Methodology Note

Methodology Note explaining the implementation of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code, in accordance with the Irish Pharmaceutical Healthcare Association (IPHA) Code of Marketing Practice.

Bayer Limited

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Introduction

We at Bayer believe that close cooperation with healthcare professionals is key to achieving better outcomes for the patients we strive to help.

We are committed to transparency regarding how healthcare professionals (HCPs) and healthcare organisations (HCOs) are paid by or receive a benefit in kind from Bayer for the time and expertise they provide. When collaborating with medical experts, we comply with all applicable laws, regulations and codes of practice, such as the EFPIA Disclosure Code in Europe, and various local legal reporting obligations fully respecting the independence and integrity of these professionals. The EFPIA Disclosure Code has been incorporated by the Irish Pharmaceutical Healthcare Association (IPHA) into the IPHA Code of Marketing Practice. These codes are intended to ensure that even the impression of potential conflicts of interest is avoided. The purpose of making the cooperation between the industry and the medical community more transparent is so that the general public can gain a better understanding of the importance and value of this cooperation for patient well-being and the development of medicines.

In order to make the nature and the extent of the interaction between the pharmaceutical industry, healthcare professionals and organisations more transparent, Bayer will document and disclose all transfers of value that are in scope of the EFPIA Disclosure Code. A transfer of value (ToV) can be a monetary value or a benefit in kind and could be made directly or indirectly, for the benefit of HCPs or HCOs. The reporting period is always a full calendar year. Disclosure of transfer of value made in the previous calendar year will be published at the latest by the end of June of the current year. This process will be repeated every year.

The purpose of this methodology note is to allow any person accessing the report to understand how Bayer is documenting and disclosing the relevant information. In particular, it will explain the details of the data collection and how these data are reported. The general rules of the EFPIA Disclosure Code apply to all member companies and all companies will disclose relevant ToV in a pre-defined format. However, some details of the reporting methodology are left for the individual companies to decide in order to allow the necessary flexibility to adjust for internal company processes.

If in doubt about the duty to disclose a specific ToV, Bayer will always aim for full disclosure. Only if a ToV is clearly out of scope of the Disclosure Code, will it not be included in the published report.

This methodology note is structured as follows: based on a specific question, we will explain in detail, how Bayer handles disclosure of ToV to HCPs and HCOs. The general explanation will – where possible – also be illustrated by examples to ensure a clear understanding.

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Data Privacy

1. Data Privacy – Consent for publication of data

What is the importance of HCPs consent to the publication of data?

Legal Background

As the Disclosure Code is a voluntary self-obligation of the pharmaceutical industry, publication of data is dependent on the consent of healthcare professionals concerned. Everyone is entitled by law to protection of data relating to them. This basic right covers the recording, processing and dissemination of any personal information, whereby any of these shall require the specific consent of the person affected. There are strict requirements for any such consent – it must be explicit, it needs to be visually highlighted in any contractual texts or similar documents and must be clearly and transparently worded.

Methodology

Bayer is requesting consent from all HCPs before declaring a ToV to the individual concerned. If such individual consent is not granted, Bayer will only be able to publish the ToV in the aggregated section of the report; we cannot specify the name, address or other personal data of the recipient.

If a HCP revokes his/her consent, we will publish any transfers of value to this HCP in aggregated form for the subsequent reporting periods. If and when Bayer receives a new consent from that HCP, their data will be published on an individual level going forward.

2. Data Privacy – Partial consent for publication of data

How does Bayer react if a healthcare professional, despite our best efforts to obtain full consent, only grants partial consent for the publication of selected ToVs?

Example

This situation may arise, for instance, if a healthcare professional consents to the publication of accommodation costs for participation in a congress, but does not consent to the publication of a speaker fee which is paid for a different event.

Methodology

Bayer is seeking overall consent (please see question 3) in other words consent of an individual HCP to declare all ToVs made to them as opposed to just selected activities. However, it is possible that they choose to withdraw consent for certain selected activities. If this happens, Bayer will report all ToVs to such healthcare professionals in the aggregated section of the report. We believe that reporting only selected ToV on an individual level decreases the level of transparency by giving a distorted picture.

3. Data Privacy – Declaration of Consent

What sort of declaration of consent is data processing at Bayer based on?

Methodology

Bayer is using the following approach to obtain consent from healthcare professionals:

Bayer is requesting consent before the first relevant reporting period with the respective healthcare professional. The healthcare professional is informed about the purpose of the EFPIA Disclosure Code and the required data processing. The healthcare professional can then decide to grant consent for at least one full reporting period or to dissent to the publication of data. Partial consent is not possible (see question 2).

