(Updated on: July 13, 2016)

Q&A on the FSA Code of Conduct on Transparency of Collaboration with Healthcare Professionals

Outline

Chapter 1: General provisions

Section 1 Scope

1. **Question**: EFPIA Question ((Question 1.02-2, Consolidated FAQ (19.12.2014), (FINAL Q&A (13.11.2013); former Section 1.02) (Batch 2 Q. 4): Does the FSA Transparency Code also apply to the disclosure of payments in the areas of medical devices, diagnostics and products that are not prescription-only medicinal products that member companies have in their portfolio?

Answer: The aim of the FSA Transparency Code is to disclose transfers of value connected with prescription-only medicinal products within the meaning of section 48 of the German Medicinal Products Act (AMG).

In light of the above, the following transfers of value do not in principle have to be disclosed:

- payments connected exclusively with OTC products;
- collaborative arrangements not covered by section 7 of the FSA Transparency Code;
- payments connected with the purchase and sale of medicinal products (section 1 para. 2 of the FSA Transparency Code).

In cases where transfers of value are connected both to prescription-only medicinal products and to other products (such as a combination of a medical device and a medicinal product or various medicinal products with a different prescription status), should the entire payment amount be disclosed in order to ensure the broadest possible transparency (because even the physician may have problems distinguishing between these). It is recommended that member companies discuss in detail how such situations are dealt with as part of the notices on the methodology used to collect and disclose information about payments (section 13 of the FSA Transparency Code).

2. **Question**: How are medical devices treated within the context of "research and development"? Are they also categorized as "research and development" and disclosed on an aggregate basis? How are "mixed activities" reported, for example where medicinal products and medical devices are provided in combination?

Answer: Where research work is focused exclusively on medical devices, the Transparency Code does not apply. The Code applies only to the recording and

disclosure of transfers of value by member companies connected with prescription-only medicinal products pursuant to section 48 AMG. If research activities involve both medicinal products and medical devices, the payments must be disclosed on an aggregate basis if the specific research activity is covered by the definition in section 6 sentence 1 item 1. If this is not the case, the name of the recipient must be disclosed explicitly.

3. **Question:** Does a payment for a lecture/event dedicated 100% to medical products require disclosure?

Answer: Because the FSA Transparency Code only pertains to cooperation in relation to prescription-only medicinal products, payments of this nature (also those involving OTC products) generally do not require disclosure. However, this requires an individual assessment as to whether there is a connection - perhaps only indirectly - to prescription-only medicinal products.

4. **Question**: EFPIA Question (EFPIA 2nd Batch Q&A no. 6): How should member companies that manufacture both prescription-only medicinal products and OTC products and/or medical devices under the same organizational structure handle the disclosure? Can the company also voluntarily disclose other benefits in kind (for example, in relation to OTC products) even if this is not required by the FSA Transparency Code?

Answer: Every FSA member company must ensure that the disclosure complies with the requirements of the FSA Transparency Code. However, the Code also permits transparency that exceeds the required information. If a company decides to disclose additional transparency information, this should be explained in detail in the notices summarizing the methodology used.

5. **Question**: EFPIA Question (FINAL Q&A (13.11.2013); 8th question (Section 2.05) (Batch 1 Q. 15): Where should the collaboration with a German healthcare professional be disclosed if the collaboration and/or the actual work takes place in another country?

Answer: According to the FSA Transparency Code, payments to "European" recipients, i.e., healthcare professionals and organizations, must be disclosed. The member company must disclose collaboration with a German recipient in Germany.

This applies regardless of which country the specific work is performed in (even if it is outside Europe).

If a member company collaborates with a European healthcare professional who is not based in or whose full-time work is not performed in Germany and/or a European healthcare organization whose (main) registered office is outside Germany that provides transfers of value, then pursuant to section 7 para. 7, this collaboration must be disclosed in the respective "European" country in accordance with the applicable code in that country, either by an affiliated company of the member company or by the member company itself. This is intended to ensure that patients or other interested stakeholders in these countries are able to find this information easily. Healthcare professionals and organizations must use business addresses to identify the respective collaborative partners.

Every FSA member company should explain how cross-border payments are disclosed in detail in the notices summarizing the methodology used.

Examples:

- The German FSA member company signs an agreement with an Italian physician under which the Italian physician will deliver a lecture in Brazil. The payment of the lecture fee and other payments (i.e., for travel and accommodation expenses) must be disclosed in Italy, either by a company affiliated with the FSA member or - if no Group company is located there - by the FSA member itself.

- An Italian Group company collaborates with a German physician. This collaboration must be disclosed in Germany by the Group's FSA member company with operations in Germany. The Italian company affiliated with the FSA member (subsidiary or affiliate) must transmit the relevant information to the German FSA member in Germany. This obligation is derived from the Italian Transparency Code and/or directly from the EFPIA Transparency Code.

- An FSA member company collaborates with an American doctor on an advisory board. Under the FSA Transparency Code, this collaboration does not have to be disclosed. However, there may be a disclosure requirement under the relevant U.S. laws (in particular, the Physician Payments Sunshine Act).

6. **Question**: EFPIA Question ((Question 2.05-3, Consolidated FAQ (119.12.2014), (FINAL Q&A (13.11.2013); 9th question (Section 2.05) (Batch 2 Q. 8): A subsidiary or affiliate of an FSA member collaborates with a German healthcare professional. Under the FSA Transparency Code, such collaborative arrangements must be disclosed in Germany. Who would be liable for a failure to disclose such collaboration, and under what conditions?

Answer: The relevant information must be transmitted to the FSA member by the company that is affiliated with the FSA member (subsidiaries or affiliates). This obligation is derived from the Transparency Code in force there and/or directly from the EFPIA Transparency Code. The FSA company is then obliged to ensure that the information sent to it by the affiliated foreign company is disclosed in compliance with the Code. If such information is not transmitted, the FSA member's failure to disclose may, under certain circumstances, not constitute an infringement of the Code. Whether the foreign company has violated the Code due to its failure to transmit or due to insufficient transmission of information will depend on the respective national Code passed to implement the EFPIA Disclosure Code in the respective country.

7. **Question**: EFPIA Question ((Question 2.05-6, Consolidated FAQ (1.12.2014), (EFPIA 2nd Batch Q&A no. 10) (Section 2.05): Are non-European companies - such as the U.S. corporate headquarters of a Group - required to disclose transfers of value to healthcare professionals or organizations in Europe?

Answer: Pursuant to section 1 para. 1 of the FSA Transparency Code, it applies to the disclosure of collaboration of member companies and their domestic subsidiaries and other affiliated companies if these affiliated companies have recognized the binding nature of the FSA Transparency Code in a separate written agreement. The FSA Transparency Code does not provide for any further strict and worldwide liability for infringements by a Group company (non-disclosure of a relevant cooperative arrangement in Germany) without the knowledge or approval of the direct FSA member. After an in-depth legal review of German law governing associations, the implementation of a corresponding requirement in the EFPIA Disclosure Code as a mandatory provision was not included. Nevertheless, a company may voluntarily submit to such an obligation. The EFPIA is currently reviewing whether such a requirement can be implemented at European level in the form of voluntary declarations of submission by the respective parent companies.

If a non-European member company of the Group collaborates with a German healthcare professional and/or an organization based in Germany and such

collaboration was not made transparent in Germany, the German FSA member cannot - at least currently - be held accountable.

8. **Question**: EFPIA Question (2nd Batch Q. no. 34) (Section 1.02 / Section 1 II): According to section 1 para. 2 of the FSA Transparency Code, it applies to the recording and disclosure of member-company transfers of value that are connected with prescription-only medicinal products pursuant to section 48 AMG. Does this mean that transfers of value made exclusively in connection with OTC products are excluded from the scope of the Transparency Code?

Answer: Yes. However, in this regard, the comments in Questions 1 and 2 should be taken into account.

9. **Question:** Does a payment for a lecture/event with no connection to a product require disclosure?

Answer: The FSA Transparency Code expressly requires no connection to a product (for instance involving invitations to further training events, etc.). That is why the connection to a product does not per se mean there is no duty to disclose.

10. **Question:** EFPIA Question ((Section 1.02-4, Consolidated FAQ (19.12.2014), Are testing substances and biological samples required to be disclosed for a study?

Answer: Because samples of medicinal products are exempted from the duty to disclose, the identical considerations shall also apply for the above-mentioned products, especially because they generally fall within the area of application of the guideline on clinical tests.

