Chiemsee Yacht Hotel in Prien. It involved an "Interdisciplinary Colloquium", certified by the Bavarian Medical Association, with topics that were relevant for general practitioners. The topics covered five indication areas of the company. The participation fee for overnight accommodation was EUR 75.

82 physicians took part in the colloquium. 31 came from the Nuremberg/Erlangen region, 26 from the Augsburg region, approx. 10 each from the greater Munich area and Ingolstadt region; and no one from the Rosenheim region, to which Prien belongs, from the Landshut region and from Allgäu.

The program began on Friday evening at 6:15 p.m. with welcoming remarks for the participants, followed by a specialist presentation from 6:30 p.m. onwards. At 8:00 p.m., dinner was served. On the following day, the event continued from 9:00 a.m. with five technical lectures, interrupted by a coffee break (30 minutes), a light lunch (1 hour) and another coffee break (30 minutes). The session ended at 4:30 p.m.

The company made the following statements:

Due to the planned large catchment area of the participants in question – from Erlangen to Rosenheim and from Augsburg to Passau – the Chiemsee region was chosen as a relatively central event location.

Given the planned size of the event with around 100 participants, many hotels were ruled out from the start due to a lack of beds or sufficient vacancies, as were hotels offering their guests free use of their wellness area.

The Yachthotel Chiemsee is not a hotel with a predominantly leisure character. It also considers itself a conference hotel with the requisite technical facilities and does not offer any free wellness treatments or special leisure activities. The hotel is said to be conveniently located and covers a relatively large catchment area. It is not a luxury hotel, but rather a typical 1970s hotel with rustic decor.

The hotel said to have been selected primarily due to its size, suitability for larger conferences (with appropriate technical facilities), good transport accessibility and cost considerations.

The strict agenda of events was said to not allow for any leisure activities.

The warning by the Arbitration Panel of the First Instance, with which an objection was raised concerning the conference venue, remained unsuccessful. The company made further statements:

It claimed there was no violation of § 20 Section 3 Sentence 2 FSA Code of Conduct Healthcare Professionals (hereafter referred to as: the FSA Code). The choice of the conference venue and the conference hotel was said to have been made exclusively based on objective reasons.

The conference venue said not to be considered extravagant; it was not known for its entertainment value.

Prien is said to be relatively easy to reach for physicians from the relevant field sales regions (north, south and northeast of Munich). The planning had already taken place in summer 2016, the reservation in November 2016. In the spring of 2017, the field sales force began inviting the physicians to the conference. In May 2017, it turned out that the response in region 118 had not been particularly large, probably because of an extended illness of the regional manager. Therefore, contrary to the original planning, the event was attended by a large majority of participants from the more distant region north of Munich.

Because the ex-ante consideration was said to be definitive in the original selection, and this was said to be appropriate, the later departure from this was claimed to be irrelevant. There was said to be no obligation to change the event venue. This was said to be neither appropriate nor reasonable, especially due to the short time frame leading up to the conference. In addition, a change would have resulted in significant financial disadvantages.

With its decision of 19 December 2017, the Arbitration Panel of the First Instance determined that the company violated § 20 Section 3 FSA Code of Conduct Healthcare Professionals. The company was obliged to refrain in the future from choosing a venue to which the company invites members of the professional community to internal training events not solely on the basis of objective criteria, as was the case at the colloquium held in the Yachthotel Chiemsee, Prien, from 23 to 24 June 2017.

For the selection of Prien as the venue, objective reasons were not convincing. The location was neither centrally located nor easily accessible for the participants, but it did offer a special attractiveness with a high recreational value.

The fact that the original planning of the event had been envisaged for a wider regional group of participants was not significant in the opinion of the Arbitration Panel of the First Instance. In the case of a period of one year in advance, the company is required to regularly check whether there is a need for changes and, if necessary, take these into account promptly, possibly also cancelling the booked conference venue and choosing another. If the company only gains knowledge of this 4–6 weeks prior to the beginning of the event, this indicates inadequate internal organisation.

If the responsible employee is ill for a longer period of time, a company of the size specified here has sufficient possibilities to ensure early replacement if necessary.

The company appealed the decision. It reiterated its arguments presented in the First Instance.

Essential grounds for the decision

The objection is admissible. It was filed within the two-week period of § 25 Section 1 FSA Code of Procedure and after the Chairman had extended the time limit for stating reasons – exceptionally due to special circumstances – was justified by the company in due time (see the report of 25 April 2018).

The subject of the proceedings of the Second Instance concerns the prohibition of the First Instance arising from § 20 Section 3 Sentence 2 FSA Code, as to whether the company selected the venue and the conference hotel venue solely on the basis of objective criteria, not, however, based on the other anonymous complaints (§ 25 Section 7 Sentence 2 FSA Code of Procedure). In this regard, the Arbitration Panel of the First Instance did not find any violations.

The company's appeal objection is unfounded. It was also the view of the Arbitration Panel of the Second Instance that the company violated § 20 Section 3 Sentence 2 FSA Code.

According to § 20 Section 3 Sentence 2 FSA Code, the selection of the conference venue and the conference hotel for internal training events, as well as the invitation of healthcare professionals, must be solely on the basis of objective criteria. According to Sentence 3, one such reason is not the leisure value of the venue, for example. According to Sentence 4, companies should avoid conference venues that are known for their entertainment value or are considered extravagant.

In this case, the choice of venue was not made solely on the basis of objective criteria.

The Arbitration Panel of the Second Instance already ruled on the interpretation of that provision stated in its decision of 17 November 2005 (Ref.: FS II 5/05/2005.5-65):

"It is to be decided whether ... has chosen the conference venue solely on the basis of objective criteria, taking into account all the circumstances of the individual case. The choice of venue should not be allowed to create the impression that the leisure and recreational character of the event is a priority. Just because according to the regulation in the Code the leisure value of the venue is not an objective reason, it does not necessarily mean that all venues having a (substantial) leisure value are excluded from the beginning, however. ...The FS Code cannot be understood as meaning that such locations are always excluded as suitable venues. Then there would be hardly any places left for further training events. Such a narrow interpretation is not warranted according to the meaning and purpose of the provision. Rather, it depends on all the circumstances of the individual case.

When weighing the circumstances, the regional make-up of the participant group needs to be taken into consideration and whether the conference venue is located within a reasonable distance of the participants. Also of importance is whether the agenda is so tightly scheduled so that hardly any or only very little leisure time remains, furthermore whether the leisure value of the location is so great that participants will be inclined to take advantage of its leisure opportunities and, as a result, neglect dissipation in the conference. It speaks against the selection of the conference venue according to objective criteria if the invitation lists the leisure opportunities or even prominently features them, or if at the same time, there is an attractive event taking place at that venue, which is known to the invitees."

These principles continue to apply.

The individual overall view indicates here that the selection of the conference venue, Prien am Chiemsee, was not made solely for objective reasons.

Contrary to the opinion of the Arbitration Panel of the First Instance, the crucial factor is the timing of the selection, not (also) later circumstances. As the company rightly pointed out, an ex-ante view is required, not an ex-post view. Accordingly, with respect to the composition of the participant group, in selecting the conference venue, the company was able to assume that roughly half the physicians would come from north or south and northeast of Munich respectively. When it turned out that most of the participants were coming from the region north of Munich, it was no longer reasonable, and indeed probably not possible, to move the conference location with a number of participants of some 80 people due to the short notice prior to beginning of the event, whereas cancelling the conference was also not acceptable.

But even the required ex-ante consideration leads to the conclusion that the selection of the conference venue was not made solely on objective grounds.

In the overall consideration of circumstances, it can be assumed that Chiemsee is a well-known Bavarian holiday destination. Accordingly, Prien am Chiemsee has an attractive location, which most of the invited physicians coming from Bavaria would probably be aware of, and from their point of view, it offered considerable recreational value. This means that physicians from the region north of Munich have an additional, unrelated incentive to participate in the training event because of the

greater distance to Lake Chiemsee, in order to be able to use that opportunity – in June – to stay in a pleasant setting during the conference. For physicians from the area around Lake Chiemsee, there is less incentive, because due to the proximity of where they live, they are more able to take an excursion to the lake at any time.

On the other hand, the company rightly states objective reasons for the selection of Prien, which are to be included in the overall assessment: The company had already had positive experiences with the conference venue and conference hotel. The hotel is suitable for larger training events and well equipped with the appropriate technical facilities. The wellness area can only be used on a fee basis. The participant has to pay EUR 75 for overnight accommodation. In addition, and not to be disputed, the certified agenda is scheduled so tightly that, apart from the appropriate short breaks, there are no leisure activities for the participating physicians afterwards. Nor did the invitation make any mention of any such activities. Furthermore, the conference venue is a reasonable distance to reach for participants from both regions, despite different travel times.

However, in the opinion of the Arbitration Panel of the Second Instance, the above-mentioned objective reasons are not sufficient, compared to the previously described non-objective incentive effect, to reach the conclusion in an overall assessment that the selection of the conference venue was made solely for objective reasons.

This does not mean that Prien am Chiemsee is not a suitable venue under any circumstances. There could be cases where additional objective grounds would apply, i.e. if it was a training event designed solely for physicians from the area around Lake Chiemsee, for whom there would be no, or hardly any, additional, non-objective incentive effect compared to physicians from more distant Bavarian regions. According to the circumstances of the case at hand, the company should have chosen a venue for the planned event outside a well-known holiday area, e.g. Rosenheim or Munich.

Accordingly, there is a violation of § 20 Section 3 Sentence 2 FSA Code. The decision of the First Instance is therefore upheld.

There are no material objections to the wording of the prohibition by the First Instance. Although it adopts the wording of the FSA Code, it then refers to the concrete form of infringement. Accordingly, the prohibition covers the concrete form of infringement, as well as actions that are essentially the same. In interpreting the prohibition, the aforementioned reasons are to be definitively observed.

Ergebnis

Berlin-Chemie AG company was obliged to refrain in the future from choosing a venue to which the company invites members of the professional community to internal training events not solely on the basis of objective criteria, as was the case at the colloquium held in the Yachthotel Chiemsee, Prien, in June 2017.

