Otsuka Pharma GmbH

(„Otsuka Germany“)

Guidelines for Implementing the FSA Transparency Code
for the 2017 Reporting Year

Preamble

As a member company of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." ("Voluntary Self-regulation for the Pharmaceutical Industry") – "FSA", we feel obliged to ensure that the nature and scope of our cooperation with healthcare professionals and organisations should be clear and transparent to the public. This is the reason behind the FSA's decision to issue its Transparency Code. The Code is intended to help avoid any suggestion of conflicts of interest and to make the general public more aware of the importance and necessity of cooperation between pharmaceutical companies and healthcare professionals and organisations. Healthcare professionals include all full-time doctors and pharmacists based in Europe, all members of the medical, dental, pharmaceutical or other healthcare professions and any other individuals prescribing or using pharmaceuticals for human application or having approval to engage in their commercial purchase or sale. This also includes public employees or employees of health insurance funds or similar bodies or associations with responsibility for prescribing, sourcing, supplying or administering pharmaceuticals or deciding on whether the costs for pharmaceuticals should be refunded or reimbursed.

In order to comply with the requirements of the FSA Transparency Code as amended on 27 November 2013, we agree to document and publish details of any Transfer of Value (ToV) we may provide directly or indirectly to any healthcare professionals or organisations. The reporting period in each case will be the previous calendar year.

The aim of these guidelines is to provide a clear and simple explanation of how we intend to record and publish this information in accordance with the FSA Transparency Code and to thereby provide a basic framework for interpreting our report. In particular, we would like to outline the underlying methodology we intend to apply and to explain specific issues as to how we will apply this in publishing the relevant information. In the event of any doubt over whether the details of any specific ToV need to be published, we will assume in the interests of transparency that such details should be published. We will only refrain from publishing the details of those ToV where this is clearly not required under the FSA Transparency Code.
These guidelines are structured as follows: Each question will be followed by an explanation or an example and specific details of how we intend to comply with the requirements set out in the FSA Transparency Code.

Any questions relating to this Methodology Note and/or the report should be directed to: transparenz@otsuka.de.
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I. DATA PROTECTION

1.1 Question

_How importance is permission from the healthcare professionals or organisations concerned in terms of publishing the personal information?_

1.2 Legal background

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.

1.3 Our approach

We require all healthcare professionals to provide their consent to us publishing details of any ToV they receive from us through a combined data privacy and disclosure consent form. If this consent is denied, we will only publish the total value of the ToV in aggregate without specifying the individual name of the recipient.¹

If consent is granted, then the name of the recipient, the name and the address of his practice or medical institution, that he is active for, the nature of the expense as well as the amount will be published in the report. In case that the recipient is active under a subordinated medical institution (e.g. specialist hospital subordinated to a major hospital) the name of the subordinated medical institution will be published as well, that is if the headquarters of this institution is located at a different address.

If consent to disclose is revoked for any individual engagement, all engagements (past and future) of that HCP will be disclosed in aggregate. However, in the event that request for revocation is received either after data has been processed for disclosure (generally thirty (30) days prior to a disclosure date) or after actual disclosure, the revocation will be

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¹ In the interest of readability, this document does not include references to male or female individuals. Nevertheless, personal designations apply for both sexes.

² For convenience, academic titles/degrees of healthcare professionals are not published in the report.
reflected after 30 days in a updated report and consent change will apply as well to any future engagements, as far as it is within Otsuka’s control to update the report.

2. **Partial consent**

2.1 **Question**

*What will we do if a healthcare professional only agrees to publication of some of the relevant information, despite our efforts to obtain full consent?*

2.2 **Example**

This situation may arise, for instance, where the healthcare professional agrees to the publication of details of having received funding to attend a professional congress or seminar, but does not agree to the publication of the travel and accommodation costs associated with the trip. Another potential example is where the person concerned agrees to the publication of the expenses paid in connection with attending such an event, but not to the publication of any associated consultancy fee.

2.3 **Our approach**

2.4 If only partial consent to publication is given, the amount of all the ToV to the healthcare professional concerned will only be included in the column indicating total amounts. Same, if an HCP didn’t take a decision or if there are legal doubts regarding the consent.

3. **Duration of publication**

3.1 **Question**

*How long do we make the information available on our Otsuka platform?*

3.2 **Our approach**

Our report is generally available for a period of three (3) years. We will amend the report accordingly in the event that any healthcare professional should withdraw their consent during such period.
II. GENERAL QUESTIONS

1. Definitions

1.1 Healthcare Professional (HCP)

Otsuka Germany has adopted the definition as per the FSA Code of Conduct.