Section 2 Definitions

Paragraph 1 – "Healthcare professionals"

11. **Question**: Must a contract with Health Insurance Fund employees also be disclosed?

Answer: According to section 2 para. 1, healthcare professionals also include employees of public authorities or employees of the funding organizations who are responsible in those positions for prescribing, buying, delivering, reimbursing or administering the medicinal products. If Health Insurance Fund employees perform this work, any contract with such contractual partners must likewise be disclosed.

The Health Insurance Fund employees responsible for tendering discount agreements would be an example of such employees.

12. **Question**: EFPIA Question ((Definitions – 2, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 57) (HCP): Does the FSA plan to draw up a list of all the occupational groups and activities that fall under the definition of healthcare professionals within the meaning of the FSA Transparency Code?

Answer: Because of the large number of professions in the healthcare field, it is impossible to provide an exhaustive list and evaluation. Therefore, member companies must in each specific case check whether the respective collaborative partner falls under the definition of healthcare professional and must therefore be disclosed or not.

13. **Question:** Are diabetes advisers and MS nurses considered HCPs?

Answer: To the extent that they use or dispense prescription medicines, yes.

Paragraph 2 – "Organizations"

14. **Question**: Do Health Insurance Funds fall under the definition of "organizations" in section 2 para. 2 if the payment is made directly to the Health Insurance Fund as part of a sponsorship?

Answer: In principle, no, because as a rule these are not "organizations" within the meaning of section 2 para. 2 of the FSA Transparency Code. However, this should be checked against the relevant definition in each case, because in certain individual cases Health Insurance Funds also may fall under the definition.

15. **Question**: EFPIA Question ((Question 3.01-23, Consolidated FAQ (19.12.2014), Does the definition of "organization" cover other areas of a university in addition to the medical faculty/hospital?

Answer: For the Transparency Code to apply, there must be a collaboration within the meaning of section 7. If this is the case, the medical faculty/hospital as a general rule is an "organization". In practice, whether it can be regarded as a payment recipient within the meaning of the Code depends, among other things, on whether the medical faculty/hospital itself has legal capacity, i.e., contracts may be concluded directly with it. In this case, the companies must disclose payments to the medical faculty/hospital accordingly. In other circumstances, for example for legal reasons, the agreements

must be concluded with the (central) administration of the university (as a rule, not itself an "organization"). Here, the respective medical faculty/hospital for which the payment from the company, as collaborative partner, is intended would be regarded as the agent implementing the collaboration. For the purposes of the disclosure, in such a situation, the administration should be named as a (quasi) "organization" along with the actual "organization" (medical faculty/hospital). Other areas or faculties of a university must be evaluated against the definition of "organization".

Examples: - A 2,000 Euro donation to the Marburg University Women's Hospital

- A 2,000 Euro donation to Marburg University (for the Women's Hospital)

16. **Question:** EFPIA Question ((Definitions – 5, Consolidated FAQ (19.12.2014), (EFPIA Final Q&A (15.11.2013) no. 27; former question (Schedule 1: HCO Definition) (Batch 1 Q. 53): Do transfers of value to Universities or educational institutions have to be disclosed under the Transparency Code?

Answer: In general, the Code does not apply to collaboration between member companies and educational institutions (such as support for management programs). However, another provision will apply if such support or involvement ultimately benefits a healthcare professional or organization (such as a University hospital). In this case, the transfer of value must be disclosed by specifically naming the recipient - in this case the educational institution.

Therefore, transfers of value to University medical faculties or to University hospitals must be disclosed under the relevant category. In practice, member companies' collaboration with organizations can vary widely. For that reason, member companies must explain the type and manner of disclosure in detail in their notices summarizing the methodology used.

If a member company makes transfers of value to a university, it must ensure that all support is documented adequately and in writing (preferably in a contract). The contract may also include a clause in which the recipient consents to individual disclosure of the transfer of value.

17. **Question**: Do research outfits such as the Fraunhofer Institute or the Max Planck Society fall under the definition of "organizations"?

Answer: In such cases, one must again initially ask whether the contractual collaboration with the respective societies or institutes even constitutes "work" or "activity" within the meaning of section 7 of the FSA Transparency Code. If this is the case, then based on the specific circumstances, one must assess whether, according to the definition, the society is an "organization", i.e. various healthcare professionals work and/or provide services there.

18. **Question**: Are there guidelines on obtaining consent when collaborating with organizations?

Answer: The FSA Transparency Code does not provide any specific guidelines, because the consent of organizations is not required under data protection laws. However, the FSA provides members with a sample clause to use in agreements with organizations that makes a disclosure possible even when the parties have otherwise agreed to keep their collaboration confidential.

19. **Question**: Where does the term "organization" begin and end if one is dealing with consultancy companies where healthcare professionals (also) perform services? To what extent should fees that consultants and/or service providers receive be disclosed if they are not physicians or are physicians who no longer practice medicine and are now working as independent consultants?

Answer: To answer this question, one must first check whether the collaboration is connected with an activity that is regulated by the FSA Transparency Code (section 7). Next, one must assess whether the contractual partners providing the service are actually healthcare professionals within the meaning of the Code. The question as to whether these conditions have been satisfied cannot be answered in general terms; instead, each specific case must be reviewed. As a result, no general statement can be made in this regard.

20. **Question**: How are the definitions of "healthcare professionals" and "organizations" interpreted? (The definition of "organizations", in particular, is unclear, because the wording of the FSA's definition encompasses every organization based in Europe (regardless of the business purpose or the mission laid down in the Articles of Association). It also encompasses healthcare professionals who provide medical services or carry out research through organizations.)

Answer: The definition of "organizations" is almost identical in sections 25, 26 of the FSA Code of Conduct Healthcare Professionals. The point of the broad definition is that, because of the potential for influencing the writing of prescriptions for medicinal products, transfers of value must be disclosed even if not a single healthcare

professional receives them but several healthcare professionals have joined forces as part of an organization. In view of the above, the intention is for the definition of "organization" to be interpreted broadly.

21. **Question:** EFPIA Question (EFPIA 1st Batch Q&A no. 51) (HCO): Can a foundation also be regarded as an "organization" within the meaning of the FSA Transparency Code?

Answer: Section 2 para. 2 of the FSA Transparency Code does not require "organizations" to have a specific legal form. This provision was defined broadly on purpose and encompasses all organizations, "regardless of their respective legal form of organization". Thus, in principle the transparency requirement also applies to foundations. Here, too, one must review on a case-by-case basis whether the organization meets the guidelines, in which case the transparency requirement applies.

22. **Question:** EFPIA Question ((Definitions – 4, Consolidated FAQ (19.12.2014), ((Definitions – 1, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 54 / 2nd Batch Q. no. 48) (HCO Definition / section 2 II): Must an independent contract research organization be regarded as an organization within the meaning of the FSA Transparency Code?

Answer: Various case groups must be distinguished here. If the contract research organization consists of healthcare professionals (such as a spin-off from a university hospital or a government institution), it must be viewed as an organization. However, if contract research organizations are not composed of healthcare professionals or affiliated with medical institutions, they fall under the FSA Transparency Code as organizations only if member companies provide transfers of value through them to recipients within the meaning of the Code (so-called pass-through costs). This, too, must be checked on a case-by-case basis.

23. **Question**: EFPIA Question ((Definitions – 6, Consolidated FAQ (19.12.2014), Question (EFPIA 2nd Batch Q&A no. 22): Should the office-based (independent) physician in Germany be viewed as an "organization"?

Answer: It is clear from the definition of "organizations" that this has to be several healthcare professionals who have joined forces. Therefore, a single office-based physician cannot be classified as an organization.

However, if a healthcare professional is the sole shareholder or partner of a legal entity, a decision must be made when drawing up the notices summarizing the

methodology used as to whether the legal entity or the healthcare professional will be listed as the recipient of payments or benefits.

24. **Question:** A pharmaceutical company gives a credit note to hospital purchasing pool. Does this credit require reporting?

Answer: No, because according to section 2 para. 2, payments associated with the buying and selling of medicinal products do not require disclosure.

25. **Question:** Is the Sponsoring Society for Advanced Medical Training in Rhineland-Palatinate an HCO? The company sponsors an event of this sponsoring society, which in turn hires HCPs as speakers.