In addition, the company was obliged to pay fines of EUR 10,000 each to the German Medical Aid Organisation, action medeor e. V., and Deutsche Stiftung Denkmalschutz (“German Historical Preservation Foundation”).

The Arbitration Panel of the Second Instance did not deem it necessary to issue a public reprimand pursuant to § 24 Section 4 Sentence 1 FSA Code of Procedure: It was neither a particularly egregious nor a repeated Code violation.

Berlin, April 2018

Wording FSA Code of Conduct Healthcare Professionals

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

(3) Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue as well as the invitation of healthcare professionals must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason. Further, the companies are to avoid conference locations which are known for their entertainment value or are considered extravagant.

§ 13 Section 1 Sentence 2 FSA Code of Conduct Healthcare Professionals

Blatant and excessive promotion targeting of a physician during a visit by a field sales representative

Ref.: 2017.2-515

Principles

1. **If the employee can or ought to recognise during a field sales visit that the addressee does not wish to receive the visit and the visit is not subsequently interrupted, for example, this constitutes blatant and excessive promotion.**

2. **Critical statements made by a field sales representative to a physician concerning the volume of prescription of a particular drug and expectations of future prescription practice are incompatible with a relationship of partnership between a physician and a field sales representative.**

Facts of the case

The subject of the proceedings is the complaint from a physician that a field sales representative of member company Daiichi Sankyo Deutschland GmbH had visited his clinic and entered his physician's office there without being asked. The employee is said to have not accepted the comment by the physician that he did not have time for this visit. Instead, he complained about the number of prescriptions issued by the clinic for one of the company's drugs, which he claimed were too low compared to drugs from other manufacturers; finally, the field sales representative is said to have asked whether he could finally rely on the fact that the physician would take this drug more thoroughly into consideration in the future for new prescriptions.

The incident said to have occurred at the door of the physician's office, where the ward is located. On the opposite side of the corridor, a few metres from the door of the physician's office, patients and relatives are said to have been within earshot. The complaining physician said that third parties had had the opportunity to follow the conversation. In his view, as a result, there was a risk that third parties would jump to undue or false conclusions as to the collaboration between the clinic and the manufacturer in terms of the prescription of drugs.

The company stated as well that while the visit actually did take place, the employee stood outside the physician's open door, which was confirmed by another colleague who had accompanied him. His visit was not formally announced because the front desk was not occupied. In an earlier conversation, the employee had agreed with the physician "to contact him soon, preferably in the afternoon". He claimed that during this visit, the prescription numbers for the drug had been mentioned; however, under no circumstances had this been proactive; therefore, a clarifying discussion had taken place with the employee involved. He claimed that other third parties had not been able to hear the conversation, to the extent they had listened in on it.

The complainant subsequently responded to this and essentially confirmed his earlier remarks. In response to the warning of the Arbitration Panel, the company did not submit a declaration of discontinuance, and it filed for verbal hearing to be conducted as further proceedings.

After this hearing, the Arbitration Panel found the following facts of the case:

- the visit was not formally announced via the front desk of the clinic;
- the employees of the company had entered the clinic via the entrance of the outpatient area, which may not have been staffed at that time;
- the field sales representative of the company stood at least in the door frame of the physician's office and spoke to the physician from there;
- who in turn repeatedly pointed out that he had no time for a conversation;
- until finally the tone of the conversation escalated and
- statements were made about what – in the employee's view – were insufficient prescription numbers;
- when the physician stood up from his desk to urge the two field sales representatives to leave, the visit was finally ended, but with reference to the expectations of future prescription numbers.

The participants differed in their perception of whether there were people on the side of the corridor opposite to the entrance to the physician's office.

Essential grounds for the decision

According to § 13 Section 1 FSA Code of Conduct Healthcare Professionals, the targeting of healthcare professionals with blatant and excessive promotion is prohibited. Promotion is deemed blatant and excessive in particular if the promotion is carried out despite its being apparent to the promoter that it is unwanted by the addressee. This fact has been established.

The purpose of the visit was to promote one of the company's drugs. The complainant clearly signalled that on the afternoon in question, he was not available for this type of discussion. Whether this was due to lack of time or other reasons is irrelevant; it is sufficient if it had to be clear to the addressee, the field sales representative, that the visitor did not wish to be available at this time.

To the extent that the employee argued in the verbal hearing that he was unable to recognise this based on the statements by the physician, the Arbitration Panel considers this statement to be only logical to a limited extent. Even if the employee had not realised at the beginning of the discussion that the physician had no time for a visit, it cannot be assumed that this uncertainty lasted during what were – indisputably – multiple statements of refusal. From the point of view of the Arbitration Panel, both the repeated rejection by the physician and the related escalation in tone can only be interpreted in such a way that his request was initially ignored and the employee did not want to cut off the visit immediately. The statements as to the scope of prescription of the drug in this clinic at the time and the subsequent question concerning future prescription practice, which are indisputable, revealed that the field sales representative only wanted to end the visit after delivering additional "messages" to the physician. This is incompatible with a relationship of partnership between physicians and field sales representatives. It is also unacceptable to ask whether the employee can rely on the physician's more thoroughly considering a particular drug when prescribing medications in the future; the therapeutic decision always lies with the physician alone. Therefore, this constitutes blatant and excessive promotion within the meaning of § 13 Section 1 FSA Code of Conduct Healthcare Professionals.

Whether patients and relatives were standing on the other side of the corridor, as the complainant stated, and whether these persons could have heard the conversation, is not decisive for the assessment of the facts within the meaning of Section 13 Section 1 FSA Code of Conduct Healthcare Professionals.

Outcome

The complaint was founded. The Arbitration Panel discovered a violation by Daiichi Sankyo Deutschland GmbH against § 13 Section 1 FSA Code. The company was obliged in future to refrain from targeting healthcare professionals with blatant and excessive promotion by not immediately interrupting field service visits or having them interrupted if the healthcare professional indicates that he does not wish to be available for a conversation at a specific point in time, as occurred in the specific case.

In determining the fine, only the minimum fine of EUR 5,000 was assessed. In the company's favour was the fact that it was presumed to be an isolated case of misconduct, that the company immediately had a clarifying discussion with the employee, took disciplinary action and finally, that the employee used the meeting at the verbal hearing to have a clarifying discussion with the physician concerned.

The fine was payable to "Against Malaria Foundation Germany", 80538 Munich, Germany.

Berlin, April 2018

Wording FSA Code of Conduct Healthcare Professionals

§ 13 Blatant and excessive promotion

(1) Promotion targeting healthcare professionals in a blatant and excessive manner is not permitted. Promotion is deemed blatant and excessive in particular if the promotion is carried out despite its being apparent to the promoter that it is unwanted by the addressee.

§ 13 Section 1 FSA Code of Conduct Healthcare Professionals

Blatant and excessive promotion targeting a healthcare professional through the sending of unwanted materials

Ref.: 2017.12-539

Principles

1. **The further sending of promotional material to healthcare professionals constitutes blatant and excessive promotion if the physician informs the representative of the company that he has not requested these documents and asks him to be removed from the distribution list.**

2. **The normal and sometimes necessary use of standard processes does not relieve the company of the task of resolving a substantiated complaint in an individual and substantiated manner, within the scope of what is reasonable. In case of doubt, general statements are not suitable.**

Facts of the case

A healthcare professional submitted a complaint to the Arbitration Panel stating that for approx. 2 years, the member company MSD Sharp & Dohme GmbH had been sending promotional material with the heading "Your requested documents" addressed to various persons in his practice. In each case, the letter thanked him "for our nice conversation" and expressed that the sender was "already very much looking forward to our next contact".

The complainant argued that he had never seen the persons who had signed the letters, nor had he ever requested any documents from them. On the contrary, he had already called the person stated on the letter after receiving it a second time and asked to be told the date on which the conversation had taken place. He subsequently received the evasive reply that sometimes letters of that kind were "also written from the desk", i.e. without a previous conversation actually having taken place. His request to remove him from the mailing list had never been complied with, although this had been promised to him. He said the promise to collect the unwanted mailings had also not been complied with.

The company explained that the mailings were probably sent by an agency commissioned by the company, which maintained telephone contact with healthcare professionals via so-called e-reps. According to the agreed procedure, mailings would only be sent individually and then only if the physician had requested this or consented to it in an individual case. No unsolicited mailings were sent.

The company's field sales staff explained they could not remember conversations with the physician to stop sending mailings or to collect the materials; there was also nothing of that nature stored in the database. The company said that an employee of the service provider who had been responsible for contacts with the complainant no longer worked there.

Specific statements by the signatories of the letters, which the complainant presented as samples, were not submitted to the Arbitration Panel.

Essential grounds for the decision

According to § 13 Section 1 of the Code, healthcare professionals are not allowed to be targeted with blatant and excessive promotion. Promotion is deemed blatant and excessive in particular if the promotion is carried out despite its being apparent to the promoter that it is unwanted by the addressee.

According to the statements by both parties, there were at least nine contacts in the period of 2016/2017, which were carried out by the e-reps of the service provider at the complainant's practice. It can be concluded from the statement of facts that at least six contacts must have been made with the physician's wife or other staff members of the practice – or, as the complainant states with reference to a telephone call with an e-rep, "from the desk". If in the following letters to the physician, reference is made to "our nice conversation", this is at least misleading, because generally no one spoke to him. However, it can also be concluded from this that there was no consent from the physician to the mailing of such documents, at best by his wife or other employees in the practice.

This, too, however, was not sufficiently substantiated by the company. The company and the service provider merely referred to the generally customary and established processes there, without having clearly demonstrated this in the individual case for the contacts relevant here. They are predominantly general and blanket statements.

By contrast, the physician's statements are precise, comprehensible and consistent. He was apparently only concerned with stopping the flow of mailings and only

when his requests to the company were unsuccessful did he make his concern the subject of a complaint to the FSA. The documents submitted by him underscore his comments.

