NORWAY **Methodology Note regarding the implementation of the EFPIA Disclosure Code, locally transposed by the Ethical rules for the pharmaceutical industry in Norway implemented by LMI- the pharmaceutical industry in Norway. Disclosure period: Calendar year 2015**

Background

If in doubt about the duty to disclose a specific Transfer of Value, our company will always aim for full disclosure. Only if a Transfer of Value is clearly out of scope of the Disclosure Code, it will 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 Transfers of Value to HCPs and HCOs. The general explanation will – where possible – also be illustrated by examples to ensure a clear understanding.

1. Data Privacy – Consent for publication of data

1.1 Question

1.2 How will Bayer gather consent?

1.3 Methodology

Bayer is requesting consent from all HCPs and applicable HCOs before starting an interaction leading to transfers of value. If such consent is not granted, Bayer will publish the transfers of value only in the aggregated section of the report, without mentioning the name, address or other personal data of the recipient.

2. Data Privacy – Partial consent for publication of data

2.1 Question

How does Bayer react, if a Healthcare Professional, despite our best efforts to reach full consent, only grants partial consent for the publication of selected Transfers of Value?

2.2 Example

This situation may arise, for instance, if a Healthcare Professional consents to the publication of accommodation costs for congress participation. However, the HCP does not consent to the publication of a speaker fee, which is paid for a speaker engagement at a different point in time.

2.3 **Methodology**

As Bayer is collecting overall consent (please see question 3), Healthcare Professionals cannot grant consent only for selected transfers of value. However, it is possible that they choose to withdraw consent for selected activities. If this happens, Bayer will report all transfers of value to such Healthcare Professionals in the aggregated section of the report. We believe that reporting only selected Transfers of Value on an individual level decreases the level of transparency by giving a distorted picture.

3. **Data Privacy – Declaration of Consent**

3.1 **Question**

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

3.2 **Methodology**

Bayer is requesting consent before the first reporting relevant transaction with the respective Healthcare Professional or (where necessary) Healthcare Organizations.

4. **Duration of publication{ TC "4. Duration of publication." \f C \l "2" * MERGEFORMAT AUTONF D3_TC}**

4.1 **Question**

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

4.2 **Methodology**

Our report is generally available for a period of three years. We will amend the report accordingly, if required for specific (e.g. legal) reasons. If the registered has withdrawn his/her consent after the publishing of data will be put on an aggregated level.

II. General questions

5. **Cross-border interactions**

5.1 **Question**

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?

5.2 **Example**

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

5.3 **Methodology**

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. In the examples given above, the Transfer of Value will be reported by our Norwegian legal entity. We will publish the information on a central website for any country where we do not have an affiliate.

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.

6. **Publication of ToV granted in a foreign currency**

6.1 **Question**

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

6.2 **Examples**

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

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.

6.3 **Methodology**

All ToV specified in our report will be denominated in NOK, Norwegian Kronor. If the original payment was not made in NOK, we will convert the amount based on the average exchange rate in the month the transfer of value was made.

In the first example, we would convert the covered attendance fee to NOK. The exchange rate will be the average exchange rate in the month of the congress.

In the second example, we would convert the costs of the flight into British Pounds. The exchange rate will be the average exchange rate in the month of the flight.

7. VAT

7.1 Question

Will the figures we publish indicate VAT?

7.2 Legal background

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

7.3 Methodology

Bayer will report all transfers of value as net amounts, excluding VAT. In case individual taxes are incurred (e.g. income tax), this will be included in the published amounts. Other employer fees and social fees connected to payroll will also be included in the published amounts.

8. Reporting period

8.1 Question

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

8.2 Example

This situation may e.g. arise:

1) When Events have taken place in 2014, however the invoice is received in 2015 and payment is therefore extracted in 2015.

2) When we have a consultancy agreement that is for several years and invoices are received different years.

Methodology

We will publish ToV in accordance with the following rules:

In the first situation the event has taken place when the EFPIA Disclosure code was not implemented, therefore such Transfers of Value will not be reported.

In the second situation we will follow the general principal of reporting the transfers of value in the reporting period which the invoice has been received- the posting date.

