[Bayer AG]

Methodology for implementing the EFPIA Disclosure Code as implemented by the Disclosure Code of Freiwillige Selbstkontrolle in der Arzneimittelindustrie e.V. (referred to below as the FSA Disclosure Code) for the 2015 reporting year

Preamble

We at Bayer firmly believe that close cooperation with doctors and ongoing support of their further training make a significant contribution to optimizing patient treatment. We are committed to ensuring transparency with regard to how we reimburse medical practitioners and establishments for their time and expertise. When working with these experts, we comply with existing legislation and requirements that regulate the relationship between industry and healthcare professionals – for example, legislation relating to healthcare and the industry's code of conduct – and we fully respect the independence and integrity of healthcare professionals.

As a member of Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (FSA), the company feels obligated to make the nature and extent of our collaboration with healthcare professionals transparent and understandable to the public. The FSA has issued the FSA Disclosure Code for this purpose. This code is intended to help avoid any semblance of a conflict of interests and to further improve the general public's understanding of the high value and necessity of collaboration between pharmaceutical companies and healthcare professionals. All full-time doctors and pharmacists based in Europe, all members of medical, dental, pharmaceutical or other healthcare professions, and all other people who prescribe, utilize or legitimately deal in medicinal products for human use in their work are regarded as healthcare professionals. This also includes, for example, employees of public bodies, and employees of health insurance companies and other cost units that are responsible for prescribing, obtaining, supplying or administering drugs or deciding whether they are reimbursable.

In implementing the FSA Disclosure Code, we will document and publish all direct or indirect transfers of value to healthcare professionals in line with the provisions of the version dated November 27, 2013. Each reporting period covers the previous calendar year and we will publish the report no later than the end of June of the following year.

The purpose of this information about methodology is to explain in an easily understandable way how our company records and discloses details that have to be published under the FSA Disclosure Code and, in this way, to provide a guideline for understanding our publication policy. In particular, we aim to clarify the basic methodology and use specific

questions to explain how our company handles these situations in terms of publication. In the event of any doubts regarding the obligation to publish a specific transfer of value, we assume for the purposes of transparency that the transfer should, on principle, be published. Only if transfers of value clearly do not fall under the scope of the disclosure obligations do we refrain from such publication.

We have structured this information about methodology as follows: A specific question is followed by any appropriate explanations or examples together with concrete details relating to how we implement the requirements of the FSA Disclosure Code for the relevant reporting year.

Contents

I. Questions relating to data privacy

1. Consenting to the publication of data

1.1 Question

How important is it for the healthcare professional to consent to data being published?

1.2 Legal background

Since the Disclosure Code is a voluntary undertaking by the pharmaceutical industry, personal data may only be published with the consent of the relevant person. All natural persons enjoy a basic legal right to data privacy. This covers the collection, processing and passing on of all personal data, which is only possible following consent from the relevant person under data protection law. Exacting requirements apply in this respect. In particular, express consent must be given, visibly highlighted in contractual texts or similar documents, and formulated clearly and transparently.

1.3 Methodology

Bayer asks all healthcare professionals receiving transfers of value to consent to their publication. If such consent is not given, we publish the transfer of value as an aggregate amount only, that is to say without naming the beneficiary.

If transfers of value are made to group practices, Bayer asks all healthcare professionals involved to consent to publication. If all parties involved do not give their consent, we will only publish the transfer of value as an aggregate amount.

If a healthcare professional withdraws consent, transfers of value to this person will only be published as aggregate amounts in subsequent reporting periods. Individual publication will only resume once we receive a new declaration of consent.

2. Partial consent for publication

2.1 Question

How do we proceed if, despite our efforts to obtain full consent, a healthcare professional only provides partial consent for the publication of data?

2.2 Example

This can occur, for example, if the healthcare professional agrees to transfers of value associated with participation in a congress (e.g. travel and accommodation expenses) being published, but not a separate consultancy fee.

2.3 Methodology

Since Bayer obtains general consent (see question 3), healthcare professionals cannot provide partial consent. It is, however, conceivable for consent to be withdrawn for specific transfers of value. Should this happen, Bayer will publish all transfers of value to these healthcare professionals in the column for aggregate amounts only. We firmly believe that disclosing individual amounts would provide an incomplete picture, which would go against the desired transparency.

3. Declaration of consent

3.1 Question

On which declaration of consent do we base our data processing?

3.2 Methodology

Consent is obtained from healthcare professionals as follows:

Bayer requests consent for publication before the first relevant activity with the recipient in question. The recipient is told about the background of the Disclosure Code and also given information about our internal data processing. This enables the recipient to decide whether to give or withhold consent for publication of all transfers of value during at least one (current or future) reporting period. If we do not receive a reply despite repeated requests, we will publish aggregate data. Partial consent is not possible (see question 2).