After weighing these factors, the Arbitration Panel comes to the conclusion that the complainant's statements are correct. The Arbitration Panel does not ignore the fact that a company maintaining contact to a large number of field sales representatives and a vast number of physicians in private practice is dependent upon standard processes and cannot document each separate case. However, this cannot lead to the substantiated complaint of a physician being resolved by referring to the existing processes and disputing them with blanket statements; rather, the company can be expected to resolve the separate cases individually within the scope of what is possible, e.g. with statements by all concerned parties, etc.

Outcome

The Arbitration Panel considered the mailing of materials to be blatant and excessive promotion within the meaning of § 13 Section 1 FSA Code of Conduct Healthcare Professionals, i.e. as promotion, although it should have been clear to the company that the addressee did not wish to receive it. Thus, the complaint was founded.

MSD Sharp & Dohme GmbH was obliged to refrain from targeting healthcare professionals with blatant and excessive promotion in the form of mailings sent to them, although it is clear to the company that the addressee does not wish to receive them, as in the case at hand. Furthermore, the company was obliged to pay a fine of EUR 8,000 to German Doctors e. V., Bonn. In the company's favour, it was assumed that the misconduct had probably occurred with one physician, yet several times in that one case, however, and that the company had taken the necessary steps to stop future mailings. The Arbitration Panel did not take into account any mailings prior to December 2016 (§ 4 Section 2 Code of Procedure).

In connection with the payment of the fine, the Arbitration Panel found that the fines imposed under the Code of Procedure constitute fines and not donations; therefore, a donation receipt cannot be issued to the company. This is consistent with practices of the Arbitration Panel and also with the regulation in the Administrative Offences Act (OWiG).

Moreover, the Arbitration Panel assumes that the publication of the payment of such fines is not necessary in the context of reporting under the Transparency Code. Fines should not fall under either the category of "monetary payments" or of a "donation" within the meaning of the Transparency Code. In these cases, transparency is guaranteed anyway due to the fact that the decision is published by the Arbitration Panel within the framework of reporting in accordance with § 15 Section 3 Sentence 1 Code of Procedure – as in this case.

Nevertheless, the Arbitration Panel has nothing against a company's publishing the payment of a fine as part of its reporting in accordance with the Transparency Code.

Berlin, July 2018

Wording FSA Code of Conduct Healthcare Professionals

§ 13 Blatant and excessive promotion

(2) Promotion targeting healthcare professionals in a blatant and excessive manner is not permitted. Promotion is deemed blatant and excessive in particular if the promotion is carried out despite its being apparent to the promoter that it is unwanted by the addressee.

§ 20 Section 5 Sentence 4 in connection with § 20 Section 3 Sentence 2 et seq. FSA Code of Conduct Healthcare Professionals

Sponsoring of a training event at the Würzburg Residence

Ref.: 2018.7-545-551

Principles

1. **The Managing Director's right of objection under § 2 Section 3 Code of Procedure is independent and is subject neither to a voting obligation nor to a right of the Board to issue instructions.**

2. **The Arbitration Panel maintains that the mere fact that a building is historically preserved does not lead to these protected structures being eliminated as admissible venues. It needs to be examined in an individual case, however, whether an existing incentive exceeds what is considered an acceptable level in an individual case, so that the outstanding decor and the event character are the clear focus. In this, all circumstances of the individual case must be taken into account.**

Facts of the case

The subject of the proceedings is the complaint by the management of the FSA that some member companies had sponsored the training event "8th Würzburg Training Symposium, Innovations from ... [followed by the indication area] 2018", which took place in the summer of 2018 in the Würzburg Residence. In the opinion of the complainant, the conference venue did not uphold the setting prescribed by § 20 Section 5 in connection with Section 3 FSA Code of Conduct Healthcare Professionals (hereinafter referred to as: "Code"). The Arbitration Panel received the invitation flyer of the organising clinic, prominently displaying on its cover the facade of the Würzburg Residence, and in the upper section with a background schematic of a part of the human body depicting the indication area of the event.

According to the program, the event began at 9:30 a.m. in the so-called "Oval Hall" of the Residence and finished up there at around 3:30 p.m. The entrance to and exit from the event led the visitors through the main entrance of the Würzburg Residence. The organiser's invitation was addressed to "referring physicians" from the clinic. The participants were presented with 10 lectures, each lasting 20 minutes,

and introduced to practical case studies (70 minutes). In between, the schedule provided for a coffee break of 30 minutes and a lunch break of 40 minutes with a buffet.

The presentation of the companies supporting the event can be summarised as follows:

The companies stated that they had supported the event, which had taken place in the same manner for 8th time, with amounts of between EUR 1,100 and EUR 1,500. As a quid pro quo, the organiser had granted them the right, among other things, to run one of the 21 promotional stands of 2 to 3 m² in an industry exhibition, which took place in the adjacent Princes' Hall and the adjoining foyer, along with various promotional opportunities. Approx. 130 participants attended the event.

It was claimed that the conference venue had maintained the framework provided by the Code of Conduct even under the conditions tightened at the beginning of this year. The city of Würzburg was said to be permissible as a conference venue, the Residence did not offer any luxurious furnishings, it was freely accessible and could not be described as "extravagant". There was said to be no promotion of the conference venue's attractive features. The ceremonial rooms of the Residence said to have not been open to the public during the event. In the more recent rulings of the Arbitration Panel, it was repeatedly stated that even historically preserved conference venues can be compliant with the Code of Conduct. Also the fact that the conference venue belongs to the properties of the university where regular teaching took place was also said to prove that it was a code-compliant venue.

The agenda of the event said to be so tightly scheduled and strictly organised that there was no time left for leisure activities. The overall presentation of the invitation was said to be unobjectionable, especially for participants who had already visited the Residence several times anyway.

According to the information indicated at the event concerning sponsors, a total of 19 companies sponsored the event with a total amount of approximately EUR 24,000.

The complaint was preceded by a series of e-mail messages and phone calls from the period prior to the staging of the event, on the one hand between member company X, FSA Managing Director and the FSA Chairman, and on the other hand between X and some of the member companies sponsoring the event. In this correspondence, X stated that he did not consider the promotion of the event to be permissible under the conditions of the Code of Conduct, which had been tightened this year, as the conference venue was said to be inappropriate. In an e-mail to

the Managing Director and the Chairman of the FSA, X speaks of an "agreement reached have the management present the matter to the Arbitration Panel for evaluation and decision".

In a phone conference with the Board, which took place two days after the event was staged, the Managing Director informed the Board members of the matter and explained that in his function as Managing Director, he was submitting a complaint against the sponsoring by the eight FSA member companies specified in the invitation flyer. The suitability of the conference venue and the complaint were then discussed, partly controversially, by the members of the Board present.

With respect to this procedure, some companies involved in the proceedings also questioned the admissibility of the complaint by the Managing Director vis-à-vis the Arbitration Panel. In their opinion, the Managing Director should have consulted with the entire Board and obtained its "demeanour" announcing the complaint.

The Arbitration Panel obtained further information from the host of the event, the State of Bavaria, the organiser and third parties. On the basis of this information, it was also discovered that

- while the Residence is also used by the university, it is not used in the north wing, where the so-called Oval Hall and the Princes' Hall are located;
- the exhibitors entered the Oval Hall via the entrance on the north wing of the Residence, where an elevator is also available, whereas only the participants used the main entrance (lobby, grand staircase);
- the Oval Hall is generally only rented out in connection with the Princes' Hall (including the foyer); its use, according to the host, impairs the visit to the adjacent State Gallery, which is also located in the north wing;
- the invitations were sent out via the organiser's mailing list, mainly to specialist physicians from the region;
- the radius of participants in the event has now expanded by word of mouth to include Fulda, Kassel and Göttingen, along with Erlangen/Nuremberg in the south and the eastern parts of Baden-Württemberg.

Essential grounds for the decision

I. The admissibility of the Managing Director's complaint

1. According to § 2 Section 3 Code of Procedure, complaints can also be submitted by the Board and by the Managing Director. The Code of Procedure specifies this with the words "independently of each other". The provision

has no restriction of the kind that would require the Managing Director to be subject to an obligatory vote with the Board. In the view of the Arbitration Panel, this leads to the conclusion that both bodies can initiate complaint proceedings independently. The wording of § 2 Section 3 Code of Procedure clearly speaks for the independence of the Managing Director's right of objection.

2. This assessment by the Arbitration Panel is confirmed by the history of how the rule was conceived: The right of objection by the Managing Director was newly inserted into the Code of Procedure by the General Meeting of 1 December 2011 upon suggestion of the Board. The proposed resolution at that time included the following statement: "The proposal to give the FSA's management its own right to initiate complaint proceedings against members of the association [– emphasis by the Arbitration Panel –] shall also serve the purpose of making self-regulation more effective." The General Meeting adopted the proposal at that time with an overwhelming majority.

3. Therefore, if the Managing Director's "own" right was introduced back then with a change of the Code of Procedure, it does not appear logical to the Arbitration Panel that its exercise today should be made dependent upon a vote/preliminary information or even a majority decision in the Board. Such a coordination would undermine the Managing Director's "own" right. Incidentally, it also did not occur either, as the arbitration judge, a participant in the above-mentioned phone conference, can confirm. It is therefore not relevant whether members of the Board, whose companies are directly affected themselves, could have participated at all in such a vote or rather would have been required to abstain; an abstention would have at least conformed to previous practice in comparable cases.

4. The Arbitration Panel can also leave unresolved the question as to whether the right of the Managing Director under § 2 Section 3 Code of Procedure could be restricted by the right of the Board to issue instructions to the Managing Director. It is undisputed that no such – formal – instruction was issued by the Board.

   However, the Arbitration Panel points out in this respect that compared to § 10 Section 3.i) Statutes, the rule in § 2 Section 3 Code of Procedure could be regarded as more specific and could thus also be viewed as the rule taking precedence.

