Methodology Note regarding the EFPIA Disclosure Code, locally transposed according to the Code of Ethics of Pharma Industry Finland.

Bayer, as member of the European federation of pharmaceutical industries and association (EFPIA), discloses all **Transfers of Value directly or indirectly**, to the benefit of **a HCPs or HCOs.** The reporting period is always a full calendar year. E.g. the report published in 2024 will cover all relevant Transfers of Value made in 2023.

This **methodology note** will help to understand how Bayer is documenting and disclosing the relevant information in Finland and shall explain the details of the data collection and reporting methodology. The general rules of the EFPIA Disclosure Code apply to all member companies and all companies will disclose relevant Transfers of Value 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 to the internal processes.

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

Contents

I. Data Privacy and the legal basis for processing

1. Legitimate Interests

In June 2022, Bayer changed its legal basis for publishing transfers of value at the individual level, from consent to legitimate interests (Data Protection Regulation Article 6(f)). This means that after this time Bayer no longer collects consent to publish transfers of value to healthcare professionals (hereinafter “HCP”) on an individual level.

For the interactions initiated after the change of legal basis, publication at the individual level is based on Bayer's legitimate interest in increasing transparency and thereby strengthening and maintaining trust in the pharmaceutical industry and the cooperation between pharmaceutical companies and healthcare. It is also in the interests of third parties (especially patients, but there is also a wider social interest) to have the opportunity to look at cooperation and interests between pharmaceutical companies and healthcare professionals. In the event that an HCP actively opposes publication on an individual level, transfers of value are reported in aggregated (anonymous) form.

2. Consent

For transfers of value initiated before the change of legal basis, publication on an individual level only takes place if consent has been given. In these cases, the request for consent has been sent to HCPs prior to publication of the value transfers. If consent has not been given, the value transfers are reported in aggregated (anonymous) form. Consent is valid indefinitely unless the data subject revokes it. Revocation can take place in accordance with Article 7 of the General Data Protection Regulation.

3. Partial consent for publication of data

Obtained consent (before transfer to legitimate interest) refers to transfers of value in general. A Healthcare Professionals cannot therefore choose to grant consent only for selected transfers of value. However, it is possible that they choose to withdraw their consent. If this happens, Bayer will report all transfers of value to such Healthcare Professionals in the aggregated section of the report.

A previous refusal to give consent is not considered an objection to disclosure in the case of disclosure based on a legitimate interest. The publication of transfers of value based on our legitimate interests takes place at the individual level unless the healthcare professional has actively opposed it. However, if the healthcare professional has received in the same year both benefits whose disclosure is based on our legitimate interests and those whose disclosure is based on consent, but for which consent has not been given, all these benefits are reported in aggregated form; All benefits for a specific healthcare professional are always reported in full either at the individual level or in the aggregated section.

4. Duration of publication

Our report is available for a period of three years. We may need to amend the report after publication, to correct possible errors or if required for specific (e.g. legal) reasons.

II. 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?

Transfers of Value made by a local affiliate to a Healthcare Professional or Organisation with primary practice in a different (European) state will be reported by our affiliate which is based in this country.

The same rules apply, if a local affiliate in a non-European country grants a Transfer of Value to a Healthcare Professional or Organisation with primary practice in a European state.

Bayer will disclose the Transfer of Value to a Healthcare Professional according to the primary practice at the time of the first collaboration for each reporting period.

6. Publication of ToV granted in a foreign currency

All ToV specified in our report will be denominated in the currency of the recipient's country of primary practice. If the original payment was not made in euros, we will convert the amount based on the average exchange rate in the month the transfer of value was made. Please refer to question 9 regarding the definition of the date, we consider as the transfer of value date.

Examples

A doctor based in Germany receives funding from us to take part in a healthcare convention in the US and the attendance fee is paid in US dollars.

The covered attendance fee would be converted to euros. The exchange rate will be the average exchange rate in the month of the congress.

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.

The costs of the flight would be converted into British Pounds. The exchange rate will be the average exchange rate in the month of the flight.

7. VAT

Will the figures we publish indicate VAT?

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

Bayer will report all transfers of value as net amounts, excluding VAT. In case individual taxes are incurred (e.g. income tax) or for non-deductible tax, this will be included in the published amounts.

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

EFPIA is the parent organization of the European pharmaceutical industry for prescription-only medications, and consequently under the EFPIA Disclosure Code, ToV are only covered in connection with prescription-only medications. However, the EFPIA's Finnish member organization Pharma Industry Finland represents the pharmaceutical industry in general, including non-prescription pharmaceuticals. Pharma Industry Finland has decided to include in the scope of the disclosure also any collaboration related to non-prescription pharmaceuticals. In practice, however, such ToV may relate to a group of products made up of a combination of prescription-only and non-prescription pharmaceuticals and other products, such as medical devices.

Example

Healthcare Professionals are invited to a scientific event, where results of a clinical trial related to medicines are presented. In the same event, information on medical devices in the same therapeutic area is provided.

If transfers of value are even partly related to medicines, Bayer will disclose such transfers of value in full.

9. Reporting period

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

This situation may arise in various situations:

- *A healthcare professional agrees during one reporting period to appear as a guest speaker at an event, the flights are already booked during this period, but the event itself takes place in the following reporting period.*

  As the event is a short term activity, all related Transfers of Value will be reported in the reporting period, in which the event takes place.

