

**OTSUKA PHARMA SCANDINAVIA AB (“OTSUKA SCANDINAVIA”)**

**EFPIA DISCLOSURE: SWEDEN**

**METHODOLOGY NOTE APPLICABLE TO**

**TRANSFERS OF VALUE FOR THE 2017 REPORTING YEAR**

**Note: 2017 disclosure data has been collected and processed by Otsuka in alignment with the below methodological note.**

**With the incoming EU General Data Protection Regulation (“GDPR”), effective as of May 25<sup>th</sup> 2018, Otsuka has decided to publish reports in an aggregated manner in all applicable report sections, until consent, which is in full alignment with the requirements of GDPR has been collected. Otsuka is working on the collection of revised consents to allow the report to be republished individually, in line with the applicable consent granted.**

**PREAMBLE**

This Methodology Note covers the disclosure of data relating to healthcare professionals (HCPs) resident or practicing in Sweden or healthcare organisations (HCOs) incorporated or trading in Sweden. For data relating to HCPs or HCOs based in other countries, please refer to the website of Otsuka Pharmaceutical Europe Ltd ([www.otsuka-europe.com](http://www.otsuka-europe.com)).

Otsuka does not have an affiliate company incorporated in Norway and Finland. In order to comply with the requirements of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (“[EFPIA Disclosure Code](#)”), Otsuka Scandinavia (an affiliate of Otsuka Pharmaceutical Europe Ltd) based in Sweden agrees to document and publish details of any Transfer of Value (ToV) that any Otsuka Group Company (as defined in section II.3.1 below) may provide directly or indirectly to any HCPs or HCOs.

The reporting period in each case will be the previous calendar year and we agree to publish the relevant report by the end of June of the following year (“**Reporting Period**”).

The aim of these guidelines is to provide a clear and simple explanation of how Otsuka Scandinavia intends to record and publish this information in accordance with the [EFPIA Disclosure Code](#). In particular, Otsuka Scandinavia would like to outline the underlying methodology applied and to explain specific issues as to how Otsuka Scandinavia will apply this in publishing the relevant information. Otsuka Scandinavia will only refrain from publishing the details of those ToVs where this is clearly not required under the [EFPIA Disclosure Code](#).

**Any questions relating to this Methodology Note and / or the report should be directed to: [info@otsuka.se](mailto:info@otsuka.se).**

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## **I. PRINCIPLES OF CONSENT MANAGEMENT**

### **1. CONSENT TO PUBLISH INFORMATION**

#### **1.1 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.

#### **1.2 OUR APPROACH**

1.2.1 We require all healthcare professionals to provide their consent to us publishing details of any ToV they receive from us on an individual named basis.

1.2.2 The consents will:

- apply for all engagements of Swedish HCPs by any Otsuka Group Company (as defined in section II.3.1 below);
- be unlimited in time unless and until revoked in writing by the HCP.

1.2.3 In the event that responses to consents have not been received from the HCPs, despite best efforts, ToVs will be reported in aggregate.

1.2.4 Consents for HCOs are not being requested, save where required by law in which case consents will be included in the written agreement with the HCO.

### **2. PARTIAL CONSENT**

#### **2.1 EXAMPLE**

This situation may arise, for instance, where the HCP 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.

## 2.2 OUR APPROACH

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 a 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 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.

## 3. DURATION OF PUBLICATION

The Otsuka Scandinavia report will remain publically available for a period of 3 years.

## II. GENERAL QUESTIONS

### 1. DEFINITIONS:

#### 1.1 HEALTHCARE PROFESSIONAL (HCP)

Otsuka Scandinavia has adopted the definition as per the [EFPIA Disclosure Code](#).

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

#### 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 Scandinavia.

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 Scandinavia with regulatory advice, ToV shall not be disclosable.

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

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

## 1.2 HEALTHCARE ORGANISATION (HCO)

Otsuka Scandinavia has adopted the definition as per the [EFPIA Disclosure Code](#).