5. Whether the complaint raised by the Managing Director was ultimately prompted by the behaviour of another member is generally irrelevant. In many cases, the Managing Director will only become aware of possible violations of the Code because member companies draw his attention to them. Nevertheless, after learning of these facts, he will arrange for his own evaluation as to whether he sees cause to make use of his right of complaint in the specific case. The fact that he did not carry out his own evaluation in the present case is neither apparent, nor is it being alleged. It seems normal to the Arbitration Panel that he exchanged views on the matter with the Chairman of the Board and the representative of X, who provided the information. To the extent that a company claims that "the Managing Director [was said to have] acted solely on the basis of a proposal by [another] Board member", to a certain extent as his "proxy", is not confirmed by the documents available to the Arbitration Panel.

6. The Code of Procedure contains no references as to the question of whether the Managing Director has a duty to mitigate damage towards member companies in such a way that if he seeks to submit a complaint, he does so at the earliest possible opportunity, i.e. before the event is actually carried out, in order to provide the companies the opportunity to correct their promised support and thus avert the Code of Conduct violation. Such an obligation could at best be derived from the overall circumstances. First, it is the sole responsibility of the sponsoring companies to thoroughly and properly verify the admissibility of support measures, regardless of whether any third party, the Board, or as in this case, the FSA Managing Director, is considering launching a complaint. After all, it is in the spirit of the Code of Conduct, to only support events that are compatible with the objectives specified in the introduction to the Code of Conduct and in §§ 4 et seq. Therefore, it is up to the companies themselves to identify the danger of Code of Conduct violations at an early stage and, if necessary, to take appropriate steps to avoid them. If companies have decided to commit their support upon completing this evaluation, it is only appropriate for third parties to hold them accountable for that decision.

7. Irrespective of this, the specific facts of the case do not contain any indications which, as an exception, indicate any obligation to provide information. The above-mentioned correspondence between the Chairman of the Board, the Managing Director and the representative of X took place 8 days prior to the event; the meeting of the Board at which the complaint was raised, two days later. The Managing Director was aware that the companies concerned had already been contacted 11 days prior to the event by X concerning the

event's lack of admissibility from his perspective, and that these companies had then re-examined the process internally and decided to stick to their commitment to support the event. He could therefore assume that the companies concerned had formed a final opinion on the admissibility in any case and that prior information concerning the intended complaint would not affect the position of those companies.

II. On the merits

8. Concerns with respect to the venue, the hospitality, the disclosure of support and the nature, scope and content of the lecture event have neither been raised nor are they apparent.

9. The admissibility of the conference venue is based on § 20 Section 5 in connection with Section 3 Code of Conduct. According to Section 20 Section 5 Code of Conduct, the financial support for organisers of external training events is permitted within a reasonable scope. The requirements for internal training events apply accordingly to the selection of the conference venue. According to § 20 Section 3 Sentence 2 FSA Code of Conduct, the selection of conference venues for internal training events, as well as the invitation to the events must be solely on the basis of objective criteria. According to Sentence 3, one such reason is not the leisure value of the venue. According to Sentence 4, companies should avoid conference venues that are known for their entertainment value or are considered extravagant.

10. Guideline 13.2 states that conference venues are considered "extravagant" if they are not primarily known as a typical business or conference hotel but rather a particularly luxurious or unusual decor is the main focus there. According to the guideline, this also includes such conference venues that are indeed adequately equipped as conference venues, yet at the same time their overall attractiveness on the basis of their decor and featured facilities must create the impression that the conference venue was chosen not for its conference options but because it is such an attraction.

11. The conference venue is located in the rooms of the Residence in Würzburg. According to its official website, (http://www.residenz-wuerzburg.de/englisch/residenz/index.htm), the Würzburg Residence embodies the attainments of Western architecture [the Baroque and Rococo periods] of its day, French château architecture, Viennese baroque and the religious and secular architecture of northern Italy and is a synthesis of the arts of astonishing universality. Its "incomparable suite of rooms – vestibule, staircase, White Hall and Imperial Hall – is considered one of the most magnificent in the history of palace architecture." In addition to the vestibule in the central entrance area of the Residence, the impression of which is shaped by a 450 square metre, spacious, hall, and the grand staircase with the largest coherent ceiling fresco in the world (19 m × 32 m, 677 m²) by Tiepolo, the Princes' Hall with a length of 25 m and a width of 7.5 m also belongs to this suite of rooms; it was used by the court society as a dining hall, as a social room and as a concert hall; a foyer is attached to it.

12. The event took place in the so-called Oval Hall and the adjacent Princes' Hall, which was used with its foyer for the industry exhibition and catering during the breaks. These rooms must be evaluated in their entirety for their conformity with the Code of Conduct.

13. According to the photographs made available to the Arbitration Panel, the Oval Hall in which the lectures were held, is a neutral and sparsely decorated room, in which the Baroque character of the Residence is not the main focus. Therefore, complaints cannot be raised in this respect. The adjacent rooms, which were used for the industry exhibition, lack this neutrality and objectivity: They reflect the splendour of their era, without restrictions, both in terms of the overall impression of the room and its furnishings; in this respect reference is made to

    https://www.schloesser.bayern.de/englisch/rooms/objects/wu_r_fuer.htm.

    The luxurious or extraordinary decor and attractiveness are clearly the focus there.

14. The manner in which the organiser prominently features the Residence on the invitation brochure and his decision to organise the entrance and exit of the participants via the above-mentioned vestibule and the grand staircase, "opened in the morning especially for the participants" and not via the entrance at the north wing, indicate, by the way, that he deliberately wanted to convey this attractiveness. The result was that he gave the participants a "mini tour" through some of the magnificent rooms of the palace, which would otherwise not have been accessible to them at this event.

15. As far as sponsoring companies have pointed out that the rooms of the Residence are partly also used for regular teaching events of the university, this is irrelevant for the assessment to be conducted here. The rooms, used by the university and mainly located in the southern wing of the Residence,

lack comparable furnishings. They bear no relevance to the event rooms selected here. Remarkably, the event did not take place there at the time. The event rooms – according to the organiser – were rented especially for this event.

16. To the extent that reference was made to the fact that in some earlier proceedings, the Arbitration Panel did not find lecture events in historically-preserved buildings to be objectionable, the Arbitration Panel wishes to point out that it is not the mere existence of a building's historical preservation that eliminates these structures from consideration as conference venues. It needs to be examined in an individual case, however, whether an incentive thus created exceeds what is considered an acceptable level in an individual case, so that the outstanding decor and the event character are the clear focus. In this, all circumstances of the individual case must be taken into account. As explained above, in the magnificent rooms of the Würzburg Residence, the attraction is the main focus. This would probably also hold true in a similar manner for many castles that are accessible to the public in a comparable way.

17. The fact that the event was held for the 8th time this year at the same location and has already been financially supported by many member companies in the past has no significant bearing on the current evaluation. This support in previous years took place under the previous Code of Conduct regulation, which was deliberately tightened at the beginning of this year.

18. The Arbitration Panel therefore tends to regard the event rooms, seen here in their entirety, including the selected entrances and exits, as being non-compliant with the Code of Conduct.

19. In ruling precedents, however, it is acknowledged that when weighing the circumstances, the regional make-up of the participant group also needs to be taken into consideration and whether the conference venue is located within a reasonable traveling distance from the participants (cf. most recent proceedings under Ref. FS II 2/17/ 2017.6-522 with further evidence). This criterion must also be examined in the present case.

20. The invitation was addressed to so-called "referring physicians" of a local Würzburg clinic, i.e. physicians in the region who usually refer their patients there. For this group of people, the incentive character of the Residence as an event venue is likely to be negligible as a general rule. These participants have the opportunity to visit the castle at any time and without the need to travel long distances. For them, the Residence is part of their everyday life and not a special incentive. The incentive character of the Residence described above would therefore not be significant for these participants.

21. Whether this assessment can be upheld in the same manner; if the participants from Fulda, Kassel and Göttingen, Erlangen/Nuremberg and the eastern regions of Baden-Württemberg were also taken into account, seems doubtful, but must remain unresolved. On the part of the sponsors, no company provided the Arbitration Panel with a list of participants that could have provided information about the proportion of outlying participants who did not come from the Würzburg region. The organiser also did not comply with the Arbitration Panel's request to submit a list of participants, anonymised where necessary, but cited data protection reasons in this matter; on the contrary, the organiser felt that his "interest in continuing to deal with this matter (was) minor". This stance is all the more revealing, as the organiser had no reservations about distributing the complete list of participants at the event, openly and for everyone to see.

    As a result, the Arbitration Board can therefore neither reconstruct whether the participants from other regions were only a few individual cases, who in a group of 130 participants would seem unlikely to be decisive, or whether the Arbitration Panel was deliberately deprived of the relevant information for other reasons.

    After sufficient clues for the acceptance of either of these two alternatives was not available, the Arbitration Panel had no choice but to conclude the proceedings pursuant to § 11 Section 1 Sentence 3 Code of Procedure.

22. The decision did not deal with the appropriateness of the amount of sponsorship after the Managing Director had clarified vis-à-vis the Arbitration Panel that his complaint related only to the conference venue.

Outcome

As a result, the complaint was therefore admissible. The proceedings therefore had to be dismissed, however, as the facts of the case could not ultimately be sufficiently clarified in a manner necessary for the decision.

The complainant did not make use of his right of appeal (§ 3 Section 1 No. 2 (a) Code of Procedure). Therefore, the dismissal was legally final.

Berlin, October 2018

Wording FSA Code of Conduct Healthcare Professionals

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

(3) Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue as well as the invitation of healthcare professionals must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason. Further, the companies are to avoid conference locations which are known for their entertainment value or are considered extravagant.

(5) Within appropriate limits, financial support for the organisers of external further training events is permissible. Member companies supporting external further training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place. Moreover, when providing financial support to external further training events, for the selection of the conference venue and for hospitality, the provisions concerning internal further training events shall apply mutatis mutandis. The presence of the participants, as well as the agenda of the event is not to be documented.