Exclusions:

a. Persons who are registered, but who do not practice as HCPs, including retired HCPs (excluding HCPs conducting research or teaching) and therefore do not prescribe, purchase, supply, recommend or administer a medicinal product, and who may be engaged to provide consulting services to Otsuka Germany.

Example 1: an HCP working for a consultancy firm but also practicing from a clinic, ToV shall be disclosable.

Example 2: a pharmacist working full time in a consultancy firm providing Otsuka Germany with regulatory advice, ToV shall not be disclosable.

b. Employees of Otsuka Germany who are still members of the said professions and able to prescribe are deemed excluded.

c. Employees of Otsuka Germany collaboration partners who are still members of the said professions and able to prescribe are deemed excluded.

1.2 Healthcare Organization (HCO)

Otsuka Germany has adopted the definition as per the FSA Code of Conduct.

a. Corporate entities providing healthcare-related advice or services that employ HCPs whose primary occupation is the provision of consulting services and not that of practising HCPs, are excluded.

Example: a HCP working for a consultancy firm engaged by Otsuka Germany to provide general advice on a disease area not related to a specific product.

b. Relative to fee for service arrangements, if payment is made to a corporate entity and not a natural person, then the amount will be disclosed as a ToV to an HCO.
1.3 **Medicinal Product** definition as per the FSA Code of Conduct with the additional clarification:

a. Medicinal Product will include products for which application for a marketing authorisation to the EMA or any National Competent Authority in Europe is made.

b. ToV relating to any activity in respect of new molecules/compounds that are commercial in nature and not directly related to Research and Development (R&D) activity, will be disclosed as individual ToV.

c. Medical Devices are not included.

d. Combination products are included.

2. **Sources of data**

The Otsuka Germany report will be based and dependent on reference data stored in the Otsuka Europe internal database (OPTICS) which is populated with data purchased from IMS (OneKey Database) as well as data sourced internally.

The data can be taken from multiple platforms:

a. **OPTICS** – the bespoke Otsuka Europe platform for reference data, document management and capturing ToV.

b. **ERP system** (Navision) where direct payments to HCP/HCOs (such as sponsorships) are managed.

   c. **Third Party systems** ad-hoc payments made by intermediaries who cannot access OPTICS. These ToV are captured via the OPTICS Template spread sheet which has to be manually uploaded.

d. Otsuka utilizes a third party to consolidate all source data and prepare report.

3. **Cross-border issues**

3.1 **Questions**

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

3.2 **Examples**

A cross-border situation exists when the pecuniary ToV is granted in a country other than the country in which the healthcare professional or organisation is based, has their practice or main office. This sort of situation includes those cases where we, as a
Germany-based subsidiary of the Otsuka Pharmaceutical Co. Ltd. Group, conclude a consultancy agreement with a doctor based in Italy.

3.3 **Our approach**

Any pecuniary ToV which we grant to healthcare professionals or organisations based in another European member state in our capacity as a German subsidiary of the Otsuka Pharmaceutical Co., Ltd. Group shall be published by our affiliated company based in that country. In the example given above, this would be our Italian affiliate. We will publish the information ourselves in any country where we do not have an affiliate.

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

4.1 **Question**

*What do we do when the ToV is granted in any currency other than euros?*

4.2 **Our approach**

Otsuka Germany reports all ToV in the base currency of the local office in the reporting country. Any amounts where the ToV has been in a foreign currency will be converted using the rate of the last day of the month when the ToV has been conducted. In some cases, the FX rate used for converting the foreign currency amount into the reporting currency amount will be different to the rate used during the payment transfer. This is largely determined by the nature of the ToV and Otsuka Europe expects the differences to be relatively insignificant.

5. **VAT**

5.1 **Question**

*Will the figures we publish indicate VAT?*

5.2 **Legal background**

The FSA Transparency Code essentially allows us to publish gross or net figures (i.e. including or excluding VAT).
5.3 **Our approach** will publish the ToV paid as a net amount, i.e. excluding VAT. Where ToV are entered into OPTICs manually after any indirect spends, the amount may include VAT.

6. **Reporting period**

6.1 **Question**

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

6.2 **Example**

This situation may arise in the event that a healthcare professional agrees during one reporting period to appear as a guest speaker at an event, but this event then actually takes place in the following reporting period. Another potential example is where ToV is granted in one reporting period, but relates to an event taking place in the next reporting period.

6.3 **Our approach**

Direct ToV will be disclosed in 2017 period during which payment are invoiced irrespective of the contract date, contract duration or event date.