4. Period of publication

4.1 Question

For how long do we make the data available on our publication platform www.bayer.com/en/payments-to-healthcare-professionals.aspx?

4.2 Methodology

On principle, the report is published for a period of four years. Bayer adapts the report if necessary (e.g. for legal reasons). Should Bayer be made aware of possible errors in the data published, it will follow this up and check the data. If it identifies an error, Bayer will correct this immediately and update the report to the extent required.

II. General fundamental questions

5. Dealing with international transactions

5.1 Question

How does our company deal with international transactions involving transfers of value to a healthcare professional or organization based in a different European country?

5.2 Examples

Transfers of value to a different country from the one where the healthcare professional has his registered office, practice or main branch are always regarded as international transactions. This is the case, for example, if our Group company in Italy engages the services of a German healthcare professional as a speaker and pays him a fee.

5.3 Methodology

Transfers of value from a company in the Bayer Group to a healthcare professional or organization based in a different European country are published by our associated company based in this country – in the above example, our Germany company. If we do not have an associated company based in the relevant country, publication in this country is by way of our central website.

The same rules apply in the event of a transfer of value from a Bayer company based outside the EFPIA area to a healthcare professional or organization in an EFPIA country.

6. Publication of transfers of value in a foreign currency

6.1 Question

What is the procedure if the transfer of value was in a currency other than the euro?

6.2 Examples

A doctor based in Germany receives financial support from us for participating in a congress in the United States and the congress fee is paid in US dollars.

A doctor based in the United Kingdom is engaged as a speaker for a training event in Italy. Our Italian subsidiary pays for the flight in euros.

6.3 **Methodology**

We indicate all transfers of value in our annual report in euros only. If the original transfer was not in euros, we convert it using the middle rate for the month during which the transfer was made. Please see question 9 for the date taken as the date of transfer.

In the first example, we would convert the congress fee into euros at the current exchange rate.

In the second example, we would convert the cost of the flight into pounds sterling at the current exchange rate.

7. Indication of VAT

7.1 **Question**

Do the transfers of value we publish include VAT?

7.2 **Legal background**

In principle, the Disclosure Code leaves it up to us whether we indicate gross or net amounts, i.e. either including or excluding the relevant VAT.

7.3 **Methodology**

When publishing transfers of value, our company indicates all sums as net amounts, that is to say excluding VAT. Any personal taxes incurred (e.g. income tax) are, however, included in the amounts published.

8. Dealing with transfers of value for product groups not exclusively comprising prescription drugs

8.1 **Question**

What is the procedure if the transfer of value relates to a group of products that does not exclusively comprise prescription drugs?

8.2 **Legal background**

The Disclosure Code only applies to transfers of value associated with prescription drugs. In practice, however, transfers of value can relate to a group of products that includes non-prescription drugs and other products in addition to prescription drugs.

8.3 **Example**

Healthcare professionals are invited to a training event at which results of trials relating to a prescription medicine are presented. At the same event, presentations are also given about non-prescription products in the same therapeutic area.

8.4 **Methodology**

As long as transfers of value are not made exclusively in relation to non-prescription medicines or medicinal products – which are not covered by the Disclosure Code – Bayer will disclose such transfers in full.

9. Selecting the reporting period

9.1 **Question**

What does our company do if there is more than one possible reporting period for publishing a transfer of value?

9.2 **Example**

This question can arise in various situations:

1) During a particular reporting period, a healthcare professional enters into an agreement with Bayer to act as a speaker. The necessary flights are booked immediately, but the event does not takes place until the next reporting period.

2) A sponsorship agreement for a training event is concluded during a particular reporting period, but this training does not take place until the next reporting period.

3) The services of a speaker are engaged for an event that is taking place at the end of a reporting period. The speaker does not submit the invoice until the following reporting period and the fee is also paid during this period.

4) A healthcare professional enters into an 18-month consultancy agreement with Bayer.

9.3 **Methodology**

We publish transfers of value according to the following rules:

For activities within a short, defined period (e.g. congresses or other scientific events), the start date of the activity determines the reporting period. In the case of long-term activities, the date on which the relevant invoice is posted at Bayer determines the reporting period. Donations are always disclosed in the reporting period during which they were made.

If an invoice for an activity that takes place within a short, defined period is not received in time to make payment in the same reporting period, this payment is disclosed in the next reporting period.

The above examples are therefore dealt with as follows:

1) Since the event is an activity within a short, defined period, all associated transfers of value are disclosed in the reporting period during which the event takes place.

