Methodology Note

Methodology Note explaining the implementation of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code, in accordance with the Association of the British Pharmaceutical Industry (ABPI) Code of Practice.

Disclosure Period: Calendar Year 2024

This Methodology Note has been developed by Bayer

Bayer PLC

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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 Prescription Medicines Code of Practice Authority (PMCPA) into the ABPI Code of 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 the UK, the ABPI Code of Practice incorporates the requirements of the EFPIA Disclosure Code. In addition, the ABPI Code of Practice requires that the reporting of payments made to healthcare organisations consisting of only one healthcare professional or other relevant decision maker will be subject to the requirements of the ABPI Code for individual healthcare professionals. The ABPI Code also requires that all transfers of value made by companies in connection with collaborative working, including joint working, between the NHS and pharmaceutical industry must be publicly disclosed.

Bayer provides donations and grants for the purpose of supporting healthcare, scientific research or education, with no obligation on the recipient organisation or institution to provide goods or services to the benefit of the pharmaceutical company in return.

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, other relevant decision makers, HCOs and specific interactions with patient organisations and the public, including patients and journalists. The reporting period is always a full calendar year. The tenth report, published in 2025 on the ABPI portal, will cover all relevant ToV made in 2024. ToVs made in accordance with the Association of British HealthTech Industries (ABHI) Code of Practice are also disclosed on the ABPI portal.

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. An example of this would be donations made to healthcare organisations as a result of employee fundraising activities.

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, other relevant decision makers, HCOs and specific interactions with patient organisations and the public, including patients and journalists. 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 – Legal basis for publication of data

Legitimate Interest used for processing of personal data.

Legal Background

Effective 1 January 2023, Bayer changed the legal basis on which it relies to process and disclose personal data within ToV information. Bayer previously relied on consent from HCPs and now relies on Bayer's legitimate interest.

In the context of the ToV disclosure process, Bayer's legitimate interest is transparency, enabling better public scrutiny of financial transactions, and compliance with the ABPI Code of Practice.

Unlike with consent, under legitimate interest individuals can no longer "opt out" of processing (including disclosure). They do have the right to object to processing activity and Bayer must consider any reasons put forward and balance them against Bayer's legitimate interests.

To object, an HCP should email hcpdisclosure@bayer.com explaining the reason why any data cannot be processed. Each objection will be reviewed by Bayer and a decision taken. The HCP will be informed of the decision.

Methodology

As there is no "opt out" available when using legitimate interest, it is important that individuals understand that their data will be disclosed prior to signing a contract under which ToV will be received.

For activities taking place from January 2023, contracts contain a highlighted clause explaining legitimate interest and a privacy statement.

With the exception of R&D, all ToVs to individuals will be disclosed individually unless an overriding objection is received from an HCP. Where an objection is considered to override Bayer's legitimate interest then Bayer will only be able to publish the ToV anonymously, in aggregate.

2. Data Privacy

What happens to activities that span the 1 January 2023 change to legitimate interest?

Examples

The situation may arise where an HCP activity took place partly in 2022 and partly in subsequent years.

HCP contract was set up prior to the change to legitimate interest and/or the legitimate interest clause is missing from the contract.

Methodology

Bayer made clear in contracts with individuals that any activities starting in 2022 and running into subsequent years, would be reported under the legitimate interest regime.

Legacy contracts may rely on HCP consent as the legal basis.

Activities are reported in accordance with the methodology set out in section 8 - Reporting Period

3. 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.

General questions

4. 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.

5. 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 Germany receives funding from us to take part in a healthcare convention in the UK and the registration fee is paid sterling.

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

Methodology

All ToVs specified in our report will be denominated in sterling. If the original payment was not made in sterling, we will convert the amount based on the average exchange rate in the month the ToV was made. Please refer to question 8 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 euros. The exchange rate will be the average exchange rate in the

month of the congress and the ToV declared by the German Bayer affiliate.

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

6. 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. Where quoted separately on invoices, Tourist Tax is excluded from ToV value.

7. 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 or devices.

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.
- ToVs made to any HCPs or HCOs that can influence the prescription of a medicine in relation to the Radiology business, will be disclosed in full.
- Bayer will disclose package deal service fees for any transfers of value not relating to ordinary course purchases and sales of medicine.

8. 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.

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

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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.

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.

A ToV is only reported once.

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.

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.

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9. 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 2023 to 31 December 2024 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).

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10. 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.

11. 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 an organisation 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.

12. 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.

13. 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.

14. 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

Where possible we allocate transportation costs to the relevant individual. However, if this is not possible the total transportation cost for a group of healthcare professionals will be disclosed on an aggregate basis.

Questions on the Report

15. 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, such as a Therapy Review 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 and this department is a legal entity in its own right, 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, or if the department is not a legal entity, we will publish the donation under the name of the hospital or trust.

16. 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 including contribution to costs related events/ meetings paid to HCOs or to organisations managing events on their behalf.

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.
- We will include sponsorships made to professional event organisers.

17. Scientific and educational events/meetings – definition

What do we define as scientific or educational events/meetings?

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.

18. Scientific and educational events/meetings – 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/meetings?

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.

19. Scientific and educational events/meetings – travel and accommodation costs

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

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, as to which ToVs have actually been provided to individual participants.

20. Scientific and educational events/meetings– 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 an 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.

21. 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.

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22. Contracted services – definition

Which TOV do we record as Contracted Services and fees?

Legal background

Contracted Services and 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 contracted services and fees, we record any ToV (monetary or non-monetary), which is granted in exchange for services provided by HCPs, HCOs, patient organisations, individuals representing patient organisations and members of the public including patients and journalists.
- Services provided by experts will be remunerated at fair market value.
- We pay the ultimate recipient of a ToV wherever possible.
- 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.
- Contracted services provided by the public, including Patients and Journalists will be reported with a description of the types of services provided, without divulging confidential information.

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23. Contracted Services, fees and expenses – reimbursement of expenses

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

Legal background

In terms of ToVs falling under the category “contracted services, fees and expenses”, 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.

24. Collaborative Working including Joint Working Projects

How will ToV created within Collaborative Working including Joint Working projects be recorded?

Legal Background

The Department of Health defines collaborative working, including joint working, between NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery,

Pooling resources can consist of financial input, seconding personnel or arranging 3rd party support from both parties (Bayer and the NHS).

For the TOV we are only reporting the contribution from Bayer.

Methodology

- Where, under the Collaborative Working, including Joint Working, contract that the ToV is financial, we will disclose the individual payments based on the date when Bayer receives the respective invoice(s).
- Equally where the ToV is for a 3rd party service we will disclose the individual payments based on the date when Bayer receives the respective invoice(s) from the contracted 3rd party supplier.
- Where the ToV is a Bayer employee seconded into an HCO we will publish the appropriate reference cost for the activity provided during the reporting period. If the secondment spans two reporting periods we will publish the relevant amounts for each reporting period respectively.

25. 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 Regulation 536/2014); 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.

26. 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 "contracted 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 2023 data, please contact hcpdisclosure@bayer.com

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