Methodological Notes on Implementing the FSA Transparency Code for the 2025 Reporting Year

Foreword

As a member of the FSA we feel obliged as a company to organise our working relationships with Healthcare Professionals and medical institutions in a way that is comprehensible and transparent for the public. The FSA has issued the Transparency Code for that purpose. The Code is intended to contribute to avoiding even the appearance of conflicts of interests from the outset and to further improve public understanding with regard to the high value of and the need for cooperation between pharmaceutical companies and Healthcare Professionals.

When implementing the FSA Transparency Code we document and disclose all direct or indirect Transfers of Value that we provide to Healthcare Professionals or medical institutions and in connection with research and development. Such Transfers of Value include for example service and consultancy fees, travel and overnight stay expenses in connection with training events and donations of money/donations in kind to medical institutions.

Healthcare Professionals include all physicians and pharmacists based in Europe and exercising their professional activities there on a full-time basis as well as any member of the medical, dental, pharmacy or other healthcare professions or any other person who in the course of their professional activities may prescribe or apply or lawfully trade in medicinal products for human use. The Transparency Code also covers employees of government agencies or employees of health insurance funds and other funders responsible for prescribing, procuring, supplying or administering medicinal products or deciding on their eligibility for reimbursement.

Irrespective of their respective legal form of organisation, ‘Organisations’ means all medical or scientific institutions or associations based in Europe that are made up of Healthcare Professionals (e.g. medical science associations) and/or through the latter provide medical services or conduct research (e.g. hospitals, university hospitals or other teaching or research institutions).
These also include institutions through which Healthcare Professionals perform services (such as consultancy firms), irrespective of what legal position or function the Healthcare Professionals hold in such Organisations. “Patient organisations” are not classed as Organisations within the meaning of this Code. Transfers of Value to patient organisations have been disclosed on our website since 2008.
Independent contract research institutes which are not composed of prescribing Healthcare Professionals or connected with medical facilities (e.g. contract research organisations (CROs)), are covered by the Code only if Member Companies provide Transfers of Value to Recipients within the meaning of the Code through such institutions (Section 2 para. 2 FSA Transparency Code).

The FSA Transparency Code also provides for disclosure of Transfers of Value in connection with the planning and performance of non-clinical studies (subject to the OECD Principles on Good Laboratory Practice), Phase I to Phase IV clinical trials (subject to Directive 2001/20/EC), and non-interventional studies within the meaning of Section 19 of the FSA Code of Conduct for Healthcare Professionals. These are grouped together (aggregated) and disclosed without naming the recipients.

The reporting period to be disclosed is always the **previous calendar year**. The report will be published on the Berlin-Chemie AG website by the **end of June** of the following year.

These Methodological Notes explain how this company handles the recording and disclosure of the information that must be disclosed according to the FSA Transparency Code.

We have structured these Methodological Notes as follows: in each case a specific question is followed by explanations, if necessary, or examples along with precise details of how we implement the requirements of the FSA Transparency Code.
In cases of doubt as to the obligation to disclose a specific Transfer of Value we assume, in the interest of transparency, that the Transfer of Value must always be disclosed as a matter of course.

All working relationships with Healthcare Professionals and medical institutions are always governed by the principles enumerated in the 'Common position for assessing cooperation between industry, medical institutions and their staff from a criminal law point of view':

1. the Separation principle, which requires clear separation of the Transfer of Value from any commercial transactions
2. the Transparency principle, which requires the disclosure of Transfers of Value in particular to managements of medical institutions
3. the Documentation principle, which states that all services, whether for payment or free of charge, must be documented in writing
4. the Equivalence principle, which states that the performance and counter-performance must be proportionate to each other

Contents

I. DATA PROTECTION LAW QUESTIONS

1. Consent to disclosure of data

1.1 Question

What is the significance of the Healthcare Professional's consent to the disclosure of data?

1.2 Legal background

Every individual's right to protection of their data is enshrined in the Basic Law. The basic right to data protection comprises the collection, processing and transmission of all personal data. These activities may only be carried out on the basis of the consent under data protection law of the person concerned. In particular, the consent must be expressly given and it must also be transparent and clearly worded. Such consent may be withdrawn at any time.

Any consent under data protection law integrated into the wording of contracts or similar documents must be given visual emphasis. Alternatively, the consent under data protection law can be provided as a separate document.