9. **Sponsoring payments made to more than one organisation**

9.1 **Question**

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

9.3 **Methodology**

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.

10. **ToV to contract research organisations (CROs)**

10.1 **Question**

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

10.2 **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.

10.3 **Methodology**

We will report ToV, if 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.

11. **Recording of ToV granted to universities and other educational establishments**

11.1 **Question**

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

11.2 **Methodology**

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.

12. Indirect ToV to healthcare professionals and organisations

12.1 Question

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

12.2 Methodology

In the event that we become aware that ToV granted by us 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.

III. Questions on the report

13. Donations –hospitals or clinics as recipients

13.1 Question

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

In Norway Donations are done restrictively so the likelihood of any transfers of value being done are small. If such however is the case they will be reported under the category “donations”.

If any educational grants have been done they will also be reported under the category “donations”.

14. Sponsorships

14.1 Question

Which ToV will we publish relating to sponsoring agreements?

14.2 Legal background

A sponsorship under the EFPIA Disclosure Code is any agreements, where Bayer grants a transfer of value in exchange for advertisement opportunities 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.

14.3 Our approach

We will publish the entire sponsorship amount agreed in the underlying sponsorship contract. The sponsorship amount is determined based on the fair market value for the advertisement opportunities obtained.

15. Scientific and educational events – attendance fees{ TC "3. Continuous professional development events – attendance fees." \f C \l "2" * MERGEFORMAT AUTONF D3_TC}

15.1 Question

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

15.2 Methodology

In Norway it is not permissible to pay for healthcare professionals or organisations attendance to external scientific or educational events.

If a healthcare professional or organisation however has attended scientific or educational events in the line of a consultancy agreement with Bayer the transfers of value for registration fees will be reported in the section devoted to "Related expenses agreed in the fee for service or consultancy contract including travel and accommodation relevant to the contract".

16. Scientific and educational events – travel and accommodation costs{ TC "4. Continuous professional development events – travel and accommodation costs." \f C \l "2" * MERGEFORMAT AUTONF D3_TC}

16.1 **Question**

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

16.2 **Methodology**

In Norway it is solely permissible to pay travel or accommodation costs for healthcare professionals or organisations in the private sector. Healthcare professionals or organisations who are working in the public sector cannot have travel or accommodation costs paid for by Bayer.

If a healthcare professional or organisation however has received travel or accommodation due to a consultancy agreement with Bayer, will the Transfers of value for such travel and accommodation be reported in the section devoted to "Related expenses agreed in the fee for service or consultancy contract including travel and accommodation relevant to the contract".

17. Scientific and educational events – organisation by an events agency{ TC "5. Continuous professional development events – organisation by an events agency." \f C \l "2" * MERGEFORMAT AUTONF D3_TC}

17.1 **Question**

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

17.2 **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 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.

18. Continuous professional development events – costs for internal events{ TC "6. Continuous professional development events – costs for internal events." \f C \l "2" * MERGEFORMAT AUTONF D3_TC}

18.1 Question

Will Bayer publish costs for internal scientific or educational events?

18.2 Methodology

For internal scientific or educational events organised by Bayer registration fees might be covered. In such case we will generally publish the payment of attendance fees as a ToV to the relevant healthcare professionals in the section devoted to "registration fees".

19. Service and consultancy fees – definition{ TC "7. Service and consultancy fees – definition." \f C \l "2" * MERGEFORMAT AUTONF D3_TC}

19.1 Question

Which TOV do we record as service and consultancy fees?

19.2 Legal background

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.

19.3 Our approach

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.

20. Service and consultancy fees – reimbursement of expenses{ TC "8. Service and consultancy fees – reimbursement of expenses." \f C \l "2" * MERGEFORMAT AUTONF D3_TC}

20.1 Question

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

20.2 Legal background

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.

20.3 Our approach

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.

20.4 Question

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

20.5 Our approach

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.

21. R&D – definition{ TC "9. R&D – definition." \f C \l "2" * MERGEFORMAT AUTONF D3_TC}

21.1 Question

Which ToV are reported under "R&D"?

21.2 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.