Answer: The FSA does not evaluate or classify individual groups into an HCO. That is why in such cases, each company should examine the specific individual case based on the definition of HCOs, in order to determine whether the conditions are met.

26. **Question:** Are ethics commissions viewed as HCOs?

Answer: Independent of the question as to whether in a specific individual case an ethics commission could be viewed as an HCO based on how it is organized, the fees charged for required statutory decisions of the ethics commissions do not fall within the transparency requirement (for this, see the explanatory notes on certification of further training events).

Paragraph 3 – "Europe"

27. **Question**: EFPIA Question ((Question 2.05-7, Consolidated FAQ (19.12.2014): How should payments coming from countries outside Europe be assessed? (Example: The Indian branch of an international Group whose head office is in the USA, which is a member of EFPIA, commissions a European medical organization whose (main) registered office is in Germany.) Does the Group's German branch have to disclose these payments?

Answer: Whether the FSA Transparency Code applies depends on whether the collaboration is with a healthcare professional who actually works in Germany and/or an organization whose principal registered office is in Germany. If the FSA member itself does not enter into a relevant collaboration, the member will have to rely on the transmission of the corresponding information by the Group for the disclosure. Section 7 para. 7 contains specific provisions for the data exchange within "Europe"

within the meaning of the EFPIA. Regarding the recording of payments by Group companies outside of Europe, see Question 6.

28. **Question**: Which details must be transmitted for cross-border issues (whereby not only the FSA Transparency Code, but also the requirements of the relevant foreign codes must be respected)?

Answer: There is no specific obligation. However, it should be noted that foreign companies must be able to satisfy their local transparency requirements with the information provided.

Paragraph 4 – "Recipient(s)"

29. **Question**: How should payments that are part of sponsorships of third-party events be handled? Naturally, these also benefit physicians indirectly.

Answer: Transparency is achieved by disclosing the payment as a sponsorship (cf. section 7 para. 2 no. 2 b) (ii) of the FSA Transparency Code).

Paragraph 5 - "Transfers of value"

30. **Question**: Which "other events" are indicated within the framework of section 2 para. 5 of the FSA Transparency Code?

Answer: The underlying term "event" is, in accordance with the EFPIA Code, defined very broadly and encompasses, for example, advisory boards, etc., which may be reimbursed for travel expenses. This is an example of "other events" within the meaning of section 2 para. 5 of the FSA Transparency Code.

Section 6 Category

Disclosure obligation - section 6 sentence 1

31. **Question:** EFPIA Question ((Applicability – 2, Consolidated FAQ (19.12.2014), (2nd Batch Q. no. 32) (Section: Applicability / section 6 of the FSA Transparency Code): How should member companies that are contracting parties to a co-promotion agreement disclose transfers of value provided by healthcare professionals under this agreement? Should the disclosure reflect the proportional cost-sharing arrangement in the agreement?

Answer: According to the FSA Transparency Code, each member company that is a party to a co-promotion agreement must disclose the transfers of value that it pays to healthcare professionals. The principle here is that a member company that contracts with healthcare professionals or organizations and actually pays them is responsible for disclosing the corresponding payments or benefits.

Number 1 "Research and development"

32. **Question:** EFPIA Question (EFPIA 1st Batch Q&A no. 58) (Research and development transfer of value): How should research studies or other studies that are not carried out for marketing authorization purposes be disclosed?

Answer: The only activities that have to be disclosed are those which fall under the definition of "research and development transfers of value". These are activities related to the planning or conduct of studies that fall under one of the following categories:

- Conducting non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice)

- Phase I to IV clinical trials (as defined in Directive 2001/20/EC)

- Non-interventional studies within the meaning of section 19 of the FSA Code of Conduct on Collaboration with Healthcare Professionals

Research activities by member companies are not undertaken solely for the purpose of obtaining marketing authorization for medicinal products. Studies that are not intended for submission to regulatory authorities do not fall under the disclosure category "research and development transfers of value". They must be disclosed as service agreements on an individual basis. It is recommended that member companies explain in detail precisely how to handle scientific situations in the notices summarizing the methodology used.

33. **Question**: EFPIA Question ((Question 3.01-24, Consolidated FAQ (19.12.2014): How should donations to organizations for research work be handled?

Answer: A donation to organizations must always be disclosed by naming the organization specifically, even if the donation is aimed at the organization’s conduct of research activities. In fact, only companies' self-serving activities - but not "altruistic" donations to organizations for research purposes - fall under the category "research and development".

34. **Question**: EFPIA Question ((Question 3.01-19, Consolidated FAQ (19.12.2014): How are payments connected with a steering committee related to a clinical trial handled?

Answer: As a rule, the activities of healthcare professionals in connection with a steering committee are considered part of research and development activities and must be disclosed under this category.

35. **Question**: Under section 6 no. 1 of the FSA Transparency Code, does the category "research and development" also include other studies (e.g., not directly related to healthcare research on or epidemiological investigation of medicinal products) and does the Code require these to be disclosed on an aggregate basis?

Answer: Such studies are not closely related to the statutory marketing authorization for a medicinal product and therefore do not fall under the category "research and development".

Number 2 "Donations and other unilateral cash payments/benefits in kind"

36. **Question** EFPIA Question (EFPIA 2nd Batch Q&A 20): How should donations in kind be handled quantitatively? Should they be reported at the cost incurred by the member company or the amount that they represent to the recipient?

Answer: The actual costs of such a donation, the "acquisition cost" (i.e. the costs incurred by the company) must be indicated.

Number 3 "Transfers of value related to events"

37. **Question**: How are pharmacies and/or pharmacists assessed as payment recipients if they receive transfers of value related to a sponsorship? Should they be included as organizations or as healthcare professionals?

Answer: see above

38. **Question**: How are costs for event participants (e.g., hotel bookings, travel expenses) who do not show up handled? Do these have to be disclosed even though they did not show up?

Answer: These expenses do not have to be disclosed, because in such cases no payments were made to the healthcare professionals who did not show up. The costs (including any cancellation fees) do not have to be apportioned to those who actually attended.

39. **Question:** For an event involving joint participation of several practices, a sponsoring amount of x is paid. To which practice/physician is this amount apportioned?

Answer: In cases such as these, where no other apportionment is known, for transparency purposes the sponsoring amount should be divided amongst the individual cooperation partners.

40. **Question:** Two or more pharmaceutical companies stage an event, and pay into a pool covering the budget for the event (travel costs, overnight accommodation for HCPs). What does the report for each company need to include?

Answer: In such a case, each company discloses its own payments.

41. **Question:** EFPIA Question ((Questions 3.01-14, Consolidated FAQ (19.12.2014), Several HCOs (e.g. university clinics) jointly stage a further training event/Congress, thereby appointing a congress agency (third party), which also handles the preparation of the agreement, i.e. the agreement between the FSA member and the third party. Is the sponsoring amount required to be apportioned to both parties? Is half the amount thus required to be apportioned to each HCO?

Answer: If HCOs hire agencies as service providers, the HCOs are also to be directly specified as payment recipients. To the extent that several HCOs stage an event and the company is not aware of any deviating apportionment, the sponsoring amount can be apportioned equally.

42. **Question:** Does this also apply if, for example, a private physician's practice and several clinics organize (or have a third party organize) an event in this manner?

Answer: In a case such as this, the transparency would have to be created in a comparable way.

43. **Question**: In practice, companies also hold so-called "joint events" with healthcare professionals or organizations. In such cases, those involved organizing events in such a way that a HCO (such as a hospital) provides the venue and develops the agenda, whilst the company is responsible for inviting and paying for the speakers. However, those involved do not exchange payments or benefits. At such events, both of the parties involved are generally listed as event organizers. How are such "joint events" treated under the FSA Transparency Code?

Answer: For joint events where the costs are shared jointly, without any mutual exchange of payments, no disclosure is required because, since there is no exchange

of payments, no transfers of value can be attributed to healthcare professionals or organizations.

44. **Question**: If a company pays the attendance fees for its own employees to the organization, is this a payment to an organization?

Answer: No, because this is not a sponsorship within the meaning of the Code.

45. **Question**: EFPIA Question ((Definition – 10, Consolidated FAQ (19.12.2014): Treatment of third parties (agencies): What rule applies if third parties are not agencies and assume the rights of scientific associations and/or professional associations to organize events on their own behalf and for their own account?