4. Duration of publication

How long do we make the information available for on our disclosure platform?

Methodology

Our report will be available for a period of three years. We will amend the report accordingly, if required for specific, e.g. legal, reasons. If Bayer is made aware of potential errors in the published data, this will be thoroughly reviewed. If an error is confirmed, Bayer will update the report to the extent necessary.

General questions

5. Cross-border interactions

What will we do in the case of cross-border interactions, where we provide ToV to a healthcare professional or organisation based in another European state?

Example

This sort of situation includes those cases where, for example, the Bayer affiliate in Italy concludes a consultancy agreement with a Germany-based HCP and pays an honorarium for the services provided.

Methodology

ToV made by a local affiliate to a healthcare professional or organisation with primary practice in a different European state will be reported by the Bayer affiliate in which the HCP or HCO is based. In the examples given above, the ToV will be reported by our German legal entity.

For those countries in which the HCP or HCO has their primary practice but there is no local Bayer affiliate, Bayer will publish the information on a central website.

The same rules apply, if a local affiliate in a non-European country grants a ToV to a healthcare professional or organisation with primary practice in a European state. In other words the ToV will be published on the central database.

6. Publication of ToV granted in a foreign currency

What do we do when the monetary donation was made in a different currency to the local currency of the recipient country?

Examples

A doctor based in the UK receives funding from us to take part in a healthcare convention in Ireland and the registration fee is paid in Euro.

A physician with primary practice in Ireland is acting as a speaker for an event in the UK. The flight is booked by our UK legal entity and is paid in sterling.

Methodology

All ToVs specified in our report will be denominated in euro. If the original payment was not made in euro, we will convert the amount based on the average exchange rate in the month the ToV was made. Please refer to question 9 regarding the definition of the date we consider as the ToV date.

In the first example, we would convert the reimbursement of the registration fee to sterling. The exchange rate will be the average exchange rate in the month of the congress and the ToV declared by the UK Bayer affiliate.

In the second example, we would convert the costs of the flight into euro. The exchange rate will be the average exchange rate in the month of the flight and the ToV would be declared by Bayer in Ireland since this is where the recipient has their primary practice.

7. VAT

Will the figures we publish include VAT?

Legal background

The EFPIA Disclosure Code allows member companies to publish gross or net figures (i.e. including or excluding VAT).

Methodology

Bayer will report all ToVs as net amounts, excluding VAT.

8. ToVs connected to product groups which do not solely comprise prescription pharmaceuticals

What will we do if a ToV is connected to a group of products which is not solely comprised of prescription-only pharmaceuticals?

Background

Under the EFPIA Disclosure Code, ToVs are only covered in connection with prescription-only medicines. In practice, however, such ToVs may relate to a group of products made up of a combination of prescription-only and non-prescription pharmaceuticals and other products.

Example

Healthcare professionals are invited to a scientific event, where results of a clinical trial related to a prescription-only medicine are presented. At the same time, information on over-the-counter medicines in the same therapeutic area is provided.

Methodology

As long as ToVs are not exclusively connected to over-the-counter medicines or medical devices – which are not in scope of the EFPIA Disclosure Code - Bayer will disclose such ToVs in full.

9. Reporting period

What will we do if more than one reporting period could be considered when publishing details of ToVs?

Examples

This situation may arise in various situations:

1. A healthcare professional agrees during one reporting period to appear as a guest speaker at an event, the flights are booked during this period, but the event itself takes place in the following reporting period.
2. A sponsorship for an event is granted in one reporting period, but relates to an event taking place in the next reporting period.
3. A speaker is engaged for an event at the end of one reporting period, but the invoice is received and the honorarium is paid in the next reporting period.
4. An HCP enters into a long-term consultancy contract with Bayer, which lasts for eighteen months i.e. a time longer that one reporting period.

Methodology

We will publish ToV in accordance with the following rules:

In the case of short term activities within a defined timeframe (e.g. congresses or other scientific events), the start date of the activity defines the reporting period. For long-term activities, the posting date of the relevant invoice determines the reporting period. Donations are always reported in the reporting period where they are made.

In the event that an invoice for a short term activity is not received in time to include the ToV in a report, the amount will be disclosed in the following report.

For the examples given above this methodology leads to the following results:

1. As the event is a short term activity, all related ToVs will be reported in the reporting period in which the event takes place.
2. As the event is a short term activity, the sponsorship will be reported in the reporting period in which the event takes place.
3. As the speaker is engaged for a specific event, the payment will be reported in the reporting period where the event took place. Only if the invoice is received too late will reporting be postponed until the next reporting period. Items paid in 2015 relating to 2014 activities are not included.
4. As the consultancy contract is a long-term activity, the ToV under this agreement will be reported in the period in which the individual invoices for specific activities are received.