- *A sponsorship for an event is granted in one reporting period, but relates to an event taking place in the next reporting period.*

  As the event is a short term activity, the sponsorship will be reported in the reporting period, in which the event takes place.

- *A speaker is engaged for an event taking place at the end of one reporting period, but the invoice is received and the honorarium is paid in the next reporting period.*

  In cases where the invoice arrives in the beginning of the following year, we strive to include the transfers of value as far as possible in the report of the year when the event took place. If this is no longer possible, we report the transfers of value in the report for the following year.

- *An HCP enters into a long-term consultancy contract with Bayer, which lasts for 18 months*

  As the consultancy contract is a long term activity, the Transfers of Value under this agreement will be reported in the period, in which the individual invoices for specific activities are received.

In case of short term activities within a defined timeframe (e.g. congresses or other scientific events), the start date of this activity is decisive. Exceptions to this are fees for speaker engagements which are reported in the period when the fees were paid. In case of 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.

Should an invoice for a short term activity not be received in time to include the Transfer of Value in a report, the amount will be disclosed in the following report.

10. 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?

This situation may arise, for example, in the event that we conclude a consultancy agreement with a doctor which has a term from 1 July 2022 to 31 December 2025 and which attracts a total consultancy fee of EUR 3,500, which is paid in several tranches.

In such case, we will disclose the individual payments based on the date, when we receive 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.).

11. Sponsoring payments made to more than one organisation

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

We will generally publish details ToV on an individual basis in accordance with the EFPIA Disclosure Code. If an individual ToV can be allocated pro rata to the relevant organisations, these shares 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.

12. ToV to Contract Research Organisations (CROs)

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

The ToVs granted to any CROs whose services we retain will be reported according to EFPIA rules in case:

- 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 to indirectly grant ToV to healthcare professionals ("pass-through costs"). In such case, we will publish these ToV in accordance with the general rules.

13. 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?

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

14. Indirect ToV to healthcare professionals and organisations

What will we do in the event that ToV are granted to healthcare professionals or organisations indirectly via third parties?

If ToV granted to a third party have been passed on to healthcare professionals or organisation, or those persons have benefitted from such, we will generally publish the details of each of those ToV 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. As an example, this kind of an third party could be a travel agency.

15. Transport costs for joint transportation

It is not necessary under the EFPIA Disclosure Code to allocate ToV paid in the form of transport costs for a group of healthcare professionals to individual healthcare professionals within that group. For example, only the total amount of the costs for a bus shuttle for a group of healthcare professionals would be published and would not be broken down according to the particular individuals involved.

III. Questions on the report

16. Donations –hospital or clinic as recipients

In the event that the donation is clearly intended for a specific faculty, department within a hospital or health centre, Bayer will publish details of the donation and give the name of the department. In the event that the donation is made to the university or hospital district as a whole, Bayer will publish the donation under the name of the university or hospital district.

17. Sponsorship

A sponsorship under the EFPIA Disclosure Code is any agreements, where Bayer grants a transfer of value in exchange for opportunities to provide information at an event. Under the EFPIA Disclosure Code, only events organized by or on behalf of an HCO are in scope of the reporting obligations.

Bayer will publish the sponsorship amount agreed in the underlying sponsorship contract.

18. Scientific and educational events

We classify 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.

i) Attendance fees

We will generally publish the payment of attendance 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. In relation to public healthcare, Bayer sends the invitation to a hospital or its department and the hospital chooses the participants. In such cases, the health care professional participating in the event is considered by Bayer as the recipient of the ToV.

ii) Travel and accommodation costs

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

We report the coverage of 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.

If travel is organized 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 transfers of value have actually been provided to individual participants.

iii) Events organized by an events agency

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

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 generally 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.

iv) Continuous professional development events – costs for internal events

Will Bayer publish costs for scientific or educational events arranged by itself?

Bayer does not charge attendance feed for its own events, therefore not transfer of value takes place in this regard. In the event that we assume 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.

19. Service and consultancy fees

Which TOV do we record as service and consultancy fees?

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

Under the category service and consultancy fees, we record any transfer of value (monetary or non-monetary), which is granted in exchange for services provided by an HCP or HCO. As the expertise of HCPs and HCOs is absolutely crucial to advance

science and patient care, 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 also be reported in that category.

i) Reimbursement of expenses

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

In terms of ToV 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.

We will publish all expenses related to services in this section. Please note: In some cases, only expenses may be reported for an HCP, because no fee is paid in exchange for the services.

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

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

20. Research and Development (R&D) – definition

Question

Which ToV are reported under "R&D"?

Our approach

In terms of the category "R&D", we will only publish those ToV relating to "regulatory necessary" studies. These are any studies which are required in order to obtain approval for a pharmaceutical product or for post-marketing surveillance. We would consider this to include the planning and implementation of non-clinical studies (in accordance with the OECD Principles on Good Laboratory Practice), Phase I to IV clinical studies (pursuant to Directive 2001/20/EC) and non-interventional studies as defined in the EFPIA Disclosure Code. We also include those studies which are necessary to demonstrate the additional benefit of a pharmaceutical product and to demonstrate or maintain that the expenses involved should be reimbursed.

21. R&D – basic research

Question

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

Our approach

Generally basic research is 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 such ToV under the category "R&D ".

If we conduct basic research unconnected to the development of new or enhancement of existing products, we will generally 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 "donations and grants".