Answer: In these cases, the payments made to these agencies must be included with a note that the payments were made for a specific event that is connected with a scientific associations (e.g., "To support the 12th annual meeting of the [name of the scientific associations]"). If there is no discernible connection to an organization within the meaning of the FSA Transparency Code, there is no disclosure requirement. The notices summarizing the methodology used should describe in detail exactly how to handle this situation.

46. **Question**: How should the sponsorship of a congress through an agency be disclosed? Payment to the agency with the actual payee (the congress) in brackets?

Answer: In such cases, one must first answer the question as to whether the scientific event being supported is connected with a medical or scientific association, etc., which itself would be classified as an "organization". This would be the case, for example, if an "organization" is ultimately responsible for holding and/or planning the congress, makes its name available for the event or a third party would gain the impression, based on the way it is portrayed in the public, that this organization has a decisive influence on the event. Even if the support for the specific event can only be provided through an (independent) third party - such as an agency, etc. - in the interest of transparency, the organization (expert panel, etc.) should be directly named as recipient of the payment within the meaning of the Transparency Code.

Example: Disclosure under "organization": Sponsoring for the *German* Society for Rheumatology: 2,000 euros

Where necessary, in order to further describe the actual payment recipient and the ultimate beneficiary of the payment, there could be a supplement mentioning that the

fiscal recipient (the agency, etc.) in parentheses is listed as additional explanation of the payment transaction.

Example: Disclosure under "organization": Sponsoring for the German Society for Rheumatology (name of the event, organized by agency XY): 2,000 euros

Regardless of the manner of description chosen, the member companies shall give a general explanation in their notices summarizing the methodology used.

47. **Question**: EFPIA Question ((Question 2.01-1. Consolidated FAQ (19.12.2014): How should one disclose any advance payments? For example, a pre-payment in December is agreed for a January sponsorship of an "organization".

Answer: Companies can decide this issue on their own. An explanation of how such cases are handled should then be included in the notices summarizing the methodology used**.**

48. **Question**: EFPIA Question ((Question 3.01-22, Consolidated FAQ (19.12.2014): Do the internal costs of the company for an internal event have to be disclosed as registration fee?

Answer: Currently, such costs (rent for the space, technical expenses, speakers, etc.) do not have to be allocated to the event participants. In any case, the Transparency Code does not apply to expenses for meals and drinks. However, it may be necessary to disclose travel and accommodation expenses paid for participants. This also applies to payments and/or reimbursements of out-of-pocket expenses of event speakers, if they are healthcare professionals. To the extent, however, that registration fees are charged with the event and these are only waived for certain participants, these participants are to be disclosed as a payment in kind.

49. **Question:** EFPIA Question ((Question 3.01-13, Consolidated FAQ (19.12.2014), (2nd Batch Q. no. 45) (Section 3.01 / section 6 no. 3 of the FSA Transparency Code): Should a member company disclose the expenses of one-off half-day events devoted to training in treatment methods or expenses of general scientific meetings for which the member company assumes the expenses for organizing the event, meals and drinks and the speakers? If so, under which category should the expenses be disclosed?

Answer: One-off events fall within the scope of the Code. Transfers of value related to such events are disclosed in the relevant categories (i.e., "events", "fees for service and consultancy", "research and development transfers of value"). Member companies

are not required to disclose logistical costs, such as the rental of the member company's equipment, that are associated with one-off events.

50. **Question:** Do the costs charged by a medical association for the certification of an event fall under the duty to disclose?

Answer: Based on the definition of the HCOs, there are some arguments in favour of medical associations also falling under this definition. In such a case, however, the medical association is not acting as the company's equal cooperation; rather, based on a special capacity as a public corporation by means of rules and fees regulations, it charges fees for official duties. Cases such as these do not involve a fact requiring disclosure.

Number 4 "Fees for service and consultancy"

51. **Question:** EFPIA Question ((Question 3.01-15,16, Consolidated FAQ (19.12.2014), (2nd Batch Q. no. 46) (Section 3.01 / section 6 no. 4 of the FSA Transparency Code): A healthcare professional asks the company to assume the expenses for translating one of the healthcare professional's trade publications into various languages. Another possible situation is the request for financial support for the publication or disclosure of such materials in scientific journals. Are companies required to disclose the related transfers of value?

Answer: In general, such support is inadmissible under the FSA Code of Conduct Healthcare Professionals and is not covered by either section 15a or section 21 of the FSA Code of Conduct Healthcare Professionals. A contrary assessment may occur if a deliverable is made dependent upon a contractual relationship. As a general rule, the disclosure will be required to be part of the agreed deliverables. If admissible, this form of support is then to be disclosed as well. The specific assessment depends upon the individual case.

52. **Question:** EFPIA Question (2nd Batch Q. no. 44) (Section 3.01 / section 7 V): In market research studies, the identity of the participants is generally unknown. Moreover, such studies are generally conducted by a market research institute. However, member companies usually know the number of healthcare professionals involved, as well as the aggregate fee paid to them. In such cases, must the members disclose the transfers of value on an aggregate basis?

Answer: The Code does not require the disclosure of transfers of value paid as part of market research studies if member companies do not know the identity of the participating healthcare professionals and/or organizations.

One of the fundamental principles of market research studies is the right of the subject to anonymity, which is an inherent part of market research definitions and the relevant requirements worldwide. However, if the member company does know the identity of the healthcare professionals and/or organizations participating in the market research, the transfers of value must be disclosed under the category "fees for service and consultancy". This only applies, though, if the member company has obtained in advance the required consent of the participant to individual disclosure.

Section 7 Individual and aggregate disclosure

On paragraph 1

53. **Question**: EFPIA Question ((Question 3.05-1, Consolidated FAQ (19.12.2014). Are gross or net amounts disclosed?

Answer: Companies can decide this on their own and must describe the chosen approach in the notices summarizing the methodology used.

54. **Question:** EFPIA Question (Question 1.01-1, Consolidated FAQ (19.12.2014). EFPIA Final Q&A (15.11.2013) no. 5; former 1st Batch Q&A no. 26) *(Section 3.01):* When disclosing payments, should the expenses actually paid by the company or the non-cash benefit actually received by the recipient be used?

Answer: The disclosure concerns only the specific transfer of value made by the company.

55. **Question:** EFPIA Question ((Preamble 2, Consolidated FAQ (19.12.2014) 2nd Batch Q. no. 29) (Preamble, section 7 I): Is there going to be an official procedure for enquiries by healthcare professionals and organizations? For how long are companies required to confirm, validate or respond to data at the request of healthcare professionals or organizations?

Answer: Member companies alone are responsible for decisions regarding the procedure for such enquiries by healthcare professionals and/or organizations.

The FSA Transparency Code does not prescribe a procedure for how member companies should handle such enquiries. Nor does the Code oblige companies to validate data before disclosure. Nevertheless, companies are advised to establish

procedures for dealing with enquiries to facilitate consultations with the healthcare professionals and organizations involved in order to ensure the accuracy of the transfers of value disclosed.

A member company should - in case there are complaints - also have processes in place to prove the accuracy of the information disclosed.

It is recommended that member companies contractually agree the intended type and manner of disclosure with the healthcare professionals and/or organizations. For healthcare professionals, this is required by law in order ensure that consent has been obtained in compliance with data protection regulations.

56. **Question:** EFPIA Question (2nd Batch Q. no. 30) (Preamble, section 7 I): Will the FSA provide the healthcare professionals and organizations with a master data list (that includes unique identifiers, names and addresses) in order to guarantee consistency between member companies?

Answer: No. The FSA will not create a specific database of healthcare professionals and/or organizations.

On the contrary, member companies themselves must ensure that every recipient is identifiable and that there is no doubt as to which healthcare professional and/or which organization has received a transfer of value.

57. **Question:** EFPIA Question ((Preamble 3, Consolidated FAQ (19.12.2014), 2nd Batch Q. no. 31) (Preamble, section 7 I): Have criteria or conditions been developed for the types of events for which member companies must re-write or amend their disclosure reports? Which data should be amended? Only the data in publicly available reports or also the source data or data in the report databases?

Answer: If a member company becomes aware of inaccuracies in its public disclosure, it must always correct the information. The company decides whether amendments to its source data or report databases are also necessary. This may depend on the type and significance of the inaccuracies found.

