IPCAA COUNTRY CODE UPDATE
WEBINAR
SPOTLIGHT ON: GERMANY

Holger Diener
Managing Director FSA
Outline

I. FSA – Short Overview

II. Events

III. Transparency
I. FSA – Short Overview

- The Association of Voluntary Self-Regulation for the Pharmaceutical Industry ("FSA") was founded in 2004 by 39 Pharmaceutical Companies

Membership is possible to all Pharmaceutical Companies

- 56 Pharmaceutical Companies
- 25 Dependant Companies

Membership cover over 75% of the total Turnover with prescription-only Products in Germany
I. FSA – Short Overview
I. FSA – Short Overview

Structure of the FSA

Office / Arbitration Chamber

Consultancy - Surveillance / Sanctions

Codes of Conduct
Outline

I. FSA – Short Overview

II. Events

III. Transparency
II. Events - Hospitality

Section 22 FSA HCP Code: Hospitality

1) Hospitality is only permissible during in-house training events and work lunches/dinners to a reasonable and socially acceptable extent. The occasion for such a work lunch/ dinner must be documented. Hospitality for companions is not permissible.

(…)

The board of management of the FSA may also issue binding guidelines according to § 6 para. 2 on the interpretation of the term “reasonable”.
II. Events - Hospitality

Guidelines of the FSA Board

17.2 A payment for hospitality is "reasonable" and does not exceed "reasonable bounds" if it is socially acceptable. An amount of roughly EUR 60.00 is a benchmark for what is still considered a reasonable hospitality arrangement in Germany, under consideration of price increases and the value-added tax increase since the Code of Conduct took effect in 2004 (effective: July 2008).

17.3 For catering carried out by a catering company, the amount specified under clause 17.2 applies only to food and drinks, but not to other miscellaneous costs of catering.
II. Events - Hospitality

Case 2016.1-495


https://www.karlheinzhauser.de/deck-7/
## II. Events - Hospitality

### Thresholds for Meals & Drinks

Based on information provided by EFPIA Members Associations

<table>
<thead>
<tr>
<th>Country</th>
<th>Value for Lunch (€)</th>
<th>Value for Dinner (€)</th>
<th>Value per Meal (€)</th>
<th>Value per Day (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td></td>
<td></td>
<td>Lower than 75 € incl. VAT and/or charges &amp; gratuities</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>40 € incl. VAT for events taking place over several days (subject to visa procedure) 20 EUR/h with a maximum of 40 € for stand-alone events</td>
<td>80 € incl. VAT for events taking place over several days (subject to visa procedure) 20 EUR/h with a maximum of 80 € for stand-alone events</td>
<td></td>
<td>The maximum hospitality of 40 € (lunch) and 80 € (dinner) can only be offered if the programme includes at least 6 hours of scientific activities.</td>
</tr>
<tr>
<td>Bulgaria</td>
<td></td>
<td></td>
<td>100 levs (50*%) incl. VAT</td>
<td></td>
</tr>
<tr>
<td>Bosnia and Herzegovina</td>
<td></td>
<td></td>
<td>Up to the maximum amount of BKn 100 (51*%) per person and a meal; and this form of hospitality must be restricted to refreshments and/or food and beverages during the Meeting</td>
<td></td>
</tr>
<tr>
<td>Croatia</td>
<td></td>
<td></td>
<td>500 HRK (65*%)</td>
<td></td>
</tr>
<tr>
<td>Cyprus</td>
<td></td>
<td></td>
<td>70 € ex. Tax &amp; gratuities</td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td>&lt; 6 hours of scientific activities: 1500 CZK &lt; 6 hours of scientific activities: 800 CZK (11*%) incl.</td>
<td>&lt; 6 hours of scientific activities: 1500 CZK (11*%) incl.</td>
<td>≥ 6 hours of scientific activities: 3000 CZK (11*%) incl. VAT</td>
<td>≥ 6 hours of scientific activities:</td>
</tr>
</tbody>
</table>
II. Events – Individual Sponsorship of HCPs

Section 22 FSA HCP Code: Hospitality

(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 center 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.
II. Events – Individual Sponsorship of HCPs