§ 20 Section 5 Sentence 4 in connection with Section 3 Sentence 2

FSA Code of Conduct Healthcare Professionals

Sponsoring of a training event in a so-called "Luxury Hotel" in Hamburg

Ref.: 2018.3-540

Major focus on luxury features instead of conference opportunities

- Bayer Vital GmbH supported the event of a Hamburg hospital in "Hotel Süllberg" with a sponsorship of EUR 1,250.
- The FSA Code of Conduct requires that a scientific character be maintained at relevant events. In choosing the conference venues, companies should avoid those known for their entertainment value or considered extravagant.
- The Arbitration Panel of the First Instance issued a warning to the company for a violation of the FSA Code of Conduct and requested it to issue a statement of discontinuance. The submission of this statement was refused.
- In its ruling, the Arbitration Panel of the First Instance then ordered the company to refrain in the future from providing financial support to external training events for organisers if the selection of the conference venue was not solely on the basis of objective criteria. The Arbitration Panel of the First Instance ordered the company to pay Medica Mondiale e. V. a fine of EUR 20,000.

Principles

1. **If luxury features are clearly in the foreground at an event location, but the conference facilities are not, the mere stay can provide a special attraction, which is suitable to unduly influence healthcare professionals in their freedom of therapy and prescription.**

2. **According to existing rulings (cf. FS II 2/17/2017.6-522), when taking due consideration of the overall situation, objective criteria, e.g. the proximity to the organising clinic, the availability of a sufficiently large conference room, the tradition of an event, are to be taken into account as a general rule.**

Facts of the case

The Arbitration Panel received the anonymous complaint that the member company Bayer Vital GmbH (referred to below as: Bayer) supported an event in the so-called "Süllberg Luxury Hotel" in Hamburg. The complainant doubted the appropriate hospitality because of the 2-star cuisine highlighted on the hotel's website. The hotel was said to promote itself with special luxury, stylish elegance and Hanseatic charm.

The company replied that it had supported the event with a sponsorship payment of EUR 1,250 to the organiser, a Hamburg hospital. In return, the organiser had promised to mention the company as a sponsor in the invitation letter and to provide the opportunity to display scientific material on one of its drugs, to make a table available and to put up a "roll-up" display.

According to the company, the hotel is a 5-star hotel and also has a restaurant that has been awarded Michelin stars. In the opinion of the company, the hotel was nevertheless an appropriate venue for the event in question and was in compliance with the Code of Conduct, as was its catering. It claimed the criteria of Guideline 11.6 had also been upheld.

The event took place for the 14th time, traditionally in an event room separate from the hotel, the so-called "ballroom". 170 participants attended the event. The hotel is the closest to the organising clinic and the only one in its vicinity which has a conference room of the required size. The invitation did not refer to the special exclusivity of the hotel.

The event and catering were clearly separated from the hotel and restaurant, and the "ballroom" – unlike on festive occasions – was equipped with business-like row seating. Due to the tightly-scheduled program, there was also no opportunity for the participants to enjoy any luxury features.

In the company's view, the mere stay in the hotel did not constitute a special attraction that was likely to unduly influence physicians in their freedom of therapy and prescription. The business character of the event was clearly the main focus.

The catering did not take place in the two restaurants of the hotel, but in the conference room.

From the invitation, it follows that the event began at 4:00 p.m. with two lectures 45 minutes each, followed by a coffee break of 15 minutes and three additional

lectures of 20 to 60 minutes each. For the time from 7:30 p.m., a light group meal was planned.

The Arbitration Panel issued a warning to the company and requested it to issue a statement of discontinuance. The submission of this declaration was rejected, elaborating on previous statements, with particular reference to the more recent case rulings on the admissibility of older, often historically preserved venues.

The Arbitration Panel then inspected the conference venue on site in order to gain an impression that went beyond its own presentation on the Internet.

Essential grounds for the decision

According to § 20 Section 3 Sentence 2 FSA Code of Conduct (hereafter referred to as: Code), the selection of the conference venue and the conference hotel for internal training events, as well as the invitation to these events, must be made solely on the basis of objective criteria. According to § 20 Section 3 Sentence 3, the leisure value of the venue is not such a reason. According to Section 4, companies should avoid conference venues that are known for their entertainment value or are considered extravagant. According to § 20 Section 5 Sentence 4 FSA Code of Conduct, these requirements also apply to external training events.

In this case, the choice of conference venue was not made solely on the basis of objective criteria.

Consistent with its rulings, the Arbitration Panel has repeatedly (see recent Ref. FS II 2/17/2017.6-522 (Second Instance) with further evidence) stated that the question as to *"whether … the venue was selected solely on the basis of objective criteria is to be answered taking into account all circumstances of the individual case. The choice of venue must not create the impression that the leisure and recreational character of the event is the main focus. […] It depends on all the circumstances of the individual case."*

These principles continue to apply in a like manner for the selection of conference venues. Guideline 11.6 states that "In weighing the reasonableness of accommodation, it should also be taken into account whether … the mere stay in the hotel in and of itself creates an attraction that would tend to unduly influence these [healthcare professionals] in their freedom of therapy and prescription. Hotels that fall within the 5-star category are not immediately eliminated as unreasonable, provided that the business character of the establishment is the main focus and the hotel is not especially renowned for its luxury features [Emphases added by the Arbitration Panel]."

Moreover, Guideline 13.2 states that a conference venue is considered "extravagant" if it is not primarily known as a typical business or conference hotel but rather prominently features particularly luxurious or unusual decor. This is especially the case if the decor and existing facilities must create the impression that the conference venue was chosen not for its conference options but because it is such an attraction.

The individual overall assessment indicates here that the selection of the conference venue was not made solely for objective reasons.

Hotel Süllberg is a historically preserved complex in the so-called "upper middle-class villa quarter" of Blankenese, including two upscale restaurants (see also the proceedings for Ref. 2016.1-495). The so-called "ballroom" is directly integrated into this ensemble and is not managed separately, i.e. structurally or in any other way. With regard to the hotel's own presentation of the entire complex and the ballroom, reference is made to the hotel's own presentation on the website, which reads as follows:

"The luxurious 5-star Süllberg Hotel in Hamburg-Blankenese offers its guests a unique atmosphere with Hanseatic charm and stylish elegance. The former coach house above Hamburg's Treppenviertel (lit. stairs quarter) forms an impressive setting for the traditionally appointed Süllberg ensemble. A hotel with an individual flair that in the course of the 1999-2002 renovation the 2-star chef … transformed into a shining spotlight of Hamburg's city history. … For family celebrations and larger events, the exclusive 5-star hotel offers a magnificent ballroom in an original art nouveau design … not centrally located, but nestled beautifully."

The event rooms are described as follows

"It is presumably very difficult to find more beautiful event rooms in Hamburg than those that the top gourmet and star chef … has assembled in his portfolio. Only on the Süllberg alone … can his team offer various rooms of various sizes and decor, all of which afford you a unique view of the Elbe. ..

It goes on:

… some of the most beautiful event rooms that exist in the Hanseatic city. "Rooms" is in fact the modest Northern German term."

The "ballroom" is described as follows:

"*The ballroom – a location with a history and a future*
Yes, it has history and yes, it is also true that it is original Art Nouveau architecture. But that doesn't mean that you can only celebrate historical costume parties in our ballroom. On the contrary! We believe this room is at least as appropriate for the present and the future. It can accommodate large Christmas parties and is available for company presentations; it is suitable for celebrating a personal anniversary or for tying the knot. For a really big event, there probably isn't a more beautiful location in Hamburg than right here - the ballroom high up on the Süllberg.

The location is just like the catering – simply the top.

With the ballroom on the Süllberg, it offers a location that is hard to surpass in terms of luxury, style and elegance. Everything here is also technically up to date; the location is thus not only recommended for private but also major business events. …"

The photos provided by the hotel on the website in this respect underscore the claim of *"luxury, style and elegance"* and cannot be reconciled with an "establishment where the business character is the main focus".

This assessment was more than confirmed by the on-site visit. Unlike the earlier cases the Arbitration Panel had to decide, e.g. the Spa House in Wiesbaden and the Royal Spa House in Bad Reichenhall, Hotel Süllberg takes on a very special quality, e.g. comparable to Brenners Parkhotel in Baden-Baden (cf. proceedings under Ref. 2015.4-470-75). On the one hand, this is due to its special location overlooking the Elbe River and embedded in a grand landscape of villas known for quietude and discretion, far away from the hectic of the city centre, and on the other hand owing to its exclusive interior design, expressed in terms of furnishings, decor (especially in the ballroom) and the generous use of space.

The luxury features are clearly the main focus, the conference opportunities not at all. Even the *"business-like row seating"* can do nothing to change this. It is obviously a conference venue that fulfils the criterion of "extravagance" within the meaning of the above-mentioned guideline.

The Arbitration Panel has no doubt that this overall impression already conveys a special attraction through the mere stay in the hotel, which is capable of unduly influencing healthcare professionals in their freedom of therapy and prescription.

There is no logical separation between the hotel, restaurant and ballroom: Both the ballroom on the one hand and the star restaurant on the other are directly adjacent to the reception area – albeit in different directions; both share the generous and spectacular view of the Elbe.

Most of the invited physicians would also presumably be familiar with this character of the conference venue, as it is already the 14th time that the event was organised in this way and the special features of the hotel would be known to many participants. It also follows from this that the choice of this venue creates an additional, unrelated incentive to participate in the training event, in order to (once again) enjoy the *"unique atmosphere with Hanseatic charm and stylish elegance"* on this occasion. This also applies even it if is acknowledged that the event has "tightly-scheduled program".

The fact that the invitation did not refer to the special exclusivity of the hotel does not play a significant role. For participants who have attended the event once or several times in previous years, this exclusivity is clear; for participants from the region who are taking part for the first time, it should be assumed in many cases that it is because of the reputation of the hotel and the restaurants.

On the other hand, Bayer rightly states objective reasons, which are to be taken into account by the Arbitration Panel in its overall assessment: The proximity to the organising clinic, the availability of a sufficiently large conference room, the tradition of an event, which now took place for the 14th time. Ultimately, however, these reasons cannot be given significant weight: In Hamburg, there are number of meeting rooms of comparable size. A necessity of the event's taking place in direct proximity to the hospital in Blankenese and not in the city centre or an adjacent district, for example, is neither demonstrated nor apparent. At best, the 14-year tradition could become considerable in combination with other relevant reasons, which are lacking here.