58. **Question:** EFPIA Question ((Question 1.101-2, Consolidated FAQ (19.12.2014), 2nd Batch no. 33): Are member companies required to disclose transfers of value made through a third party (such as agencies, distributers, etc.)? Do such disclosures require the consent of both, the third party and the healthcare professionals and/or organizations benefiting from it directly?

Answer: (1st part of question): Transfers of value and payments must always be disclosed on an individual basis. Aggregate disclosures are permitted only in exceptional cases.

If third parties represent or work for a member company, the member company must ensure that its respective obligations are satisfied. It is recommended that member companies sign a written contract with the third parties that contains the necessary agreements in order to satisfy their obligations under the FSA Transparency Code.

Example:

The FSA Transparency Code stipulates that member companies are also responsible for the obligations under the Code if they commission other parties (e.g., the contract sales force, consultants, market research firms, advertising agencies) to perform or participate in work that falls under the scope of the Code. In addition, member companies must take appropriate steps to ensure that contractual partners not acting on behalf of member companies (e.g., joint ventures, license holders) comply with the Code.

Answer: (2nd part of question): The Code requires transfers of value to be disclosed on an individual basis by naming the recipient. If a member company makes transfers of value or payments to healthcare professionals or organizations through a third party, it must conclude the necessary agreements with the immediate contractual partners.

The member company must, before making the individual disclosure, obtain the consent required under data protection laws from the respective recipient.

On paragraph 2 no. 1

59. **Question:** EFPIA Question (Question 3.01.-4, Consolidated FAQ (19.12.2014), (EFPIA Final Q&A (15.11.2013) no. 15; EFPIA 1st Batch Q&A no. 26) (Section 3.01): How should the rental of trade fair stands be disclosed?

Answer: Rentals of trade fair stands fall under the category "sponsorship" (section 6 no. 3 of the FSA Transparency Code).

60. **Question:** EFPIA Question ((Question 3.01-5, Consolidated FAQ (19.12.2014), (EFPIA Final Q&A (15.11.2013) no. 16; former (Section 3.01(1)(b)(i)) (Batch 1 Q. 42): Which transfers of value to organizations must be disclosed under the category "Registration fees"?

Answer: The aggregate amount of such fees paid to the respective organization during the course of a year must be disclosed on an individual basis under "Registration fees".

61. **Question:** EFPIA Question ((Question 3.01-6, Consolidated FAQ (19.12.2014), (EFPIA Final Q&A (15.11.2013) no. 17 (Section 3.01(2)(a)(i)) (Batch 1 Q. 43): Which transfers of value to healthcare professionals must be disclosed under the category "Registration fees"?

Answer: The aggregate amount of conference and attendance fees paid to a healthcare professional - who is a clearly identifiable recipient - during the year in question must be disclosed on an individual basis under the category "transfers of value related to (…) other events" (section 6 no. 3 of the FSA Transparency Code).

62. **Question:** EFPIA Question ((Question 3.01-11, Consolidated FAQ (19.12.2014), (EFPIA Final Q&A (15.11.2013) No. 42 (EFPIA 1st Batch Q&A no. 28): What has to be disclosed under the category "Travel and accommodation expenses"?

Answer: This category covers all expenses related to "travel and accommodation", such as airfares, train tickets, taxis, tolls, parking fees and hotel accommodation.

However, the FSA Transparency Code does not require the disaggregation of transfers of value made to a group of healthcare professionals, such as expenses for group transportation to an event (e.g., for chartering a bus). These costs may be disclosed on an aggregate basis and do not have to be allocated separately to every individual healthcare professional.

Member companies must describe in their notices summarizing the methodology used which transfers of value they include under the category "travel and accommodation expenses".

In order to avoid uncertainty, it should be noted that "meals and drinks" do not fall within the scope of the Transparency Code.

63. **Question:** EFPIA Question ((Question 3.01-8, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 44) (Section 3.01(1)(b)(ii)): Which transfers of value fall under the category " direct or indirect support of organizations in connection with the preparation, organization or holding of such events (Sponsoring)" (section 6 no. 3 of the FSA Transparency Code)?

Answer: The sponsorship agreement must include the purpose of the sponsorship as well as the transfers of value connected with it. If the contract also lists "registration fees" and "travel and accommodation expenses" as transfers of value, these must be disclosed separately under the respective relevant category on an individual basis.

The following activities should, at a minimum, be covered by the sponsorship agreement:

- Rental of trade fair stands at an event;

- Advertising space (in hard copy, electronic or other format);

- Satellite symposia at a congress;

- Support for a speaker/a faculty;

- Drinks and meals provided by the event organizer, if they are part of the overall package (included in the sponsorship agreement);

- Courses provided by an organization (but at which the member company does not select the specific healthcare professional presenting the course).

It is recommended that member companies include in the notes on methods used information explaining how to determine which transfers of value belong in this category.

64. **Question:** EFPIA Question ((Question 3.01-9, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 48) (Section 3.01(1)(c) & (2)(b)): Which transfers of value made directly or indirectly through a third party to healthcare professionals/organizations fall under the category "service and consultancy agreements"?

Answer: Examples of transfers of value included in service and consultancy agreements are:

- Speaker's fee;

- Speaker training;

- Medical literature;

- Data analyses and evaluations;

- Production of training materials;

- General consultancy work.

Payments made to the recipient as part of the contractual relationship must be disclosed as transfers of value to the respective recipient. Recipients may be healthcare professionals or organizations.

Where necessary, member companies should describe the nature of the transfers of value in their notices summarizing the methodology used.

65. **Question:** Where should sponsoring payments outside of the further training events be entered in the template?

Answer: Because sponsoring payments are a special form of service and consulting activities, cooperation of this nature should also be entered in this field.

66. **Question:** Does the placement of advertisements in media of an HCO constitute a donation requiring disclosure?

Answer: This question requires that specific aspects of the individual case be taken into consideration. A threshold in this context is Section 1 para. 2 sentence 2 FSA Transparency Code, which declares this inapplicable in connection with the buying and selling of medicinal products, which also covers the associated activities.

<u>On paragraph 2 no. 2</u>

67. **Question:** EFPIA Question ((Question 3.01-2, Consolidated FAQ (19.12.2014), (EFPIA Final Q&A (15.11.2013) no. 13; EFPIA 1st Batch Q&A no. 24) (Section 3.01): How should incidental costs which the parties to a consultancy agreement have agreed to be treated under the Code?

Answer: Incidental costs agreed as part of a service or consultancy agreement must always be disclosed in the respective category. This may be done by separating the "amount of the fee" and the "amount of the incidental costs" for the service or consultancy (see the FSA's sample template for data entry).

68. **Question:** EFPIA Question ((Question 3.01-3, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 25) (Section 3.01): Do payments for services provided as

part of a congress held by third parties have to be disclosed under the category "transfers of value related to […] other events" or under "fees for service and consultancy"?

Answer: In this case, services are provided either by a healthcare professional or an organization. As a result, associated transfers of value must be disclosed under the category "fees for service and consultancy".

69. **Question:** Under which category must financial payments related to advisory boards be disclosed?

Answer: Financial payments related to advisory boards fall under the definition of "event" within the meaning of section 6 no. 3 of the FSA Transparency Code.

If the payments related to the advisory board are made as part of a contractual relationship, they must be disclosed on an individual basis under "fees for service and consultancy" unless they are clearly part of an activity that is covered by the definition for "research and development". In this case, they must be disclosed on an aggregate basis under the category "research and development".

70. **Question:** EFPIA Question ((Question 3.01-7, Consolidated FAQ (19.12.2014), (2nd Batch Q. no. 40) (Section 3.01): How should an indirect sponsorship of a healthcare professional by an organization be disclosed (such as support for a hospital in order to make it possible for a hospital physician to attend the congress)?

Answer: An indirect sponsorship of a physician by an organization must be disclosed under transfers of value to the organization, as recipient. This disclosure falls under the category "*transfers of value in connection with training events*, other events and sponsorships" (section 6 no. 3 of the FSA Transparency Code).

71. **Question**: If a contract is concluded with the hospital administration, but one or more physicians is/are specifically named as collaborative partner(s) and (therefore probably) has/have at least a partial financial interest in the collaboration, then do both the hospital, as the "organization", and the "healthcare professional(s)" have to be disclosed – and if so, in what manner and/or to what extent? In such a case, would the physician also have to sign a consent form under data protection laws?