Guidelines of the FSA Board

9.11 Support of healthcare professionals is precluded, particularly if
(a) they have been promised by employees in the sales and marketing department of the company that costs would be assumed, without prior involvement in the decision by the medical department of the company or by the company department otherwise responsible (see below clauses 9.13 and 9.14);
(b) in association with cost assumption by the company, they have referred directly or indirectly to their therapy, prescription or sourcing decisions or have promised them as a quid pro quo for these decisions, and/or have not ensured that the selection of the participants is not made based on sales-related parameters (e.g. relationship between volume of prescription/patient numbers);
(c) they have not submitted the required written documents, e.g. employer approval for hospital physicians, a declaration of consent or proof that the administration or employer or fulfilled the conditions of the employer or institutions for acceptance of support prior to the beginning of the further training event as planned.
II. Events – Individual Sponsorship of HCPs

Guidelines of the FSA Board

9.12 Residual risks can be minimized, for example, through

(a) support of further training events limited per healthcare professional for a certain period and to a particular number;
(b) a maximum amount for support of a healthcare professional per year, which, if exceeded, either precludes the support of participation or only allows it under the condition of cost participation of the healthcare professional;
(c) having healthcare professionals participate in overall costs (registration fee, travel, and/or accommodation costs), e.g. (i) by way of a percentage cost participation in overall costs or (ii) through assumption of a specific portion (such as the registration fee and/or travel costs);
(d) an overall budget for support of further training events, from which the support of healthcare professionals is paid countrywide, instead of regional budgets. In doing so, the budget responsibility lies in the medical department and not with sales and marketing.
(e) the companies’ entrusting independent bodies with the selection of suitable further training events, as well as possible participants for a particular further training event.
II. Events – Sponsorship of third party events

Article 20 FSA HCP Code

(5) Within appropriate limits, financial support for the organisers of external further training events is permissible. However, entertainment programs are not allowed to receive financial support or donations, nor are they allowed to be organized. **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, the provisions shall apply mutatis mutandis towards in the selection of the conference venue and the hospitality. The presence of the participants, as well as the agenda of the event are not to be documented.
II. Events – Sponsorship of third party events

Offenlegung des Sponsorings der FSA-Mitgliedsunternehmen nach §20 Abs. 5 Satz 3 des FSA-Kodex

AMGEN GmbH
71.625,00 € für einen Ausstellungsstand und ein Symposium

Astellas Pharma GmbH
21.000,00 € für einen Ausstellungsstand

AstraZeneca GmbH
117.750,00 € für einen Ausstellungsstand und zwei Symposien

B.Braun Melsungen AG
13.600,00 € für einen Ausstellungsstand

Baxalta Deutschland GmbH
62.500,00 € für einen Ausstellungsstand und ein Symposium

Baxter Deutschland GmbH
35.925,00 € für einen Ausstellungsstand und ein Symposium

Bayer Vital GmbH
39.000,00 € für einen Ausstellungsstand

Boehringer Ingelheim Pharma GmbH & Co. KG
88.625,00 € für einen Ausstellungsstand, den Anzeigen in den Druckmedien des Krebsforums

Bristol-Myers Squibb GmbH & Co. KgAA

II. Events – Sponsorship of third party events

Article 20 FSA HCP Code

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FSA Case (2015.4-470)

https://www.fsa-pharma.de/de/schiedstelle/berichterstattung/fachkreise/az-2015.4-470-75-20-abs-3-bis-6-fsa-kodex-fachkreise-externe-fortbildungsveranstaltungen-angemessenheit-des-sponsoring-sp/
II. Events – Sponsorship of third party events

"At the training in Baden-Baden participants met in the five star hotel. Who was allowed to talk as speaker and about what the sponsors suggested.

(…)

"That this was effectively a pharmaceutical event, everyone has probably seen this," writes one of the speakers on request incensed.

(…)

The companies also paid generously. E.g. over 6 000 Euros for a 30 Minutes talk plus 15 minutes discussion as well as 100 free tickets and one small exhibition booth.