1.3 Methodological implementation

This company requires all Healthcare Professionals receiving Transfers of Value to consent to the disclosure of such Transfer. If consent is not given or if consent is withdrawn, we disclose the Transfer of Value only as an aggregated sum, that is, without mentioning the recipient of the Transfer by name.

2. Consent

2.1 Question

Which consent statement is our data processing based on?

2.2 Methodological implementation

When dealing with Healthcare Professionals this company uses a data protection statement as a separate document applicable to all Transfers of Value in the period from 1 January 2018. The data protection statement provides for either agreement to or refusal of individual disclosure of all Transfers of Value. Partial consent is not possible.

When dealing with Organisations it is not necessary to obtain a statement for data protection reasons, as individuals are not concerned here. In our contracts that we

conclude with Organisations we refer to the FSA Transparency Code and by signing the contract the Organisations consent to individual disclosure.

3. Disclosure period

3.1 Question

How long do we keep the data up on our website?

3.2 Methodological implementation

In principle, the data disclosure period is one calendar year. These data are available on our website for a period of **three** years. If the Healthcare Professional withdraws consent to individual disclosure before the end of that period, we adapt the report accordingly.

II. GENERAL QUESTIONS OF PRINCIPLE

4. Treatment of cross-border situations

4.1 Question

What does this company do in cross-border situations where we provide Transfers of Value to a Healthcare Professional or Organisation based in another European country?

4.2 Examples

A cross-border situation occurs whenever the Transfer of Value is provided in a different country to the country where the Healthcare Professional has his or her head office, practice or principal place of business. An example of a cross-border situation would be if we, as a Germany-based subsidiary of the Menarini Group, were to conclude a speaker's agreement with a physician based in Italy.

4.3 Methodological implementation

In the above example the disclosure is handled by our Italy-based affiliated company. If there is no affiliated company based in the country concerned, we are responsible for disclosure in that country.

5. Disclosure of Transfers of Value in foreign currency

5.1 Question

What do we do if the Transfer of Value was in a currency other than the euro?

5.2 Examples

A physician based in Germany receives financial assistance from us to attend a medical conference in the USA. The conference fee is paid in US dollars.

5.3 Methodological implementation

In our annual report we show all Transfers of Value in euros exclusively. If the original Transfer of Value was not made in euros, conversion takes place at the current rate on the date of the external voucher (date of incoming invoice).

6. Showing VAT

6.1 Question

Is VAT shown in respect of the Transfers of Value that we disclose?

6.2 Legal background

In principle, under the FSA Transparency Code we are at liberty to indicate the amounts shown as either net or gross amounts, that is, either with or without VAT.

6.3 Methodological implementation

In our disclosure of Transfers of Value made, this company shows all amounts as gross amounts, that is, inclusive of VAT.

7. Transfers of Value in the case of non-prescription products

7.1 Question

What do we do if the Transfer of Value relates to non-prescription products?

7.2 Legal background

Only Transfers of Value made in connection with prescription medicines come within the area of application of the FSA Transparency Code.

In the interest of transparency we have decided to disclose additional Transfers of Value in the field of IVD medical devices (in vitro diagnostic tests, e.g. blood glucose meters) in accordance with the rules of the FSA Transparency Code.

7.3 Methodological procedure

This company reports Transfers of Value in the field of IVD medical devices in a separate template, similarly to the template for prescription medicines.

8. Choice of reporting period

8.1 Question

What does this company do if the disclosure of a Transfer of Value relates to more than one reporting period?

8.2 Example

This question arises for instance if a Healthcare Professional is a speaker at an event in one reporting period but the Transfer of Value does not take place until the subsequent reporting period.

8.3 **Methodological implementation**

We disclose the Transfer of Value in accordance with our internal accounting rules in the reporting period in which the Transfer of Value was actually made to the Healthcare Professional or Healthcare Organisation and entered in our books.

9. **Recording sponsorship for the benefit of more than one Organisation**

9.1 **Question**

How do we treat cases where we conclude a sponsorship agreement with several HCOs?

9.2 **Methodological implementation**

In principle, we disclose the Transfers of Value on an individualised basis according to the FSA Transparency Code. If the Transfer of Value can be allocated pro rata to the different Organisations, the shares are disclosed with the names of the respective Organisations.