Answer: In such cases, for the direct payment, the "organization", as payment recipient, must always be named - unless the company is aware that a specific physician will benefit in whole or in part from the payment. In this case, the physician

would also have to be named and under the data protection law his/her consent would be required.

72. **Question**: Opposite case from question 71: The agreement is concluded directly with the physician. In the subsequent disclosure, however, the address and name of the hospital are given as employer. Is the hospital required to consent to this?

Answer: Under data protection laws, for such a collaboration the hospital probably does not have to consent to the use of its address.

73. **Question:** EFPIA Question (Question 3.01-10, Consolidated FAQ (19.12.2014), (2nd Batch Q. no. 41) (Section 3.01): In a case where a transfer of value is made to a legal entity owned by a physician as part of a service agreement (such as a consultancy or speaker agreement), does the related transfer of value have to be disclosed as a payment to an organization or as a payment to a healthcare professional? In such a case, how should a transfer of value to a hospital that employs a physician be treated?

Answer: The transfer of value made to the legal entity owned by a physician must be disclosed under the name of the legal entity as an organization, because it is the recipient of the transfer of value. If the hospital is the contractual partner, in the event of an individual disclosure, the name of the hospital must be listed as the recipient. As part of the individual disclosure, the Code requires member companies to disclose the name of the individual or legal entity benefiting from the transfer of value (recipient).

74. **Question:** EFPIA Question (2nd Batch Q. no. 42) (Section 3.01): What falls under the category "travel and accommodation expenses"?

Answer: This category includes all payments that are related to travel and accommodation, such as airfares, train tickets, rental car expenses, tolls, parking fees, taxis and hotel accommodation. Under the Code, transfers of value benefiting a group of healthcare professionals do not have to be disclosed on an individual basis. These include, for example, the expenses for group transportation (chartering a bus) that was booked for an event. These expenses may be disclosed on an aggregate basis and do not have to be broken down and allocated to the specific healthcare professionals benefiting from them on an individual basis under the category "travel and accommodation expenses".

For the sake of clarity, every member should explain in detail in its notices summarizing the methodology used which items are included under the category "travel and accommodation expenses".

"Meals and drinks" do not have to be disclosed under the Transparency Code.

75. **Question:** EFPIA Question (2nd Batch Q. no. 47) (Section 3.01 / section 7 para. 2 no. 2 c): Indirect payments (example): A member company has commissioned a university to provide various services. The company is aware that the specific university employee who actually performs the services for the university is a physician. Here, no payments are made to the physician, because he/she provides the services within the scope of his/her work for the university. Is it correct to classify the payments under the Transparency Code as transfers of value to the university and not as indirect payments to a healthcare professional?

Answer: Yes. In the example, the university is the recipient of the transfer of value, so it must be disclosed under the category "fees for service and consultancy" to an organization.

On paragraph 5

76. **Question:** EFPIA Question ((Question 3.01-12, Consolidated FAQ (19.12.2014), (EFPIA 2nd Batch Q&A no. 43): In market research studies, the identity of the parties surveyed is generally unknown. Moreover, such research is normally carried out by market research institutes. However, member companies generally are aware of the number of healthcare professionals involved and the aggregate amount of payments made to them. In such cases, must the members disclose the related transfers of value on an aggregate basis?

Answer: The FSA Transparency Code does not require the disclosure of transfers of value paid as part of market research studies if member companies do not know the identity of the participating healthcare professionals and/or organizations. This shall not apply if member companies do know or are able to identify the healthcare professionals and/or organizations surveyed that benefit from the transfer of value. In this case, the information must be disclosed under the category "fees for service and consultancy", with reference to these healthcare professionals and organizations.

77. **Question:** EFPIA Question (EFPIA 2nd Batch Q&A no. 16): Do transfers of value paid to surveyed physicians as part of a market research study have to be disclosed on an individual basis as transfers of value to healthcare professionals?

Answer: If, by way of exception, the member company knows the identity of the healthcare professional involved in a market research study, it must disclose the transfers of value in the category "fees for service and consultancy" on an individual

basis. If the company does not know the identity of the healthcare professional, the transfer of value does not have to be disclosed.

78. **Question:** EFPIA Question (EFPIA 2nd Batch Q&A no. 17): Laboratory tests are required after a medicinal product is authorized for marketing (e.g., genetic tests for a specific patient group before a physician can prescribe the medication), whereby they themselves become a part of the requirements for marketing authorization. In many countries these tests are reimbursed, in other countries they are not, so companies are often asked to support these laboratory tests or to provide money or contributions in kind (such as reagents, supplies, expertise) in order to ensure that accredited laboratories can validate the required tests.

Do such transfers of value have to be disclosed under the Transparency Code?

Answer: If the laboratory tests are part of an activity that falls within the scope of the FSA Transparency Code, the associated transfers of value must be disclosed in accordance with the respective Code requirement. However, in Germany, such support would be inadmissible under the FSA Code of Conduct on Collaboration with Healthcare Professionals, so the question as to whether such payments should be disclosed is superfluous under the FSA Code of Conduct Healthcare Professionals.

79. **Question**: Is it correct that advisory boards in general do not fall within the scope of the category "research and development" and therefore must be disclosed separately? Or should advisory boards that are part of an activity covered by the category "research and development" be disclosed on an aggregate basis?

Answer: Every member company must decide on a case-by-case basis whether an advisory board activity falls under the definition of "research and development".

Below are some examples of this:

- Advisory boards that contribute to the development of a research plan or a study protocol that are aimed at obtaining marketing authorization for medicinal products must be allocated consistently to "research and development" activities and therefore disclosed under this category on an aggregate basis.

- By contrast, advisory boards that merely analyze already available study results and give suggestions on their publication do not fall within the scope of the category "research and development". As a general rule, they should be disclosed under the category "fees for service and consultancy" on an individual basis (for more on this, see also question 68).

80. **Question:** EFPIA Question (EFPIA 2nd Batch Q&A no. 19): Do transfers of value related to epidemiological studies and/or registries and other retrospective studies have to be disclosed on an individual or aggregate basis under the category "research and development"?

Answer: Such transfers of value generally fall under the category "research and development" and therefore must be disclosed accordingly (on an aggregate basis) if they are conducted for regulatory reasons to obtain marketing authorization for a medicinal product and/or to maintain and administer an authorization that has already been granted (for more on this, see also the next question).

81. **Question:** EFPIA Question (EFPIA 1st Batch Q&A no. 30) (Section 3.04): Do all types of research activities fall within the scope of the category "research and development" (section 6 no. 1 of the FSA Transparency Code)?

Answer: Only activities that fall under the category "research and development" must be disclosed on an aggregate basis. Activities that do not fall into this category must be disclosed on an individual basis (e.g., transfers of value to healthcare professionals and organizations) – in accordance with the national (data protection) laws and regulations.

The basic rule is that certain studies (such as non-clinical trials, Phase I to IV trials and non-interventional studies) must be allocated to the category "research and development" (section 6 para. 1 no. 1 of the FSA Transparency Code). The FSA Transparency Code places in this category all research and development activities carried out for regulatory reasons for the purpose of introducing a medicinal product to the market, i.e. to obtain marketing authorization for a medicinal product or for post-marketing surveillance of a medicinal product that has already been granted marketing authorization. In addition to the studies expressly listed in section 6 para. 1 no. 1 of the FSA Transparency Code, these also include studies that are required for the medicinal products to be eligible for reimbursement (such as studies conducted to prove an additional benefit of the medicinal product).

Examples:

According to the OECD Principles on Good Laboratory Practice, non-clinical health and environmental safety tests are investigations conducted with a test article under laboratory or environmental conditions in order to obtain data on its properties and/or its safety which are submitted to the competent regulatory authorities. These are normally activities that fall under the category "research and development".

Nevertheless, not every study conducted by a member company is done for regulatory reasons. Non-clinical health and environment safety tests that are not conducted for submission to a marketing authorization board do not fall under the category "research and development". Such studies must be disclosed on an individual basis under the respective relevant category.

Pure healthcare research that is not primarily aimed at proving the eligibility for reimbursement of a medicinal product does not fall under the category "research and development".

For so-called basic research, one must distinguish whether the relevant research studies are related to a product and, for example, are aimed at later expansion of the list of uses of a medicinal product. If so, transfers of value must be included under the category "research and development". By contrast, if the basic research is of a general, non-product-specific nature, no disclosure is required under the category "research and development".