### Exclusion:

- 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 Scandinavia to provide general advice on a disease area not related to a specific product.

- b. Relative to fee for services 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 PRODUCTS

Otsuka Scandinavia has adopted the definition as per the [EFPIA Disclosure Code](#), 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. Transfers of Value relating to any activity in respect of new molecule/compound 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 product are included.

## 2. SOURCES OF DATA:

Data will be captured through a number of platforms:

- a. OPTICS – the bespoke Otsuka platform for reference data, document management and capturing Transfers of Value.
- b. ERP system (Navision or SAP) where direct payments to HCP/HCO's are managed.
- c. Third Party systems – ad hoc payments made by intermediaries who cannot access OPTICS. These Transfers of Value are captured via the OPTICS Template spreadsheet which has to be manually uploaded.
- d. Otsuka utilizes a third party to consolidate all source data and prepare reports.

## 3. CROSS-BORDER ENGAGEMENTS

### 3.1 BACKGROUND

Otsuka companies in scope for providing ToV data for EFPIA reporting are all Otsuka group companies (incorporated in any jurisdiction) that:

- develop or commercialise Medicinal Products (as defined);
- are controlled (i.e. more than 50% ownership) by Otsuka Pharmaceutical Co., Ltd., (“OPC”); Otsuka America Inc. (“OAI”); Otsuka Pharmaceutical Europe Ltd. (“OPEL”) and any subsidiary of these three companies
- engage (provide transfers of value to) HCPs resident or practicing in Sweden  
  
(hereafter referred to as “**Otsuka Group Companies**”)

### 3.2 EXAMPLES

A cross-border situation exists when the ToV is paid by an Otsuka Group Company incorporated in a country other than the country in which the HCP or HCO is based, has their practice or main office. This sort of situation includes those cases where  
a

subsidiary of the Otsuka Group Companies based outside Sweden, concludes an agreement with an HCP or HCO resident or practicing in Sweden.

### 3.3 OUR APPROACH

Otsuka Scandinavia will disclose all ToVs made to Swedish HCPs/ HCOs for engagements by any Otsuka Group Companies. In these cases, disclosure will be made in accordance with the [EFPIA Disclosure Code](#).

Example: if Otsuka US engages a Swedish HCP, Otsuka Scandinavia will disclose ToV made to the Swedish HCP on behalf of Otsuka US.

## 4. PUBLICATION OF TOV GRANTED IN A FOREIGN CURRENCY: CURRENCY ASPECTS

Otsuka Scandinavia reports all ToV in the base currency of the reporting country. Any amounts where the ToV has been paid 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 Scandinavia expects the differences to be relatively insignificant.

Last day of month	SEK - EUR
January-17	9,451
February-17	9,568
March-17	9,532
April-18	9,632
May-17	9,756
June-17	9,640
July-17	9,542
August-17	9,482
September-17	9,649
October-17	9,742
November-17	9,921
December-17	9,844

Example (1): A Swedish HCP was paid EUR 1,000 by Otsuka Europe on the 01/10/2017; the invoice is stated in EUR. The payment will be included in the EFPIA disclosure in SEK using the conversion rate of the last day of October 2017 (e.g. 9.742 EUR to SEK). The amount disclosed would be 9,742.00 SEK.

## 5. TREATMENT OF VAT

On the most part, Otsuka Scandinavia 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 OF TRANSFERS OF VALUE (TOV) OUR

### APPROACH

6.1.1 Direct ToV will be disclosed in 2017 period during which the value has been physically transferred, 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 transferred 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.

6.1.2 Indirect ToV will be disclosed with the date provided to Otsuka Scandinavia by the intermediary. In the event that the payment date is not provided by the intermediary, then the event date is used.

6.1.3 Provision of Product for study purpose:

- Value study drug for marketed products as per the COG price, except where quantities are of nominal value;
- Where product is not commercialised following authorisation, no value is attributed.