To the extent that the complainant takes a critical view of the type of hospitality, the Arbitration Panel does not follow this reasoning based on the facts presented. Coffee/tea and sheet cake, as well as a light meal at the end of the event, starting with a salad and two main dishes from the buffet worth a total of EUR 49 (including room rental and conference equipment) seem to be reasonable to the Arbitration Panel, even if the legal precedent of the Arbitration Panel is taken into account in exhausting the catering threshold for shorter events (cf. FS II 1/06/2005.9-90).

It was possible to leave unanswered the question as to whether this could apply even if the catering had been prepared by the star chef, because the Arbitration

Panel, following the arguments presented by the company, assumed that the catering was not carried out by the team of the star chef, but rather by separate chefs and service staff. Moreover, it was logically explained to the Arbitration Panel that the cuisine of the star restaurant could not be used for catering participants of the event already due to capacity reasons.

In the required overall assessment, the objective reasons stated, undue incentives, however, in order to come to the conclusion that the selection of the conference venue was made solely for objective reasons.

Outcome

After all this, the Arbitration Panel determined that Bayer Vital GmbH violated § 20 Section 5 Sentence 4 in connection with Section 3 Sentence 2 FSA Code of Conduct Healthcare Professionals, and ordered the company to refrain in the future from providing financial support to external training events for organisers if the selection of the conference venue was not based solely on the basis of objective criteria, as was the case in the event in question.

The company paid a fine of EUR 20,000 to Medica Mondiale e. V., Cologne.

Berlin, August/October 2018

Wording FSA Code of Conduct Healthcare Professionals

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

(3) Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue as well as the invitation of healthcare professionals must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason. Further, the companies are to avoid conference locations which are known for their entertainment value or are considered extravagant.

(5) Within appropriate limits, financial support for the organisers of external further training events is permissible. Member companies supporting external further training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place. Moreover, when providing financial support to external further training events, for the selection of the conference venue and for hospitality, the provisions concerning internal further training events shall apply mutatis mutandis. The presence of the participants, as well as the agenda of the event is not to be documented.

§ 20 Section 5 FSA Code of Conduct Healthcare Professionals

Sponsoring of a training event; "fair market value" of sponsoring

Ref. 2018-3-541

Principles

1. **An average fee of approximately EUR 1,200 for the speaker of a 30-minute presentation on a subject for which he is considered a "recognised specialist" would be difficult to reconcile with the principles of "fair market value".**

2. **§ 20 Section 5 Code of Conduct Healthcare Professionals requires the company to apply the Code's rules for internal events to external events as well, but this is expressly limited to the selection of the conference venue and catering. The Code of Conduct does not contain any comparable obligation of the companies for the amount of the speaker fees paid by the external organiser. § 18 Section 1 No. 6 Code of Conduct Healthcare Professionals does not apply mutatis mutandis.**

Facts of the case

The anonymous complaint is directed against the promotion of an external training event by a member company. The subject of the event focuses on current developments in pathology and therapy in a specific indication area. The complainant explained that the event was actually the company's own event, disguised as sponsoring. In any case, if genuine sponsoring was actually involved, the support of EUR 13,000 for a 3–3.5-hour event far exceeded the "fair market value" for sponsoring.

The company confirmed that it had supported the event with an amount of EUR 13,000. In exchange, the company was allowed a series of promotion opportunities, including setting up an information stand and the participation of 6 employees. The event would take place annually in the same format and be exclusively supported by only one company at a time. The company was said to have not supported this event in previous years. The company claimed the sponsoring sum was appropriate.

Further, the venue was claimed to be in accordance with the Code of Conduct, the catering had been in a socially adequate setting: a stand-up light meal with warm food after the event.

The company was said to have no influence on the agenda or the selection of speakers. The presenters were "recognised specialists" in the field of indication. Two of the four speakers were said to have already provided consulting services to the company.

According to the agenda, the event began at 4:00 p.m. with the arrival of the participants, followed by four presentations of 30 minutes each from 4:30 p.m., interrupted by a half-hour break. The schedule from 7:00 p.m. provided for the summarising discussion, farewell and a light meal. The organiser's budget plan submitted by the company essentially lists the catering costs at EUR 5,400 for approx. 90 participants (EUR 60 each) and the speakers' fees at EUR 4,800; it concludes with a total sum of EUR 13,000.

Essential grounds for the decision

According to § 20 Section 5 FSA Code of Conduct Healthcare Professionals, financial support provided to the organisers of external training events is basically permitted. Accordingly, (among other things), the requirements of § 20 Section 3 apply to the selection of the conference venue; in particular, the selection of the conference venue must be solely on the basis of objective criteria.

The selected venue and the catering offered, at a total value of EUR 60 per person, were also unobjectionable from the Arbitration Panel's perspective.

To the extent that the complainant assumes that the "event was actually [the company's] own" and was "disguised as sponsoring", this could not be confirmed by the facts presented to the Arbitration Panel. Specifically, the company stated that the type and content of the event had been managed solely within the organiser's scope of responsibility, without the company's cooperation. The documents submitted did not allow any other conclusion to the contrary to be drawn either. The complainant himself made no further substantiation for his allegation.

In any case, the Arbitration Panel did not see any confirmation of the other supporting allegation brought forth by the complainant, that at any rate, the "fair market value" was "far exceeded for a 3–3.5 hour event" for sponsoring in the amount of EUR 13,000.

The budget plan presented initially showed that the estimated costs were identical to the promised support. A special fee for the organiser was not listed, but was apparently included in the items contract and accounting, preparation of invitations, implementation, certification, follow-up (etc.). The amounts of just under EUR 2,000 budgeted for this purpose still seemed justifiable to the Arbitration Panel.

To the extent that speaker fees of EUR 4,800 (incl. travel expenses) were listed for four persons each giving a presentation of 30 minutes, the Arbitration Panel found this quite difficult to comprehend. The speakers had been described as "recognised specialists". It could therefore be expected from them that they would be very familiar with the latest developments in the indication area and that they would not need any significant preparation or follow-up for a short lecture – especially not if – as was the case with two of the speakers - they recently performed services for the sponsor in the indication area.

High travel costs of the speakers were to be excluded: Two of the speakers work at the same location, a third in the neighbouring town (less than 30 km away); only the fourth could have had a journey of roughly 300 km. As a result, this led to the assumption that the lecturers had received an average fee of approx. 1,200 EUR for a 30-minute presentation with a very limited, brief preparation time. In the view of the Arbitration Panel, this was hardly compatible with the principles of "fair market value".

However, this assessment did not lead to the determination that the company had violated the Code of Conduct. The Code's provisions with respect to the reasonableness of fees only apply if the company is the contractual partner of the speaker. That condition was not met in this case, as these contractual relationships were the exclusive responsibility of the organiser. While compliance with the provisions of the Code had been agreed upon between the company and the organiser, a (conceivably possible) breach of this obligation would at best lead to contractual claims by the company against the organiser, but it would not constitute a breach of the Code by the company.

After all, nothing different can be deduced from § 20 Section 5 Code of Conduct Healthcare Professionals. It requires the company to apply the Code's rules for internal events to external events as well, but this is expressly limited to the selection of the conference venue and catering. This does not include the provisions of § 18 Section 1 No. 6 Code of Conduct Healthcare Professionals

Outcome

The complaint was therefore unfounded. The proceedings were dismissed.

Berlin, June 2018

Wording 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 further training events is permissible. Member companies supporting external further training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place. Moreover, when providing financial support to external further training events, for the selection of the conference venue and for hospitality, the provisions concerning internal further training events shall apply mutatis mutandis. The presence of the participants, as well as the agenda of the event is not to be documented.

§ 20 Section 5 Sentence 4 in connection with Section 3 Sentence 2 et seq. FSA Code of Conduct Healthcare Professionals

Cancellation of Sponsorship of a Training Event at the Würzburg Residence

Ref.: 2018.7.-553

Proceedings dismissed: No financial support for training events by FSA member companies

A complaint by the FSA management against a member company that it had sponsored an event in the Würzburg Residence in the summer of 2018 proved to be unfounded. The company explained that it had withdrawn its original sponsorship commitment prior to the beginning of the event. The proceedings were therefore dismissed.

- The company was accused of having financially supported a training event at the Würzburg Residence. The complaint was based on the fact that the conference venue exceeded the scope of the Code of Conduct.
- The company had initially promised financial support approx. seven weeks prior to the event, but then revoked this promise eight days before the event.
- As § 20 Section 5 of the Code of Conduct to be applied only relates to financial support actually provided, the conditions by violation were not fulfilled.
- The question of the admissibility of this event was already the subject of reporting on the parallel proceedings in Ref. 2018.7-545-551.

Principles

The wording of § 20 Section 5 Code of Conduct refers to actually provided financial support of external training events and generally does not encompass cases in which a sponsoring promise is later withdrawn.

Facts of the case

The subject of these proceedings is the complaint by the management of the FSA that some member companies had sponsored the training event "8th Würzburg Training Symposium, Innovations from ... [followed by the indication area] 2018", which took place in the summer of 2018 in the Würzburg Residence. In the opinion of the

complainant, the conference venue did not uphold the setting prescribed by § 20 Section 5 in connection with Section 3 FSA Code of Conduct Healthcare Professionals (hereinafter referred to as: "Code"). Reference was made to the reporting on the parallel proceedings in Ref. 2018.7-545-551 on the FSA website.

In the proceedings at hand, the company pointed out that it had withdrawn its original commitment to support the event eight days before the date of the event, after it had reached the conclusion that the event did not comply with the Code.

It is undisputed that the company had initially promised to sponsor the event approx. 7 weeks prior to the date of the event and was mentioned as a sponsor in the invitation flyer and on the event website, but not on the board exhibited at the event, listing the sponsors. The naming as a sponsor occurred uninterrupted on the website even months after the event had taken place; it was still available there at the beginning of October 2018.