Basic research supported by companies through charitable donations (for example to university research laboratories) must be disclosed under the category "donations" due to the support payments' altruistic focus on the common good.

It is recommended that companies include in their notes on methods used practical examples of categories that require greater clarification.

82. **Question:** EFPIA Question (EFPIA 1st Batch Q&A no. 31) (Section 3.04): Do laboratory tests performed by an (external?) laboratory fall within the scope of the Code and do they therefore have to be disclosed? In this regard, are laboratories organizations within the meaning of the Code?

Answer: Laboratories are typically organizations that employ healthcare professionals, technicians and other staff. Most laboratories do not fall under the Code's definition of "organizations", as set forth in section 2 para. 2 of the FSA Transparency Code. Therefore, the laboratory tests listed are generally classified as normal business transactions, so they do not fall within the Code's disclosure requirements. Consequently, such payments in principle do not fall within the scope of the Code and therefore do not have to be disclosed.

83. **Question:** EFPIA Question (EFPIA 1st Batch Q&A no. 34) (Section 3.01): Should "Global health outcomes"/global research studies be disclosed under the category "fees for service and consultancy" (section 6 no. 4 of the FSA Transparency Code) or

under the category "research and development" (section 6 no. 1 of the FSA Transparency Code)?

Answer: That depends on the purpose of the "Global health outcomes" study:

if it relates to an activity that falls within the scope of "research and development" (as defined in schedule 1 of the EFPIA Code), the transfer of value must be disclosed under this category as part of the aggregate amount. This must be checked on a case-by-case basis.

84. **Question:** EFPIA Question ((Question 3.01-20, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 37): How should investigator-initiated studies be disclosed under the Code?

Answer: For "investigator-initiated studies", the aggregate amount that must be disclosed under the category "research and development" must be included, if the activity is related to the planning or conduct of a study that belongs in one of the following categories:

- Conducting non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice)

- Phase I to IV clinical trials (as defined in Directive 2001/20/EC)

- Non-interventional studies within the meaning of section 19 of the FSA Code of Conduct Healthcare Professionals

However, here one should take into account that "investigator-initiated studies" supported by companies merely for altruistic reasons aimed at the common good - such as through a charitable donation to a university to promote research - must be disclosed under the category "donation". Therefore, payments for "investigator-initiated studies" are included under the category "research and development" only if the study results are of interest to the company itself with a view to obtaining marketing authorization for a medicinal product or, otherwise, are of interest for the company's medicinal products from a regulatory perspective. This is generally the case when a company buys clinical data from "investigator-initiated studies".

85. **Question:** EFPIA Question ((Question 3.01-21, Consolidated FAQ (19.12.2014) (EFPIA 1st Batch Q&A no. 38): How should investigator meetings be disclosed under the Code?

Answer: Investigator meetings fall under the category "transfers of value in connection with training events and other events" (section 6 no. 3).

If, as is usually the case, an investigator meeting is related to studies within the meaning of the category "research and development", transfers of value for this purpose must be disclosed on an aggregate basis under the category "research and development".

86. **Question:** EFPIA Question (2nd Batch Q. no. 41, 43) (Section 3.04 / section 7 para. 5 of the FSA Transparency Code): "Research and development" – if investigator meetings and other meetings related to research and development are events within the meaning of the FSA Transparency Code, then should they not be disclosed under the category "transfers of value related to (training) events" on an individual basis (provided that consent has been given) instead of in an aggregate disclosure under the category "research and development"?

Answer: No. The Code explicitly states that transfers of value for events related to research and development activities must be disclosed on an aggregate basis under the category "research and development" (section 7 para. 5 of the FSA Transparency Code).

The Transparency Code does not define the term "event" in greater detail. In the EFPIA HCP Code, events are defined as promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events (such as advisory board meetings, visits to research or manufacturing facilities and planning, training or investigator meetings for clinical trials and non-interventional studies) organized or sponsored by or on behalf of the member company (section 10.01 of the HCP Code). However, this broad definition of "event" does not mean that all events within the meaning of the EFPIA HCP Code fall under the category of "events" in the FSA Transparency Code.

However, if it is possible that the category "research and development" may apply, member companies should first check this carefully:

- If the answer is **YES**, the disclosure must be made on an aggregate basis under the category "research and development" (section 7 para. 5 of the FSA Transparency Code)

- If the answer is **NO**, the disclosure must be made on an individual basis

Related transfers of value must be disclosed as follows, e.g.:

- Events that fall under the category "research and development" are disclosed as part of "research and development" transfers of value (as an aggregate amount for all healthcare professionals and/or organizations);

- If the event is unrelated to the category "research and development", the transfers of value must be disclosed on an individual basis under the respective relevant category in accordance with the general rules.

87. **Question:** EFPIA Question (EFPIA 1st Batch Q&A no. 40) (Section 3.01): Does lending laboratory equipment as part of a study have to be disclosed?

Answer: No, lending (providing) laboratory equipment that is used exclusively for conducting the study and will be returned to the member company at the end of the study is not considered a transfer of value because it does not permanently improve the economic status of the recipient.

88. **Question:** EFPIA Question (EFPIA 1st Batch Q&A no. 50): Do the "travel and accommodation expenses" of healthcare professionals relating to research (research advisory board meetings, investigator meetings, etc.) have to be disclosed on an aggregate basis under the category "research and development" transfers of value?

Answer: If the underlying activity is related to planning or conducting studies that fall under one of the categories below, the transfer of value must be disclosed on an aggregate basis under the category "research and development":

- Conducting non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice)

- Phase I to IV clinical trials (as defined in Directive 2001/20/EC)

- non-interventional studies within the meaning of section 19 of the FSA Code of Conduct on Collaboration with Healthcare Professionals

All transfers of value not related to these activities must be disclosed on an individual basis in the respective relevant category.

Transfers of value received by the Principal must be disclosed as transfers of value to the Principal. Here, the Principal may be a healthcare professional or an organization.

As a general principle, incidental expenses (if they are material) must be regarded as part of the transfers of value and disclosed separately in accordance with the FSA Transparency Code.

On paragraph 6

89. **Question:** EFPIA Question ((Question 3.02-22, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 22) (Section 3.02): Which "legal reasons" make it impossible to disclose specific recipients by name?

Answer: These include, for example, cases in which an individual disclosure may be made only with the recipient's consent, due to national data protection laws such as the German Federal Data Protection Act.

Member companies must comply with the relevant (data protection law) requirements, which may limit the admissibility of individual disclosures.

In every case, prior to disclosure, member companies must check the requirements of data protection laws at national level (e.g., the case law of the recipient's country).

90. **Question**: In principle, for companies that are "organizations", the Federal Data Protection Act does not apply. But what happens if an "organization" refuses to sign the transparency clause? Is this also a case as stipulated in section 7 para. 6 of the Transparency Code, with the result that collaboration is possible, but the relevant amount must be disclosed on an aggregate basis?

Answer: In principle, it should be noted that, in implementing the EFPIA Disclosure Code, even the FSA Transparency Code does not distinguish between "organizations" and "healthcare professionals" as recipients. The Code stipulates an explicit exception from the general transparency obligation for recipients of transfers of value only for "legal reasons". In general, companies can ensure the required level of transparency for collaboration with "organizations" through individual contract negotiations. In practice, though, it is still possible that, despite intensive efforts, an "organization" may not be willing to consent to a relaxation of the confidentiality of the major terms of an agreement. Based on the fundamental assessment of the EFPIA Transparency Code that, above all, transparency must not render collaboration impossible, such refusal may constitute a "legal reason". That said, one will of course have to place exacting demands upon companies' serious and intensive efforts during the individual contract negotiations; these demands must be documented and substantiated by the companies.

91. **Question:** EFPIA Question ((Question 3.02-1, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 23) (Section 3.02): How should the member company proceed if it does not receive the declaration of consent required for the individual disclosure on the healthcare professional (or organization, as the case may be)?

Answer: Member companies should make every effort to obtain the consent required under data protection laws within the meaning of section 4 a of the Federal Data Protection Act (BDSG) to disclose transfers of value on an individual basis. If it is not possible to obtain this declaration of consent, which must be given voluntarily by the respective healthcare professional in question, the data must be disclosed on an aggregate basis, i.e., in a summarized form.