2) Since the training event is an activity within a short, defined period, all associated transfers of value are disclosed in the reporting period during which it takes place.

3) Since the speaker's services are engaged for a specific event, relevant transfers of value are disclosed in the reporting period during which this event takes place. Only if invoices (e.g. for the fee) are received too late to make payments is the relevant payment disclosed in the following reporting period.

4) Since the consultancy relationship is a long-term activity, relevant transfers of value are disclosed in the reporting period during which the associated invoices are posted at Bayer.

Should our rules change with the result that a transfer of value would be published in the later reporting period according to the previous rules but in the earlier reporting period following the change, we would still publish the transfer in the later reporting period. Consequently, a change to our in-house rules would not result in a transfer of value that is subject to a disclosure obligation remaining unpublished.

10. Publication of transfers of value in the case of agreements lasting several years

10.1 Question

What is the procedure for publishing a transfer of value based on an agreement spanning several years?

10.2 Example

This question arises, for example, if our company concludes a consultancy agreement with a doctor that runs from July 1, 2015 to December 31, 2018 with a total fee of EUR 3,500.

10.3 Methodology

In this case, we publish the individual fee payments based on the date on which the relevant invoices are posted at Bayer (see also question 9). Details depend on the specific consultancy agreement (e.g. which services are to be provided during which period, what partial fee is payable for this, etc.).

11. Recording sponsorship payments benefiting more than one organization

11.1 Question

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

11.2 Methodology

On principle, we publish transfers of value separately under the Disclosure Code. If it is possible to assign the transfer proportionally to the relevant organizations, the specific shares are published under the designation for the respective organization.

If this is not possible, we assume that each organization receives the same proportion of the total amount and publish this information accordingly.

12. Transfers of value to a contract research organization (CRO)

12.1 Question

What is the procedure for making transfers of value to contract research organizations (CROs)?

12.2 Background

Contract/clinical research organizations are institutes that act as service providers and are paid to perform planning tasks and conduct clinical trials for companies in the pharmaceutical industry.

12.3 Methodology

On principle, we do not publish payments we make when using a CRO. The only exceptions are as follows:

- If the CRO is made up of healthcare professionals or is associated with a medical institution (such as a university hospital or a public institution). In this case, it is regarded as a healthcare organization and we publish transfers of value to it in line with the general rules.

- If the CRO makes indirect transfers of value to healthcare professionals (pass-through costs). In this case, we publish the transfers of value in line with the general rules. These are normally for research and development activities and are published as aggregate amounts.

13. **Recording transfers of value to universities and other educational establishments**

13.1 **Question**

How do we deal with publishing transfers of value to universities and other educational establishments?

13.2 **Methodology**

In principle, the FSA Disclosure Code does not apply to transfers of value from us to universities or other educational establishments. We only publish such transfers if they go indirectly to an organization such as a university hospital or to one or more healthcare professionals. In this case, we record the transfer of value under the name of the university or other educational establishment to which it is made.

14. **Indirect transfers of value to healthcare professionals**

14.1 **Question**

What is the procedure in the case of indirect transfers of value to healthcare professionals via third parties?

14.2 **Methodology**

In principle, if we are aware that transfers of value from us to third parties benefit or are received by a healthcare professional or organization, we publish this transfer and give the name of the relevant healthcare professional/organization following consultation with them.

III. Specific questions about the data collection sheet

15. **Donations – publication if a hospital is the beneficiary**

15.1 **Question**

How do we handle publication of donations to a hospital?

15.2 **Examples**

A donation to a hospital – a university hospital, for example – may be transferred to the hospital as such, but it is also possible for it to benefit a single unit or department such as the oncology department.

15.3 **Methodology**

If the donation is clearly going to a specific hospital department and this is a legal entity, we record the transfer of value accordingly under the designation of the relevant department. If, on the other hand, the donation is made to the hospital in general, the transfer of value is published under the designation of the hospital.

16. **Sponsorship**

16.1 **Question**

Which transfers of value do we record in the sponsorship agreements category?

16.2 **Legal background**

Within the meaning of the Disclosure Code, a sponsorship agreement is any agreement through which Bayer makes a transfer of value in return for an appropriate service (e.g. being mentioned as a sponsor or the right to operate a stand or organize a company symposium). According to the Disclosure Code, only support to healthcare organizations must be disclosed.

16.3 **Methodology**

Bayer publishes the total sponsorship sum in the basic agreement. This is calculated according to the fair market value for the service obtained.

17. **Training event – definition**

17.1 **Question**

What does our company understand by training events?