Against this background, one of the other sponsors of the event held the view that the member company had achieved a major promotional effect in connection with the event since the display/distribution of the flyers and was deliberately having the organiser promote the company without any contractual basis. From this it was concluded that the company had not done everything expected or possible to counter the false impression of the sponsoring activity and to "relinquish" the unjustly obtained promotional advantage.

Essential grounds for the decision

In the parallel proceedings mentioned above, the Arbitration Panel stated that it tends to regard the entirety of the event facilities chosen here as not becoming compliance with the Code due to their incentive character; the Arbitration Panel thus shares the company's view on the admissibility of the conference venue in this regard.

However, the Arbitration Panel also found that this assessment cannot be upheld for physicians from the region who typically refer their patients to the organiser's hospital. The incentive character mentioned is not significant for these participants. However, the Arbitration Panel had to leave open the question as to whether this assessment would have to be viewed in relative terms, in light of the fact that some of the participants were from outside the region, as it remained unresolved as to whether it only involved a few individual cases which, given that 130 people were participating, were not likely to be decisive. The Arbitration Panel therefore felt prompted to discontinue the parallel proceedings pursuant to § 11 Section 1 Sentence 3 Code of Procedure.

This assessment must be applied to the facts at hand here, in which the original sponsorship commitment was later revoked, so that here, too, there is no choice but to dismiss the proceedings.

Moreover, the wording of the provision of § 20 Section 5 Code refers to – actual – financial support for external training events. According to the arguments presented, however, the company "did not offer, promise or grant any advantages to the organiser, and in particular, did not grant any financial support to this external training event in accordance with § 20 Section 5 of the Code", but instead withdrew the promised support shortly before the event. This withdrawal is confirmed by the board displayed at the event, listing the sponsors. Therefore, the conditions of the rule were not met: There is no actual support within the meaning of Section 20 Section 5 of the Code.

The fact that the company has achieved a major promotional effect and, as the continued listing on the website suggests, did not ultimately take effective steps to eliminate this promotional effect, raises the question as to how this is consistent with the purported cancellation of the sponsorship commitment. After all, it is not clear why the company only withdrew its commitment to sponsor this event six weeks later and then immediately prior to the date of the event; it is also conspicuous that the sponsoring notice on the event website remained unchanged on the Internet months following the end of the event.

These facts are not covered by the wording of the provisions in Sections 3 and 4 of the Code, however. The Arbitration Panel did not examine whether an analogous application of the rules to the present case could be considered, since it was obvious that, in view of the uncertainty as to the origin of the participants, the only solution in any case was dismissal of the proceedings.

Outcome

The complaint was therefore unfounded. The proceedings were dismissed. The complainant did not make use of his right of appeal (§ 3 Section 1 No. 2 (a) FSA Code of Procedure).

Berlin, October/December 2018

Wording FSA Code of Conduct Healthcare Professionals

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

(3) Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue as well as the invitation of healthcare professionals must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason. Further, the companies are to avoid conference locations which are known for their entertainment value or are considered extravagant.

(5) Within appropriate limits, financial support for the organisers of external further training events is permissible. Member companies supporting external further training events must request that the financial support be officially disclosed by the organiser when the event is announced and when it takes place. Moreover, when providing financial support to external further training events, for the selection of the conference venue and for hospitality, the provisions concerning internal further training events shall apply mutatis mutandis. The presence of the participants, as well as the agenda of the event is not to be documented.

Violation of § 21 Section 1 FSA Code of Conduct Healthcare Professionals

here: VHF clinic discharge letter

Ref.: 2018.4-542

Template with product recommendation on a USB stick as a prohibited gift

The Arbitration Panel of the FSA ordered Bayer Vital GmbH (Bayer) to pay a fine of EUR 15,000 due to the prohibited pre-wording of hospital discharge letters containing product recommendations. The company had distributed corresponding templates on a USB stick to physicians. The complaint against Bayer was initiated by another member of the FSA.

- The templates contained therapy recommendations for patients after a hospital stay. Under the items, “Therapy recommendations for discharge” and “Further possible justifications for the use of (...)”, a pre-wording was provided on how a prescription of the drug should be worded as an argument against a “cheaper therapy recommendation”.
- The corresponding passage could then easily be copied into discharge letters. In this manner, the prescription of the Bayer drug was facilitated.
- The Arbitration Panel considered the distribution of the USB stick with the template of a discharge letter to be a violation of the prohibition on gifts in § 21 Section 1 FSA Code of Conduct.
- Following a warning by the Arbitration Panel, Bayer issued a statement of discontinuance in which it obliged in the future not to provide clinic physicians with pre-worded discharge letters as a WORD file containing product recommendations.
- Bayer also paid a fine of EUR 15,000 to the association “Helping the needy in Greece” (“Griechenland Hilfe, die ankommt e. V.”).
- The amount of the fine took into account the distribution of the stick and the economic significance of the drug.

Principles

1. **If the complaint is expressly limited to the content in a detachable part of promotional material, the Arbitration Panel generally has no leeway in terms of evaluating the remaining content of the promotional material with respect to its compatibility with the Code of Conduct.**

2. **If WORD templates with text modules are made available free of charge to healthcare professionals, the contents of which are predominantly and inevitably part of typical text modules and are known to the medical profession, these templates are comparable to normal clinical supplies, which the physician must keep in stock at all times anyway. As a rule, they are not subject to the exceptions in § 15a (cf. Q&A on § 15a and § 21, question 2).**

3. **If healthcare professionals are provided with additional components of an informational or training nature within the above-mentioned scope, giving the physician "bite-sized" pre-worded templates of what he would otherwise necessarily have to add and formulate himself, the time and effort thus saved may constitute a payment in kind which is no longer compatible with the prohibition on gifts in § 21 Section 1 Code of Conduct.**

Facts of the case

A member company complained to the Arbitration Panel that a member company, Bayer Vital GmbH (hereafter referred to as: Bayer), was distributing a USB stick to clinical physicians. The stick was said to contain a pre-formulated template (hereafter referred to as: template) in WORD format for a letter that had to be written by hospital physicians to general practitioners and/or patients as part of so-called "hospital discharge management". The complainant saw this as a violation of § 21 Section 1 FSA Code of Conduct Healthcare Professionals (hereinafter referred to as: Code).

Bayer confirmed the distribution of the stick and replied that essential elements of the letter were information on the drug and its indications, in particular the guideline recommendations. It was said to address topics essential for further treatment following a hospital stay, along with uncertainties about the correct dosage. The embedding of this information in the template was done to ensure that important content for the patient was given the best possible attention by the physician in private practice. Form letters with text modules for the creation of such discharge letters were said to exist in every hospital, but without this specific information.

Contrary to this, the complainant held the view that it was prohibited to assist the physician with respect to his duties to inform and document towards his patients using tools relying on general text modules and templates already available elsewhere, even if in the process, indication and/or product-related medical and scientific information were included. The fact that the template of the discharge letter was provided in a WORD template, which can be processed and used quickly and practically at any clinic or physician's PC via the USB stick, was said to underscore

the fact that Bayer is was also concerned with relieving the workload of healthcare professionals, which, however, falls under the prohibition on gifts.

The complainant company provided the Arbitration Panel with an original stick, the review of which revealed that, in addition to the template subject to the complaint, the stick contained a series of animations on the pathology and mode of action of a substance, as well as two patient films that explicitly address the use of a Bayer preparation and also showed original packages.

The complainant specifically did not base the complaint on the fact that the stick, which had a capacity of 2 GB, contained further information in addition to the template.

Essential grounds for the decision

According to § 21 Section 1 Code, it is not permitted to promise, offer or grant gifts to healthcare professionals. A USB stick can also represent such a gift.

However, § 15a Section 1 No. 1 Code and the Q&A on § 15a and § 21 as amended on 30 May 2014, make it clear that healthcare professionals may be provided with information and training materials if they are of low value, have direct bearing on the professional practice of the healthcare professional and are closely related to patient care. Guideline 3.4 of the FSA Board further explains that such information and training materials can also be provided on digital media (e.g. a USB stick).

After the complainant expressly limited the subject of the complaint to the template of the "clinic discharge letter", there was no leeway for the Arbitration Panel to evaluate the remaining content of the stick with respect to its compatibility with the Code of Conduct.

The "clinic discharge letter" template as part of the stick was therefore to be examined independently within the framework of § 21 Section 1 Code. In doing so, the Arbitration Panel began by referring to consistent rulings stating that the exceptional circumstances of § 15a Code must be interpreted narrowly (cf. Ref. 2017.4-521).

a) Among other things, the template contained a series of patient-specific information that reflected the requirements of § 9 Section 3 of the Framework Agreement on Discharge Management when transitioning into private practice after hospital treatment according to § 39 Section 1a p. 9 German Social Book (SGB) V. These contents of the template correspond to the mandatory contents specified in § 9 Section 3 Framework Agreement. They are predominately and

inevitably a component of typical templates with text modules for the preparation of these types of discharge letters and are known to healthcare professionals.

These types of documents are comparable to typical practice supplies, which the physician has to keep constantly available anyway. They are not subject to the exceptions in § 15a Code (cf. Q&A on § 15a and § 21, question 2) and therefore violate the prohibition on gifts in § 21 Section 1 Code of Conduct.

b) However, the pre-written text on the stick went beyond the usual information prescribed in the framework agreement to the extent that, in the section "Therapy recommendations for discharge", it makes a suggestion on how to word the recommendation for further prescription of the drug. This additional content could be regarded as product-related and safety-relevant information about the product and could therefore fall under the privileged treatment of § 15a Section 1 No. 1 Code. With this recommended wording, it would appear that the aim (is also) to ensure continuous prescription of the drug, because according to § 115c Social Code Book (SGB) V, the hospital physician would primarily be called upon to make a different, more economical therapy suggestion to the physician in private practice. This "assistance" is further supplemented by the passage, "Additional possible justifications for the use of (...)" on page 2 of the template, which demonstrates other conceivable patient groups who would presumably constitute medically justified exceptions as defined by § 115c Social Code Book (SGB) V.