If the transfer of value payment is made in connection with a contract, the contract offers the possibility of obtaining consent from the recipient in question required under the Code. However, it is important to ensure that the declaration of consent is clear, unambiguous and highlighted. If the contract contains the general terms and conditions of doing business, sections 305 et seq. of the German Civil Code (BGB) must be observed. If in doubt, one should obtain independent legal advice or - if there is one - consult with the respective data protection officer.

In addition, it is recommended that member companies prepare and keep on file the consent and related documents as evidence so that they are in a position to prove that the required consent was requested and provided.

Additional questions and answers on the requirements of data protection law can be found in the Q&As on data protection law.

92. **Question:** EFPIA Question ((Question 2.02-1, Consolidated FAQ (19.12.2014), (2nd Batch Q. no. 36) (Section 2.02 / section 7 VI): Which obligations does the member company have if a recipient revokes the consent to disclosure provided previously? Will it suffice to refrain from disclosing the relevant individual information in future or are member companies obliged to go back and amend and/or rephrase historical reports that have already been published? Are they obliged, in this regard, to delete all related information from all sources, reports, databases, etc.?

Answer: In this case, relevant national data protection laws, such as the German Federal Data Protection Act (BDSG) and other relevant national laws and regulations, must be respected. Member companies must examine the implications of such a revocation on a case-by-case basis and, if necessary, seek legal advice.

As soon as the respective recipient revokes consent, the companies must know when the revocation will take effect and must adjust the individual disclosure accordingly. In the event of a revocation, the member company is, from the date of receiving the revocation, absolutely no longer permitted to disclose individual data on the recipient in question in future. Moreover, the member company may be obliged to delete all previously disclosed information about the recipient. Independently of this, depending

on the legal implications of the revocation at the national level, the members must retain data related to specific activities and reports on the transfers of value in question in aggregated form and must comply with the relevant laws and regulations.

Additional questions and answers on the requirements of data protection law can be found in the Q&As on data protection law.

On paragraph 7

93. **Question:** EFPIA Question ((Question 2.05-2, Consolidated FAQ (19.12.2014), (2nd Batch Q. no. 38) (Section 2.05 / section 8): Does the Code also require disclosure about a second practice and/or a second place of business which are/is not the registered office where the main business activity takes place?

Answer: The Code requires the disclosure in the country where the recipient's main full-time practice and/or registered office are/is located. All transfers of value made to the recipient in question are disclosed at that location. Therefore, in principle, disclosure of transfers of value in the country where the recipient's second practice and/or second place of business are/is located is not required. However, there is an exception if this would result in a substantial increase in transparency (e.g., if the main practice and/or the main place of business are/is in a country that is not a member of the EFPIA).

Member companies should provide further clarification in their notices summarizing the methodology used.

Section 8 Information about recipients

94. **Question:** EFPIA Question ((Question 3.01-1, Consolidated FAQ (19.12.2014), (EFPIA 1st Batch Q&A no. 33) (Section 3.01 / section 8): What is the meaning of the term "clearly identifiable" recipient within the meaning of section 8 para. 1 of the FSA Transparency Code?

Answer: Member companies must ensure that every recipient is identifiable such that all doubts about the identity of the healthcare professional and/or organization are eliminated.

Section 10 Disclosure date

95. **Question**: How should updates triggered by a revocation of consent after disclosure be handled?

Answer: See Q&A on Sample privacy statement.

96. **Question**: EFPIA Question ((Question 2.01-1, Consolidated FAQ (119.12.2014): Which date is relevant for reporting? The date on which the service was provided or the payment date?

Answer: It is up to the member companies to either decide upon the date on which the service was provided or the payment date. A uniform disclosure of the factual circumstances (like expenses for attending a congress etc.) is recommended. Furthermore it is recommended that the member companies explain their choice and handling of the relevant reporting date in their notices summarizing the methodology used in more detail.

97. **Question:** EFPIA Question (Consolidated FAQ (19.12.2014), 2nd Batch Q. no. 35) (Section 2.01 / section 10):

Regarding disclosure, how should one proceed if a healthcare professional signs a speaker agreement in October 2015, but the member company does not receive and pay the invoice until 28 January 2016? Should the disclosure be made in 2016 or 2017?

Answer: Member companies should follow relevant internal Group accounting and valuation principles in dealing with such cases. Nevertheless, the application of such principles may not result in a situation in which, because of a change in the principles from one year to the next, transfers of value remain undisclosed. Information on how member companies deal with such issues must be included in the notices summarizing the methodology used.

Section 11 Place and duration of disclosure

98. **Question**: Should the disclosure rule stipulated in section 11 para. 1 of the FSA Transparency Code be interpreted as being alternative or cumulative?

Answer: It is a minimum requirement. The information can also be published in several places.

99. **Question:** EFPIA Question ((Question 2.05-5, Consolidated FAQ (19.12.2014), (FINAL Q&A (13.11.2013) no. 7) former Sections 2.04 & 2.0, Batch 1 Q. 14):

Which legal entities are required to disclose? Will it suffice for the parent company to make the disclosure or do the local affiliates have to make disclosures on their own? Can the same company's affiliates in a single country each make their own disclosures for their respective shares of the transfer of value?

Answer: If the member company has independent organizations based in the same country, it may, at its discretion, decide which legal entity is best suited to make the disclosure. All transfers of value to the same recipient must be combined and disclosed at a single location. At the same time, the disclosure must be made in the country in which the recipient's practice and/or registered office are/is located. It must include all transfers of value paid to the same healthcare professionals and/or to the same organizations. This applies regardless of which country they were made and/or arose in (e.g., whether in or outside of the country in which the recipient's practice and/or registered office are/is located).

100. **Question:** How are different national companies within a corporate group required to make disclosures (disclosure for affiliated companies)?

Answer: Based on the viewpoint of the EFPIA, a member company is free to make individual disclosures on separate websites of affiliated companies. As an alternative, however, there is also the option of publishing the transparency information on a consolidated, national website. In a case such as this, however, there should be a link from the particular affiliated companies to the consolidated disclosure platform.

101. **Question:** A company sponsors an international professional society which stages its annual congress at various locations in Europe. Where and how should the report be made?

Answer: The definition of the organizations is related to the headquarters of the respective institution, which means the donation must be disclosed in that country. Where the individual congresses of these organizations are staged is irrelevant for transparency.

102. **Question**: What happens if a healthcare professional and/or an organization requests that the data be deleted after they have been disclosed? Do the old reports then have to be constantly updated and/or recalculated? How should one proceed if a healthcare professional and/or an organization object(s) to a disclosure in 2017? Do the data in previous reports then have to be anonymous, too?

Answer: If a healthcare professional and/or an organization request(s) that the data be deleted after disclosure, this request must be complied with under the provisions of the data protection laws. Reports must, therefore, be continually updated.

Section 13 Notes on methods used

103. **Question**: EFPIA Question ((Applicability – 2, Consolidated FAQ (19.12.2014), FINAL Q&A (15.11.2013); former EFPIA Q&A Batch 2 no. 2, General):

What should member companies do if there is a risk that the documents covered by the disclosure obligation also include sensitive data or other information that the member company may not disclose and/or which are not suitable for disclosure by the member company? Will the FSA issue a guideline addressing this?

Answer: In their notices summarizing the methodology used, member companies must describe their data management system and explain what steps are taken to ensure that the companies do not disclose any information categorized as sensitive data under antitrust laws and that they are in compliance with all relevant laws and regulations with respect to disclosure.

Member companies are solely responsible for the information contained in the notices summarizing the methodology used. The FSA will not be issuing any additional guidelines on this matter.

Section 14 Record retention obligations

104. **Question:** EFPIA Question ((Question 2.07-1, Consolidated FAQ (19..12.2014), (2nd Batch Q. no. 39) (Section 2.07 / section 14): Which "documents" are member companies required to retain? Do they include all data sources, such as transactions, reports, databases, etc. related to individual healthcare professionals and/or to the individual organization? In addition, are printouts of additional documents such as contracts, receipts, reports, etc. included?

Answer: The definition of the term "documents" depends on the nature of the transfers of value. In the event of enquiries/investigations/complaints, the member company must always be in a position to prove that the disclosure was handled correctly and with due diligence at the time of the publication. In addition, the member company must be able to respond to enquiries by the recipient in question or by a government agency within the meaning of section 7 para. 1 of the FSA Transparency Code, in accordance with the respective applicable laws, in particular the Data Protection Act (including with respect to retention periods/documents). The

requirements of the Transparency Code are in addition to other retention obligations of member companies.