10. **Transfers of Value to a Contract Research Organisation (CRO)**

10.1 **Question**

How do we handle Transfers of Value to Contract Research Organisations (CROs)?

10.2 **Background**

Contract or Clinical Research Organisations are external research facilities that provide services for payment to companies in the pharmaceutical industry in the area of planning and conducting clinical trials.

10.3 **Methodological implementation**

In principle we do not disclose Transfers of Value to a CRO we have commissioned. An exception applies only if Transfers of Value are made indirectly to Healthcare Professionals via the CRO (these are called ‘pass-through costs’). In that case, we disclose the Transfers of Value on an individualised basis, allocating them to the Healthcare Professional concerned.

11. Recording Transfers of Value to universities and other educational establishments

11.1 Question

How do we treat the disclosure of Transfers of Value to universities and other educational establishments?

11.2 Methodological implementation

In principle, Transfers of Value made by us to universities or other educational establishments do not come within the area of application of the FSA Transparency Code. We will disclose them only if the Transfers of Value indirectly reach an Organisation, such as a university hospital, or one or more Healthcare Professionals. In this case we will record the Transfer of Value under the name of the university hospital to which it was made. If it is known which Healthcare Professional at the university hospital received the Transfer of Value and if that person has consented to individual disclosure, his or her name will additionally be indicated.

12. Indirect provision of Transfers of Value to Healthcare Professionals

12.1 Question

What do we do if Transfers of Value are made to Healthcare Professionals indirectly via third parties?

12.2 Methodological implementation

If we know that a Transfer of Value made by us to a third party benefits or reaches a Healthcare Professional, we will disclose this in principle, giving the name of the Healthcare Professional concerned, if we have been given consent for individual disclosure in accordance with our data protection statement. In the absence of such consent the Transfer of Value will be disclosed on an aggregated basis.

13. Travel expenses for groups of Healthcare Professionals

13.1 Question

How do we treat the disclosure of travel expenses when conveying groups of Healthcare Professionals?

13.2 Legal background

Under the FSA Transparency Code it is not necessary to allocate Transfers of Value made in the form of meeting the travel expenses of a group of Healthcare Professionals to individual Healthcare Professionals.

13.3 **Methodological implementation**

For instance, if a shuttle bus is laid on for a group of Healthcare Professionals and the work of recording the details separately is disproportionate to the value, the expenses will be reported on an aggregated basis.

14. Organisation by event organizer (fictitious HCOs)

14.1 **Question**

How do we treat the disclosure of Transfers of Value if the training event is arranged by an event organizer?

14.2 **Methodological implementation**

If a scientific event (congress, conference, symposium, etc.) is organised by an event organizer and the Transfer of Value is made to the latter, this Transfer of Value shall then be disclosed in a separate table together with the title of the event and the name of the organizer and of the scientific organizer.

For the sake of transparency, we have decided to also disclose Transfers of Value for scientific training events organized by commercial agencies. In this instance, such Transfers of Value shall be disclosed together with the name of the event organizer and a declaration stating the purpose of the Transfer of Value.

15. Expenses in connection with training events

15.1 **Question**

How do we treat HCPs' additional payments in connection with training events?

15.2 **Methodological implementation**

If we collect an additional payment for attendance at a training event this is disregarded for the purposes of reporting Transfers of Value in accordance with the Transparency Code, that is, the amount of the additional payment does not reduce the amount shown.

III. SPECIFIC QUESTIONS ABOUT THE TEMPLATE

16. Donations – definition

16.1 Question

What does this company understand by donations?

16.2 Methodological implementation

By ‘donations’ within the meaning of the Transparency Code we understand unilateral gifts of money to institutions, Organisations or associations that are composed of Healthcare Professionals (e.g. scientific expert associations) and/or that provide medical services or carry out research (e.g. hospitals or university hospitals) (definition as per Section 25 para. 1 FSA Code of Conduct for Healthcare Professionals). As well as complying with the relevant statutory requirements, donations must:

1. serve the purposes of the health service (including for instance the purposes of research, teaching, education and training) or comparable purposes;

2. be properly documented, and the documentation must be retained for a period of at least 5 years after termination of the contractual relationship; and

3. not be misused as an incentive to influence therapy, prescribing and procurement decisions (definition as per Section 25 para. 1 FSA Code of Conduct for Healthcare Professionals).

We do not make any donations in kind or provide any other unilateral benefits in kind.