To the extent that these components are merely of an informational or training nature, they could be privileged by § 15a Section 1 No. 1 Code. However, the specific format of the presentation goes beyond the narrow framework privileged by § 15a Section 1 No. 1 Code.

With the "Therapy recommendations for discharge" and "Further possible justifications for the use of (...)", pre-formulated text is "bite-sized" to the physician, showing him how to argue for continuous prescription of the drug instead of a "cheaper therapy recommendation" and how to write the letter himself. However, this would be associated with a certain amount of effort for him. The method offered to the physician by the template is far more "economical" because it saves him time and effort, and gives the company the confidence that the further prescription of its drug will also be made by the physician in private practice.

This assistance is ultimately optimised by the fact that these elements are provided as a pre-worded template as a file, which can be easily copied from on WORD document to another. This format seems to suggest that the above-described work facilitation for the clinical physician is the main focus.

Thus, this part of the template represents a payment in kind to the clinic physician, which goes beyond the privileged materials according to § 15a Section 1 No. 1 Code and is therefore – just as the contents under a) – no longer compatible with the prohibition on gifts spelled out in § 21 Section 1 Code.

Only as a supplement, the Arbitration Panel noted that the "Therapy recommendations on discharge" could also influence the physician's individual prescription recommendation, which may not be readily compatible with § 6 Section 1 No. 1 Code.

Outcome

The Arbitration Panel considered the distribution of the USB stick with the template of a discharge letter to be a violation of the prohibition on gifts in § 21 Section 1 FSA Code of Conduct.

Following a warning by the Arbitration Panel, Bayer Vital GmbH issued a declaration of discontinuance in which it obliged in the future not to provide clinic physicians a pre-worded discharge letter for physicians in private practice as a WORD file, as was the case here with the USB stick subject to the proceedings.

Bayer Vital GmbH also paid a fine of EUR 15,000 to the association "Helping the needy in Greece" ("Griechenland Hilfe, die ankommt e. V."). The amount of the fine took into account the scope of distribution of the stick and the economic significance of the drug.

Berlin, August 2018

Wording FSA Code of Conduct Healthcare Professionals

§ 21 Gifts

(1) It is prohibited to promise, offer or grant gifts to healthcare professionals. This applies irrespective to product-related or non-product-related advertising.

§ 20 Section 2 Sentence 2, Section 3 Sentence 1 FSA Code of Conduct Healthcare Professionals in conjunction with Guideline 11.4 Sentence 2

Delivery of 0.33 l water bottles to a convention stand

Ref.: 2018.6-544

Water bottles with a company logo represent appropriate hospitality

The FSA Arbitration Panel rejected as unfounded a complaint in which the "active distribution" of water bottles with a company logo during a convention was depicted as inadmissible.

- At a convention in April 2018, water (0.33 litter bottles with a printed company logo) was distributed free of charge to healthcare professionals at the stand of an FSA member company.
- The complainant raised the allegation that the water bottles had clearly not been intended for consumption directly at the stand, but as free hospitality to take away. It was claimed that this constituted an inadmissible incentive to visit the stand. In addition, hostesses actively distributed the water bottles – even to guests who were not visitors to the stand.
- According to Guideline 11.4 Sentence 2, which specifies § 20 Section 2 Sentence 2 and Section 3 Sentence 1 FSA Code of Conduct Healthcare Professionals, catering at convention stands of external training events is permitted within appropriate bounds. This typically includes bottled water (Guideline 11.4.2).
- In addition, the FSA decided that the 0.33 litter volume was unobjectionable and socially acceptable.
- Whether the member company had actively distributed water bottles through hostesses, as claimed by the complaint, or had only actively distributed flyers through its hostesses, could not be resolved with sufficient certainty.
- The complaint was therefore unfounded. The proceedings were dismissed.

Principles

1. **The distribution of water bottles with a volume of 0.33 l generally complies with the scope of Guideline 11.4, Sentence 2.**
2. **If the guideline speaks of delivery "to convention stands", this is not to be construed in such a restrictive manner that if a visitor doesn't finish his beverage, he has to stay at the stand until the glass is empty, or as an alternative, to pour what is left down the drain; he may also take the drink with him to other stands.**
3. **Adequate hospitality may also be provided if the food and beverages presented are not "open" but are distributed in a pre-packaged form.**
4. **The labelling of pre-packaged small foods or beverages with the company logo is generally permitted (cf. Q&A on § 15a and § 21 FSA Code of Conduct, question 17).**

Facts of the case

The Arbitration Panel received a complaint that at a convention in April 2018, a member company was giving out 0.33 l water bottles at his stand free of charge to healthcare professionals visiting the industry exhibition of the convention. The bottles were covered with a large taped sleeve prominently displaying the company's logo, and subject to a deposit.

In the complaint, it was further explained that the water bottles had been handed over by hostesses on the stand, actively like flyers, to be taken with them and not only to persons who were at the stand. Due to the prominent labelling with the company logo, visitors had also become aware of their being distributed, which they had not yet noticed in passing.

The complainant raised the allegation that the water bottles had clearly not been intended for consumption directly at the stand, but as free hospitality to take away. For immediate consumption, consumption quantities of 0.2 l were also more customary.

It was claimed that giving out water bottles constituted a prohibited incentive to visit the stand; it involved a prohibited item for free distribution.

The company replied that it had not actively handed anything out, nor had the hostesses; they were only handing out flyers. It claimed that the filling volume was not objectionable. The purchase price of the bottles was said to be EUR 1.01; the bottles were not covered by a deposit. A portion of the empty bottles was said to have been disposed of at the stand.

Essential grounds for the decision

According to Guideline 11.4 Sentence 2, which specifies § 20 Section 2 Sentence 2, Section 3 Sentence 1 FSA Code of Conduct Healthcare Professionals, catering at conference stands of external training events is permitted within appropriate bounds. This typically includes water (Guideline 11.4.2).

In the present case, it was not the delivery of water per se that was contested, but the quantity of 0.33 l and the form, i.e. the "active handing out" of PET bottles prominently labelled with the manufacturer's logo. Neither the Code of Conduct nor the Guidelines contain any further clarifications in this respect; they merely refer to catering "at congress stands".

The quantity of 0.33 l corresponds to the filling volume of a large water or juice glass. The Arbitration Panel can attest, based on its own experience, that this quantity can easily be drunk during a short conversation, especially when climatic conditions make people thirsty. But even if a participant goes from one stand to the next, holding a drink from the previously visited stand, this does not go beyond the appropriate bounds prescribed by the Code of Conduct and the Guidelines.

If the guideline speaks of a handout "at convention stands", in the view of the Arbitration Panel, this is not to be construed in such a restrictive manner that if a visitor doesn't finish his beverage, he has to stay at the stand until the glass is empty, or as an alternative, to pour what is left down the drain. That would not be socially adequate.

It was not evident based on the facts that the bounds in this case had been exceeded to any excessive degree; in particular, the allegation of "active distribution" had remained disputed, so that the Arbitration Panel saw no basis for claiming the company did it.

From the perspective of the Arbitration Panel, the form was also unobjectionable. Whether reasonable hospitality requires offering "open" foods and beverages or also permits pre-packaged items is not explicitly delineated in the Code of Conduct and the Guidelines. From the point of view of the Arbitration Panel, however, the "appropriate" bounds on which the statute is based is maintained even if pre-packaged beverages or small foods such as snacks, bars, etc. are delivered. Based on the commonplace practice of many consumers these days of carrying small water bottles and/or small sweets with them, it can be concluded that the form chosen here is also quite customary and socially adequate.

This is not affected by the labelling with the company logo. The use of company and product logos on giveaway items is a frequently used practice which has been expressly permitted in certain cases (Guidelines 3.4, 3.9; Questions 14 and 17 of the Q&A on § 15a and § 21 FSA Code of Conduct). For coffee cups, the Q&A on § 5a and § 21 FSA Code contain a specific assessment in Question 17. The Arbitration Panel did not see any basis for assuming that the application of a company logo on a water bottle intended for catering would be assessed more strictly.

Outcome

The complaint was therefore unfounded. The proceedings were dismissed.

Berlin, July/November 2018

Wording FSA Code of Conduct Healthcare Professionals

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

(2) The company may only pay reasonable travel and accommodation costs for the invited physicians, if the job-related, scientific character of the in-house training event clearly takes centre stage. During such training events, reasonable hospitality arrangements for the participants are also possible. However, the company must neither finance nor organise any entertainment- and leisure time programs of the participants (e.g. theatre, concert or sports events). The actual participation of the invited persons and the event program must be documented.

(3) Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue as well as the invitation of healthcare professionals must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason. Further, the companies are to avoid conference locations which are known for their entertainment value or are considered extravagant.

Guidelines by the FSA Board of Management

11.4 According to Section 20 Subsection 2 Sentence 2 of the Code a “reasonable hospitality arrangement” may be provided to participants of in-house training events. Within the bounds specified below, this also applies to the hospitality at conference stands of external training events.

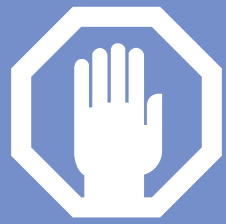
As the main purpose of the convention stand is to provide information on the company’s products, indications and areas of research, hospitality should clearly play a secondary role and should not constitute an independent incentive to visit the stand.

Appropriate refreshments are typically hot beverages such as various types of coffee, tea, cocoa, as well as non-alcoholic beverages such as soft drinks and water. An additional selection of drinks such as non-alcoholic beer, freshly pressed fruit juices, fruit juice cocktails, etc. exceeds these bounds.

Cookies, sweets, small muffins, mini sheet cakes, pieces of cut fruit, or basic sandwiches or open-faced rolls served with cold cuts are deemed appropriate. Warm meals such as waffles, tarte flambée, spring rolls, pastry finger foods, popcorn, wieners, small schnitzel or desserts such as ice cream, red fruit pudding, exceed these bounds.

Not appropriate is “extravagant” hospitality that, due to the decoration and set-up, creates the impression that the experience character is intended to take precedence over an opportunity to engage in a professional discussion.

The staffing of a convention stand with a bartender or a chef suggests extravagance.



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