In the event that our reporting methodology should change, we will ensure that all relevant ToVs are correctly reported. This means that any changes to our methodology will not result in any failure to publish details of any ToV subject to a publication requirement.

10. Review of data

Will HCPs and HCOs be able to review the data before publication?

Methodology

Yes, an Attestation Letter is sent to each HCx prior to the publication and the HCx will have time to review the data and contact Bayer with any queries.

11. Publication of ToV relating to contractual arrangements lasting several years

What will we do in the event of publishing details of a ToV granted in relation to a contract stretching over several years?

Example

This situation may arise, for example, in the event that we have a consultancy agreement with a doctor which has a term from 1 July 2015 to 31 December 2018 and which attracts a total consultancy fee of EUR 3,500, which is paid in stages.

Methodology

In such a case, we will disclose the individual payments based on the date when Bayer receives the respective invoices. Details depend on the contract with the consultant (e.g. what services are agreed for which time period, which amounts are foreseen for these services, etc).

12. Sponsoring payments made to more than one organisation

What will we do in cases where we have a sponsoring agreement with several healthcare organisations?

Methodology

We will publish details of ToVs on an individual HCO basis in accordance with the EFPIA Disclosure Code. If an individual ToV can be allocated pro rata to the relevant organisation, then ToVs will be published under the name of the respective organisation.

If such an allocation is not possible, we will assume that each organisation receives an equal share and will publish this accordingly.

13. ToV to Contract Research Organisations (CROs)

What will we do in the event of ToV being granted to contract research organisations (CROs)?

Background

Contract / clinical research organisations are research organisations which provide clinical study planning and execution services to companies in the pharmaceutical sector in return for payment.

Methodology

We will not publish details of any ToV granted to any CROs whose services we retain. However, we will report ToV, if:

- The CRO is comprised of healthcare professionals or has links to a medical institution (like a university hospital or a publicly-run organisation). In such case, the CRO is considered to be a HCO and details of any ToV granted to it will be published by us in accordance with the general rules.
- The CRO is used indirectly to grant ToV to healthcare professionals (“pass-through costs”). In such case, we will publish these ToVs in accordance with the general rules.

14. Recording of ToV granted to universities and other educational establishments

What will we do in terms of the publication of ToV granted to universities and other educational establishments?

Methodology

Universities and other educational establishments or organisations are not in scope of the EFPIA Disclosure Code per se. We will however publish details of such ToVs in the event that they are indirect ToVs to a healthcare organisation, such as a university hospital, or one or more healthcare professionals. In such cases, we will publish the details of each of those ToVs under the name of the university or other educational establishment to which they were granted.

15. Indirect ToVs to healthcare professionals and organisations

What will we do in the event that ToVs are granted to healthcare professionals or organisations indirectly via third parties, such as travel or event agencies?

Methodology

In the event that we become aware that ToVs granted by us to a third party have been passed on to healthcare professionals or healthcare organisations, we will publish the details of each of those ToVs under the name of the relevant healthcare professional or organisation. Our contractual arrangements with third parties include the obligation to report the relevant data to us in the necessary level of detail. Our contract partners are also obliged to ensure that such information transfer is in line with applicable data privacy laws.

16. Transport costs for joint transportation

What will we do about publishing details of transport costs for joint transportation or for the transportation of groups of healthcare professionals?

Methodology

The total transportation cost for a group of healthcare professionals will be divided equally to the relevant individuals and disclosed accordingly

Questions on the report

17. Donations – hospitals or clinics as recipients

What will we do about the publication of donations to hospitals or clinics?

Example

It is possible in this case that the donation will be made to a hospital or clinic as a whole or to a department or unit within that institution, such as the oncology unit.

Methodology

In the event that the donation is clearly intended for a specific department or unit within a hospital we will publish details of the donation and give the name of the department. In the event that the donation is made to the hospital as a whole, we will publish the donation under the name of the hospital.

18. Sponsorships

Which ToVs will we publish relating to sponsoring agreements?

Legal background

A sponsorship under the EFPIA Disclosure Code is any agreement, where Bayer grants a ToV in exchange for advertisement opportunities at an event. Under the EFPIA Disclosure Code, only events organised by or on behalf of a HCO are in scope of the reporting obligations.