6.1.4 Participant attendance at sponsored events and “no-shows”:

- If Otsuka Europe sponsors a Swedish HCP/HCO to attend an event and the relevant HCP does not attend, a transfer of value will not be disclosed for that HCP.

6.1.5 Payment to charities on behalf of HCPs



- In the event that Otsuka Scandinavia make payment to an entity, at the request of an HCP in relation to a fee for service engagement, such payment shall not be disclosed in this report on the basis that no ToV have been made to an HCP/HCO.
- Example: HCP requests that his fee for service be paid to a charitable organisation of his choice.

## 7. INDIRECT PAYMENT OF ToV TO HEALTHCARE PROFESSIONALS

In the event that we become aware that ToV granted by us to a third party have been passed onto an HCP, or those persons have benefitted from such, we will generally publish the details of each of those ToV under the name of the relevant HCP. Our contractual arrangements with third parties include a data protection provision that third parties require the consent of their own contracting partner for the publication of details relating to ToV and must demonstrate such to us.

## 8. EXPENSE CATEGORIES USED BY OTSUKA SCANDINAVIA

EXPENSE CATEGORY	DESCRIPTION
HCO Medical Educational Grant & Donation	Donation and grant in money or kind (e.g. medical educational books and brochures, scholarship) to HCO. <b>Refer to section 9</b> Error! Reference source not found. <b>for further explanation.</b>
HCP/HCO Registration Fee	Fee paid to allow an HCP or member of an HCO to attend a congress, course, educational event.
HCP/ HCO Travel & Accommodation	E.g. flight, train, taxi, hotel. Meals are not included (except breakfast if it is included in the hotel amount)
HCO Sponsorship	All expenses agreed with an HCO (e.g. booth hire, advertisement space, space for satellite symposia, and contribution towards the cost of meetings).
HCP/ HCO Fee for Service	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). <b>Refer to section 11 for further</b>
HCP/HCO agreement related expenses	Travel and accommodation or any other expense as per the fee-for-services agreement (e.g. taxi, out of pocket expense).
R&D related expenses	Expenses related to the planning and conduct of an Otsuka Scandinavia sponsored study. <b>Refer to section 10 for further explanation.</b>

9. **GRANTS AND DONATIONS:**

9.1 9.1. Definition: any ToV related to medical and educational goods and services which enhance patient care, or benefit the healthcare system and maintain patient care.

9.2. Donations either in cash or kind that support healthcare are included.

10. **RESEARCH AND DEVELOPMENT (R&D)**

10.1 Otsuka Scandinavia has adopted the definition as per the [EFPIA Disclosure Code](#) with the additional clarification:

a. Otsuka Scandinavia 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.

b. Support by Otsuka Scandinavia to medical publication in connection to R&D activities, whether direct or indirect, will be disclosed under this category.

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

11. **FEE FOR SERVICES TO HCOs**

11.1 In addition to fee for service in relation to consultancy services, Otsuka Scandinavia will disclose under this category any ToV relating to retrospective non interventional studies sponsored by investigator (e.g. Investigator Sponsored Studies (ISS)).

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

12. **COLLABORATION PARTNERS**

12.1 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.

12.2 Any ToV made by collaboration partners of Otsuka Scandinavia in respect of a product not licenced or commercialised in Sweden will not be disclosed.

12.3 Exclusive Distributors of Otsuka Scandinavia 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 Transfer of Value solely for services with respect to a civil or criminal action or an administrative proceeding, such Transfers of Value are excluded from disclosure. These proceedings include:

- Legal defence,
- Prosecution, and
- Settlement or judgement of a civil or criminal action and arbitration or other legal action.

14. **DATA QUALITY**

Otsuka Scandinavia 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 Scandinavia to HCPs/HCOs located in Sweden 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 1 January 2018 - 31 December 2018.