Membership subscriptions to e.g. medical expert associations are likewise disclosed under the category of donations.

17. Donations

17.1 Question

How do we treat the disclosure of donations made to a hospital?

17.2 Examples

Here it is conceivable that the donation to the hospital, for instance a university hospital, will be given as such. However, another possibility is that the donation is intended to benefit an individual department or unit, such as the Oncology Clinic.

17.3 **Methodological implementation**

If the donation is clearly given to a particular department of the hospital and that department is a legal entity, we record the gift accordingly under the name of the department concerned. If, on the other hand, the donation is given to the hospital generally, the gift is disclosed under the name of the hospital.

18. **Training events – definition**

18.1 **Question**

What does this company understand by training events?

18.2 **Methodological implementation**

By training events we understand congresses, conferences, symposiums, etc. that have a medical focus and provide further training for Healthcare Professionals.

19. **Training events – sponsorship**

19.1 **Question**

What does this company understand by sponsorship?

19.2 **Legal background**

By sponsorship we understand the giving of Transfers of Value to recipients where such gifts are also intended to further our own, company-related promotion or PR aims.

19.3 **Methodological implementation**

The performances and counter-performances are set down in a contractual agreement in which the nature and scope of the exchange are established. Under such agreements we cover things like the renting of an exhibition stand or the mentioning of this company in the invitation to external training events, seminars or conferences.

If sponsorship is provided in the context of external training events, seminars or conferences, we disclose this as a Transfer of Value to the organizer.

20. **Training events – conference and attendance fees**

20.1 **Question**

How are attendance fees for external training events that we undertake to pay on behalf of Healthcare Professionals disclosed?

20.2 **Methodological implementation**

In principle, we disclose attendance fees as a Transfer of Value to the Healthcare Professional concerned under the heading of 'Conference and Attendance Fees'. The total amount of the conference and attendance fees that we have undertaken to pay in the reporting period are disclosed there, individualised for each Healthcare Professional, provided that consent to individual disclosure has been obtained. If that is not the case, such Transfers of Value are disclosed on an aggregated basis without giving names.

21. **Training events – travel and overnight stay expenses**

21.1 **Question**

What expenses do we disclose if we undertake to pay travel and overnight stay expenses in connection with training events?

21.2 **Methodological implementation**

By travel and overnight stay expenses this company understands the expenses arising in connection with Healthcare Professionals attending medical training events. In accordance with the FSA Code we undertake to pay the expenses of return travel on or near the date of the event and necessary overnight stay expenses.

If we undertake to pay travel and overnight stay expenses for people attending medical training events, we disclose them in the relevant category, giving the name of the Healthcare Professional, provided that the Healthcare Professional has consented to individual disclosure. In the absence of such consent the expenses will be disclosed on an aggregated basis without indicating individuals.

22. **Service and consultancy fees – definition**

22.1 **Question**

What does this company understand by service and consultancy fees?

22.2 **Methodological implementation**

In the category of service and consultancy fees we include fees and, separately, travel and overnight stay expenses (reimbursement of out-of-pocket expenses) for Healthcare Professionals in connection with e.g. advising this company on medical matters, appearing as speakers at medical training events or contributing to the production of training materials and/or publications.

23. Research and development – definition

23.1 Question

Which Transfers of Value come into the category of 'Research and Development'?

23.2 Methodological implementation

Under the category of 'Research and Development' we disclose only Transfers of Value relating to studies that are 'necessary for regulatory reasons'. We consider studies to be necessary for regulatory reasons if they are needed in order to maintain the marketing authorisation for a medicine or to carry out post-marketing surveillance. The following in particular count for this company in this area: the planning and performance of non-clinical studies (subject to the OECD Principles on Good Laboratory Practice), Phase I to Phase IV clinical trials (subject to Directive 2001/20/EC), and prospective non-interventional studies within the meaning of Section 19 of the FSA Code. We also include in the 'Research and Development' category those studies that are necessary to demonstrate the additional benefit of a medicine and thus substantiate or maintain eligibility for reimbursement.

24. Research and development

24.1 Question

How do we handle the disclosure of Transfers of Value in connection with research and development activities?

24.2 Methodological implementation

If Transfers of Value relate to activities that can be classed as research and development, we disclose such Transfers of Value only in aggregated form, that is, without mentioning the name of the recipient.