II. Events – Sponsorship - Venue

examples of recent cases

Kurhaus Wiesbaden – Wikipedia
dc.wikipedia.org

Das Königliche Kurhaus Bad Reichenhall
bad-reichenhall.de

examples of other venues under discussion

dc.wikipedia.org

Die Zeche Zollverein im Wandel der Zeit - Alte ...
dw.com
II. Events – Sponsorship of third party events

EFPIA Codes Consolidation

ARTICLE 10 EVENTS AND HOSPITALITY

Section 10.01. All Events must be held in “appropriate” Locations and Venues that are conducive to the main purpose of the Event, avoiding those that are “renowned” for their entertainment facilities or are “extravagant”.

II. Events – Sponsorship and non HCPs

- **Section 10 FSA PO Code**

  **Observance of promotional restrictions**
  Member companies must observe all applicable legal restrictions concerning the promotion of prescription-only pharmaceuticals (in particular Section 10 of the German Advertising in the Health Care System Act (HWG)).

- **Section 10 German Act on Drug Advertising (“Heilmittelwerbegesetz”)**

  1) Prescription medicines may only be advertised to **doctors, dentists, veterinarians, pharmacists and persons who are legally allowed to trade in these medicines.**
II. Events – Sponsorship of third party events

„Role of the industry in medical education“
Outline

I. FSA – Short Overview

II. Events

III. Transparency
III. Latest News on the FSA Code of Transparency

Transparency Code from FSA and vfa

Effective: June 24, 2019

56 pharmaceutical companies, covering 75% of the German market for prescription medicines, are publishing their payments made to:

- Physicians
- Healthcare professionals
- Medical organizations
- Medical institutions

64.6% for research & development for carrying out clinical studies and non-interventional studies (approx. EUR 413 mill.)

16.6% to institutions for the support of events, donations and endowments (approx. EUR 120 mill.)

18.8% to individuals for seminars and lecture fees (approx. EUR 106 mill.)

© The “Association of Voluntary Self-Regulation for the Pharmaceutical Industry” (FSA – Freiwillige Selbstkontrolle für die Arzneimittelindustrie) and the Association of Research-based Pharmaceutical Companies (vfa – Verband forschender Pharma-Unternehmen)
III. Latest News on the FSA Code of Transparency

„Transparency provides clarity“
III. Latest News on the FSA Code of Transparency

Patients must be able to trust their physicians. We ensure that the cooperation between physicians and the industry is transparent.

© FSA

https://twitter.com/fsa_pharma?lang=de
III. Latest News on the FSA Code of Transparency

IHR BEITRAG FÜR MEHR TRANSPR
In the view of FSA Managing Director Holger Diener, the increasing number of physicians consenting to being mentioned by name shows "that the Transparency Code has become established in the healthcare field". He continued to advocate for the greatest possible support by physicians.
III. Latest News on the FSA Code of Transparency

21 percent of the physicians consent to being mentioned by name

FSA Managing Director Holger Diener indicated he was pleased that the share of physicians consenting to being mentioned by name has increased slightly from 20 to 21 percent. The FSA rejects a Physician Payments Sunshine Act modeled after the United States, as called for by the Drug Commission of the German Medical Association.

The FSA’s work already enables extensive self-regulation. That is why in the view of the FSA, there is said to be no need for any additional regulatory restriction in what is already a complex and heavily-regulated market for pharmaceutical products.

III. Latest News on the FSA Code of Transparency

Only on the receiving end – among physicians themselves – the transparency initiative doesn’t seem to be taking root. But why so much reticence? The argument that patients could become scared off due to public disclosure does not hold water. The contrary is the case, they are frightened off when non-transparent business practices are exposed. Each and every physician can safeguard against this.

https://www.aerztezeitung.de/politik_gesellschaft/arzneimittelpolitik/article/991096/kommentar-transparenzinitiative-luft-nach-oben.html
Questions
Diskussion/Fragen

Holger Diener
Managing Director

Freiwillige Selbstkontrolle für
die Arzneimittelindustrie e.V.

www.fsa-pharma.de

Grolmanstr. 44-45, 10623 Berlin
Tel. 030 / 88728 – 1700
Fax 030 / 88728 – 1705

h.diener@fsa-pharma.de