17.2 **Methodology**

We understand a training event as any event (e.g. congresses, conferences, symposia, etc.) with a medical/scientific focus that serves to further the training of healthcare professionals.

18. Training events – participation fees

18.1 Question

How do we publish participation fees for external training events that we pay on behalf of healthcare professionals?

18.2 Methodology

In principle, we publish participation fees as transfers of value to the relevant healthcare professional under conference and participation fees. The total amount of conference and participation fees paid for each individual healthcare professional in the reporting period appears here.

It is also possible to report the payment of such fees under the name of an organization. For example, Bayer can promise to pay the participation fees for a certain number of doctors selected by a hospital. In this case, the hospital is the beneficiary.

19. Training events – travel and accommodation expenses

19.1 Question

Which costs do we publish if we pay travel and accommodation expenses in connection with training events?

19.2 Methodology

In this category, Bayer reports any travel and accommodation expenses it pays that are not associated with services or research and development activities, including flight, taxi and hotel costs and the cost of rail travel.

If travel is organized by an external travel agency, we do not report the agency's administrative charges. Such agencies are contractually obliged to provide us with the necessary detailed information to enable separate reporting for the individual participants.

20. Training events – organization by an event organizer

20.1 Question

How do we handle the publication of transfers of value if the training event is organized by an event organizer?

20.2 Methodology

If a scientific event (congress, conference, symposium, etc.) is organized by an event organizer and the transfer of value is to this organizer but a healthcare organization according to §2 (2) or a healthcare professional benefits indirectly from it, the entire sponsorship sum is published by naming the relevant organization or healthcare professional.

With regard to a healthcare organization such indirect benefits could for example result from a link between the organization and the scientific event by the fact that the organization is involved into the planning and realization of the event or provides its name for the event.

21. Training events – costs of internal training events

21.1 Question

How do we handle the publication of costs of internal training events?

21.2 Methodology

Internal training events are events that Bayer organizes itself. We publish any travel and accommodation expenses we pay for participants in such events, naming the relevant healthcare professional, in the relevant category (provided consent has been given).

22. Service and consultancy fees – definition

22.1 Question

Which specific transfers of value do we record under service and consultancy fees?

22.2 Legal background

Service and consultancy fees are based on relevant service and consultancy agreements. Bayer understands these fees as any transfer of value in return for any service that does not fall under other reporting categories.

22.3 **Methodology**

We record any transfer of value in return for a service in the service and consultancy fees category. Since the expertise of healthcare professionals and organizations is essential for the further development of science and patient care, we pay the fair market value for such services.

This category includes in particular fees for speaker or consultancy agreements. If services are associated with activities that fall under the research and development category, we will publish the relevant fees under this category.

23. **Service and consultancy fees – reimbursement of expenses**

23.1 **Question**

How do we handle the publication of expenses reimbursed in connection with service and consultancy fees?

23.2 **Legal background**

As regards transfers of value in the service and consultancy fees category, the standardized data template provides for separate publication of the actual fee and the expenses reimbursed, such as travel and accommodation expenses.

23.3 **Methodology**

Bayer will publish all expenses relating to the provision of services in this category. N.B.: Expenses may be published for a healthcare professional, but no fees. This is because, in some cases, the healthcare professional waives a fee for the service.

24. **Research and development**

24.1 **Question**

How do we handle the publication of transfers of value associated with research and development activities?

24.2 **Methodology**

If transfers of value relate to research and development activities, we publish these as aggregate amounts only, that is to say without naming the recipient. All transfers of value for research and development activities are shown as an aggregate amount in the report in line with the specifications of the FSA Disclosure Code.

25. Research and development – definition

25.1 Question

Which transfers of value fall under the research and development category?

25.2 Methodology

Only transfers of value relating to trials required by the regulations are published under the research and development category. We regard trials that are necessary to license a drug or to monitor it once a license has been issued (post-marketing surveillance) as being required by the regulations. In concrete terms, our company considers this to apply in particular to the planning and conduct of non-clinical trials (in line with the OECD Principles of Good Laboratory Practice), phase I to IV clinical trials (in line with Directive 2001/20/EC) and non-interventional trials as defined in the Disclosure Code. Trials that are necessary to provide evidence of the additional benefits of a drug so as to prove or maintain its eligibility for reimbursement are also included in the research and development category.

26. Research and development – fundamental research

26.1 Question

How do we handle the publication of payments we make in the field of fundamental research?

26.2 Methodology

Fundamental research is normally used to develop new products or extend the range of applications of existing products. We therefore normally publish transfers of value in the field of fundamental research under the research and development category.

If we perform fundamental research that is not associated with the development of new products or the further development of existing ones, we will publish transfers of value under the service and consultancy fees category.