Our approach

We will publish the entire sponsorship amount agreed in the underlying sponsorship contract unless a breakdown into disclosable versus non-disclosable items is documented. The sponsorship amount is determined based on the fair market value for the advertisement opportunities obtained.

19. Scientific and educational events – definition

What do we define as scientific or educational events?

Methodology

We define any event (e.g. conventions, conferences, symposia etc.) with a focus on providing medical or scientific information or serving to further the medical training of healthcare professionals as scientific and educational events.

20. Scientific and educational events – registration fees

What will we do about the publication of ToVs related to registration fees we have paid for healthcare professionals or organisations to attend external scientific or educational events?

Methodology

We will publish the payment of registration fees as a ToV to the relevant healthcare professionals in the section devoted to “registration fees”. The total amount of such fees assumed during the reporting period will be published for each individual healthcare professional. Such fees can also be reported for a healthcare organisation, e.g. if Bayer supports the participation of a certain number of physicians working at a hospital and the hospital chooses the participants. In such case, the hospital is seen as the recipient of the ToV.

21. Scientific and educational events – travel and accommodation costs

Which costs will we publish when we have paid travel and accommodation costs relating to scientific and educational events?

Methodology

We will disclose any travel and accommodation costs for HCPs and HCOs that are not related to services or Research & Development activities in this category. This includes, for example, costs for flights, train, taxi and hotel costs (including daily delegate rates).

If travel is organised through an external travel agency, the administrative costs of that travel agency will not be reported. Such travel agency is contractually obliged to provide us with the information, which ToVs have actually been provided to individual participants.

22. Scientific and educational events – organisation by an events agency

What will we do about publishing details of ToVs if a scientific or educational event is organised by an events agency?

Methodology

If an event (convention, conference, symposium etc.) is organised by an events agency and the ToV is paid to that agency, but the event has a clear relevance to a HCO, we will publish details of such ToV under the name of the related HCO. As a general rule, we report the entire sponsorship amount. Only if we receive specific information that a limited amount is transferred to the HCO, we will report only this limited amount. This can happen, for example, if the HCO has out-licenced the name of a traditional event and is only receiving a certain percentage of sponsorship amounts as licence fees.

23. Continuous professional development events – costs for internal events

Will Bayer publish costs for internal scientific or educational events?

Methodology

Internal events are defined as events organised by Bayer itself. Bayer does not charge registration fees for its own events; therefore no ToV takes place in this regard. In the event that we have paid the travel and accommodation costs for those persons attending our internal events, details of such will be published specifying the name of the relevant healthcare professional in the category provided for this purpose.

24. Service and consultancy fees – definition

Which TOV do we record as service and consultancy fees?

Legal background

Service and consultancy fees are due under corresponding service and consultancy agreements. We understand these to be any ToV granted in exchange for any kind of service, which is not covered by another reporting category of the EFPIA Disclosure Code.

Our approach

Under the category service and consultancy fees, we record any ToV (monetary or non-monetary), which is granted in exchange for services provided by a HCP or HCO. Services provided by experts will be remunerated at fair market value.

Generally, fees for services are honoraria paid for services like speaker engagements or consultancy. If services provided are connected to activities in scope of the category “Research and Development”, the fees will be reported in that category.

25. Service and consultancy fees – reimbursement of expenses

What will we do about the publication of any expenses reimbursed in connection with service and consultancy fees?

Legal background

In terms of ToVs falling under the category “service and consultancy fees”, the data record template provides for any expenses reimbursed being published in addition to and separately from the fee itself. These expenses generally include travel and accommodation costs.

What will we do about the publication of any ToVs relating to R&D activities?

Our approach

In the event that the ToV relates to any R&D activities, we will only publish the total ToV without specifying the name of the recipient.

26. Research & Development (R&D)

Which ToVs are reported under “R&D”?

Our approach

For the purpose of disclosure, research and development, ToVs are ToVs to health professionals or healthcare organisations related to the planning or conduct of non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice); clinical trials (as defined in Directive 2001/20/EC); non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study. Costs that are subsidiary to these activities can be included in the aggregate amount.

27. Basic research

What will we do about publishing TOVs relating to basic research?

Our approach

As basic research is usually targeted at either developing new products or relates to a specific product and is intended to extend its scope of use, we will publish the total value of ToV under the category “R&D”.

If we conduct basic research unconnected to the development of new or enhancement of existing products, we will publish it under the category “service agreements” rather than under “R&D”.

In the event, however, that we support basic research in the form of donations to a university hospital, for example, we will publish the corresponding ToV under the category “monetary donations / donations in kind”.

For any queries relating to the disclosure of data, please contact transparency.ie@bayer.com

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