Example (1): for an event in December 2017, it is possible that part of the ToVs for that event are invoiced in 2017 and the remainder in 2018. Only invoices processed in 2018 are disclosed for the period 1 January - 31 December 2018. The ToVs related to the event and payment in December 2017, have been part of the 2017 ToV disclosure in 2018 calendar year.

Example (2): for multi-year contracts, ToVs to the same HCP/ HCO under the same contract will be disclosed as per date of individual invoices.

In the event that ToV disclosable for this Reporting Period are discovered subsequent to publication of the disclosure report, these ToV shall be included in the next disclosure report for the Reporting Period of 1 January 2018 - 31 December 2018.

Indirect ToV will be disclosed with the date provided to Otsuka Europe by the intermediary.

In the event that the payment date is not provided by the intermediary, then the event date is used.
7. **Sponsoring payments made to more than one organisation**

7.1 **Question**

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

7.2 **Our approach**

We will generally publish details ToV on an individual basis in accordance with the FSA Transparency 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.

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

8.1 **Question**

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

8.2 **Our approach**

Generally speaking, any ToV we may grant to universities and other educational establishments are not covered by the FSA Transparency Code. We will only publish details of such ToV in the event that they indirectly find their way to an 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.

9. **Indirect payment of ToV to healthcare professionals**

9.1 **Question**

*What will we do in the event that ToV are paid to healthcare professionals indirectly via third parties?*

9.2 **Our approach**

In the event that we become aware that ToV granted by us to a third party have been passed on to healthcare professionals, 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. Handling of consent management is determined in the contract with the third party.

10. **Transport costs for joint transportation**

10.1 **Question**

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

10.2 **Legal background**

It is not necessary under the FSA Transparency 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.

10.3 **Our approach**

We will publish these transport costs per healthcare professional per head.

### III. QUESTIONS ON THE DATA FORMS

1. **Expense Types used by Otsuka Germany**

<table>
<thead>
<tr>
<th>EXPENSE CATEGORY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCO Medical Educational Grant &amp; Donation</td>
<td>Donation and grant in money or kind (e.g. medical educational books and brochures, scholarship) to HCO. <a href="#">Refer to section 2 for further explanation.</a></td>
</tr>
<tr>
<td>HCP/HCO Registration Fee</td>
<td>Fee paid to allow an HCP or member of an HCO to attend a congress, course, educational event. <a href="#">Refer to section 4 for further explanation.</a></td>
</tr>
<tr>
<td>HCP/ HCO Travel &amp; Accommodation</td>
<td>E.g. flight, train, taxi, hotel. Meals are not included (except breakfast if it is included in the hotel amount) <a href="#">Refer to section 5 for further explanation.</a></td>
</tr>
<tr>
<td>HCO Sponsorship</td>
<td>All expenses agreed with an HCO (e.g. booth hire, advertisement space, space for satellite symposia, and contribution towards the cost of meetings).</td>
</tr>
<tr>
<td>HCP/ HCO Fee for Service</td>
<td>Compensation provided for any kind of service provided by an HCP or member of an HCO (e.g. speaker fee, consultant fee, compensation for market research when the identity of the HCP is clear, speaker training, medical writing and data analysis). <a href="#">Refer to section 11 for further explanation.</a></td>
</tr>
<tr>
<td>HCP/HCO agreement related expenses</td>
<td>Travel and accommodation or any other expense as per the fee-for-services agreement (e.g. taxi, out of pocket expense).</td>
</tr>
</tbody>
</table>
2. **Donations – publication of ToV granted to hospitals or clinics**

2.1 **Question**

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

2.2 **Examples**

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.

2.3 **Our approach**

2.4 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, we will publish the details with the given name of the hospital.

3. **Continuous professional development events – definition**

3.1 **Question**

*What do we understand by continuous professional development events?*

3.2 **Our approach**

We classify any conventions, conferences, symposia etc. with a medical or scientific focus or serving to further the training of healthcare professionals as continuous professional development events.

4. **Continuous professional development events – attendance fees**

4.1 **Question**

*What will we do about the publication of the fees we have assumed for healthcare professionals or organisations to attend external continuous professional development events?*

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| R&D related expenses | Expenses related to the planning and conduct of an Otsuka Switzerland sponsored study. Refer to section 10 for further explanation. |
4.2 **Our approach**

We will generally publish the payment of attendance fees as a ToV to the relevant healthcare professionals in the section devoted to "conference and attendance fees". The total amount of such fees assumed during the reporting period will be published for each individual healthcare professional.

5. **Continuous professional development events – travel and accommodation costs**

5.1 **Question**

*Which costs will we publish when we assume travel and accommodation costs relating to continuous professional development events?*

5.2 **Our approach**

We understand travel and accommodation costs to be appropriate costs for train, flight, public transportation, taxi, car, transfer, parking and hotel. Meals are not included (except breakfast if it is included in the hotel amount).

(Management Fees (booking charges etc.) from Third Parties included)

6. **Continuous professional development events – organisation by an events agency**

6.1 **Question**

*What will we do about publishing details of TOV in the event that a continuous professional development event is organised by an events agency?*

6.2 **Our approach**

In the event that the ToV has been granted by a third party, which is not an HCO or a medical institution, such as event organisation agencies, which plan scientific events for HCOs or medical institutions (initiator for Congress, Conference, Symposia), the disclosure will be conducted as follows under these different scenarios:

a) In the event that the name of the HCO or medical institution is known to Otsuka, the event name, the event organiser name and the HCO/medical institution name will be disclosed as such against the ToV.

b) In the event that the name of the HCO or medical institution is not known to Otsuka, the event name, and the name of the event organiser will be disclosed as such against the ToV.

In the event that third parties cannot be positively identified as HCO or medical institution, but has however a medical industry background and acts both as an event
initiator/organiser, then this such a recipient will be treated as an HCO and disclosed as such.

7. Continuous professional development events – costs for internal events

7.1 Question

What will we do about publishing costs for internal continuous professional development events?

7.2 Our approach

In the event that we charge an attendance fee for one of our own internal continuous professional development events and waive it for certain healthcare professionals, we will publish this as a ToV granted to the relevant professional. In the event that we assume the travel and accommodation costs for those persons attending our internal continuous professional development events, details of such will be published specifying the name of the relevant healthcare professional in the category provided for this purpose.

8. Service and consultancy fees – definition

8.1 Question

Which TOV do we record as service and consultancy fees?

8.2 Legal background

Service and consultancy fees are due under corresponding service and consultancy agreements.

8.3 Our approach

Under the category service and consultancy fees, we record Compensation for any kind of service provided by an HCP/member of HCO (e.g. speaker fee, consultant fee, compensation for Market research when the HCP identity is clear, speaker training, medical writing and data analysis).

In addition to the above, Otsuka Germany will disclose under this category any ToV relating to retrospective non interventional studies sponsored by investigator (e.g. Investigator Sponsered Studies - ISS). It should be noted that this will increase the total amount disclosed against this category for certain HCOs.
9. **Service and consultancy fees – reimbursement of expenses**

9.1 **Question**

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

9.2 **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 may include travel and accommodation costs.

9.3 **Our approach**

We will publish these expenses per head and healthcare professional.

10. **R&D – definition**

10.1 **Question**

*Which ToV come under "R&D"?*

10.2 **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 within the meaning of Section 19 FSA 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.

11. **R&D – basic research**

11.1 Otsuka Germany had adopted the definition as per the FSA [Code of Conduct](#) with the additional clarification:

Otsuka Germany will disclose under this category any ToV relating to prospective non interventional studies sponsored by investigator (e.g. Investigator Sponsored Studies - ISS), as they are prospective in nature and involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study.
Support by Otsuka Germany to medical publication in connection to R&D activities, whether direct or indirect, will be disclosed under this category.

It should be noted that this will increase the total annual amount disclosed against this category.

11.2 Question

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

11.3 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.

12. Collaboration Partners

The principle: each partner company will disclose ToV made by that entity to HCPs/HCOs, irrespective of reimbursement. However, each country has defined the process applicable to any jointly sponsored event.

Any ToV made by collaboration partners of Otsuka Germany in respect of a product not licensed or commercialized in Germany will not be disclosed.

Exclusive Distributors of Otsuka Germany Medicinal Products are responsible for disclosing ToV in accordance with their own compliance requirements.

13. Civil or Criminal Action or Administrative Proceeding

In the case of an HCP who received a ToV solely for services with respect to a civil or criminal action or an administrative proceeding, such ToV are excluded from disclosure. These proceedings include:

- legal defence,
- prosecution and
- settlement or judgment of a civil or criminal action and arbitration or other legal action.

14. Data Quality

Otsuka Germany is confident that the data included in the disclosure report is a complete and accurate account of the ToV made by or on behalf of Otsuka Germany to HCPs/HCOs located in Germany for the period of January 1, 2017 to December 31, 2017.
In the event that ToV disclosable for this Reporting Period are discovered subsequent to publication of the disclosure report, these ToV shall be included in the next disclosure report for the Reporting Period of January 1, 2018 until December 31, 2018.