

Otsuka Pharma Scandinavia AB

EFPIA disclosure: Norway

Methodology note applicable to transfers of value, for the reporting year: 2022

1. Introduction

In order to comply with the requirements of the EFPIA Code of Practice and the Association of the Pharmaceutical Industry in Norway (LMI) code, Otsuka Pharma Scandinavia AB agrees to document and publish details of any Transfer of Value (ToV) we may provide directly or indirectly to any healthcare professionals (HCPs) or healthcare organisations (HCOs). The reporting period in each case will be a full calendar year. The report will be published by the end of June of the year following when the ToV payments were made.

The aim of this Methodology Note is to provide clear explanations and definitions of how Otsuka Pharma Scandinavia AB intends to record and publish this information in accordance with the EFPIA Code of Practice, and the LMI code. In particular, Otsuka Pharma Scandinavia AB outlines the underlying methodology applied and explains specific issues which will apply in publishing the disclosed data. Otsuka Pharma Scandinavia AB will only refrain from publishing the details of those ToV where this is clearly not required under the EFPIA Code of Practice, and the LMI code.

Any questions relating to this Methodology Note and / or the disclosure report should be directed to: info@otsuka.se



2. Definitions

2.1. Recipients – Healthcare Professional (HCP)

Otsuka Pharma Scandinavia AB has adopted the definition as per the EFPIA Code of Practice.

Otsuka Pharma Scandinavia AB report will be based and dependent on reference data stored in Otsuka Pharma Scandinavia AB systems and tools, which are populated with data purchased from IMS (OneKey Database) and data sourced during recipient interactions.

Exclusions:

- 2.1.1. 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 Pharma Scandinavia AB

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

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

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

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

2.2. Recipients – Healthcare Organisation (HCO)

Otsuka Pharma Scandinavia AB has adopted the definition as per the EFPIA Code of Practice.

Exclusions:

2.2.1. 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: an HCP working for a consultancy firm engaged by Otsuka Pharma Scandinavia AB to provide general advice on a disease area not related to a specific product.

2.2.2. 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 ToV to an HCO.

2.3. Kind of ToV

Expense Category	Description
HCO Medical Educational Grant & Donation	Donation and grant (e.g. medical educational books and brochures, scholarship) to HCO, which enhance patient care, or benefit the healthcare system and maintain patient care. Donations and grants – either in cash or kind – that support healthcare are included.
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	Examples: 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 services 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). In addition to fee for services in relation to consultancy services, Otsuka Pharma Scandinavia AB will disclose under this category any ToV relating to retrospective non interventional studies sponsored by investigator (e.g. Investigator Sponsored Studies (ISS)). It should be noted that this will increase the total annual amount disclosed against this category for certain recipients.
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 Pharma Scandinavia AB sponsored study. Refer to section 5.5 for further explanation.

3. Disclosure's scope

3.1. Products concerned

Otsuka Pharma Scandinavia AB has adopted the definition as per the EFPIA Code of Practice, with the additional clarification:

- 3.1.1. Medicinal Product will include products for which application for a marketing authorisation to the EMA or any National Competent Authority in Europe is made.
- 3.1.2. ToV relating to any activity in respect of a 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.
- 3.1.3. Medical Devices are not included.
- 3.1.4. Combination products are included.

3.2. Company concerned (affiliate – merger)

In Europe, Otsuka Pharmaceutical Europe Ltd – and its subsidiary affiliates (including Otsuka Pharma Scandinavia AB) – provides governance, oversight, and compliance monitoring for interactions between Otsuka Group companies and European recipients. Throughout this methodological note, Otsuka Pharma Scandinavia AB represents the presence and interactions of Otsuka Group companies and affiliates within Europe.

Collaboration Partners – principle: each partner company will disclose ToVs made by that entity to HCPs/ HCOs, irrespective of reimbursement. However, each country has defined the process applicable to jointly sponsored event. Any ToVs made by Otsuka Pharma Scandinavia AB partners in respect of a product not licenced or commercialised in Europe will not be disclosed. Exclusive Distributors of Otsuka Europe Medicinal Products are responsible for disclosing ToVs in accordance with their own compliance requirements.

3.3. Excluded ToV

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 ToVs 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.

4. ToV date

Direct ToV will be disclosed in the ToV period during which payments are invoiced, irrespective of the contract date, contract duration or event date. Indirect ToV will be disclosed based on the payment date provided to Otsuka Pharma Scandinavia AB by the intermediary. In the event that the payment date is not provided by the intermediary, then the event date is used. Refer to section 5.1 for further detail and examples.

5. Transfers of Value (ToV)

5.1. Direct ToV

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

Example (1): for an event in December 2022, it is possible that part of the ToVs for that event are invoiced in 2022 and the remainder in 2023. Invoices processed in 2022 are disclosed for the period 1 January - 31 December 2022. The ToVs related to the event and payment in December 2022, have been part of the 2022 ToV disclosure in 2023 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. Refer to section 7 for more detail.

In the event that ToV disclosable for this Reporting Period are discovered subsequent to cut-off date for disclosure data, or publication of the disclosure report, wherever possible the published report will be updated to include these additional ToV. Where a report update is not possible, these ToV shall be included in the next disclosure report for the subsequent Reporting Period.

5.2. Indirect ToV

Indirect ToV will be disclosed based on the payment date provided to Otsuka Pharma Scandinavia AB by the intermediary. In the event that the payment date is not provided by the intermediary, then the event date is used.

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. Our contractual arrangements with third parties include the 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.

5.3. ToV in case of partial attendances or cancellation

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

- If Otsuka Pharma Scandinavia AB sponsors an HCP/HCO to attend an event and the relevant HCP does not attend, a ToV will not be disclosed for that HCP.

5.4. Cross-border activities

Otsuka group 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; and
- engage (provide ToVs to) HCPs resident or practicing in any of the European Member State (hereafter referred to as “Otsuka Group Companies”)

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 healthcare professional or organisation 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 Norway, concludes an agreement with an HCP or HCO, that are resident or practicing in Norway.

Otsuka Pharma Scandinavia AB will disclose all ToVs made to Norwegian HCPs for engagements by any Otsuka Group Companies. In these cases, disclosure will be made in accordance with the EFPIA Code of Practice, and the LMI code.

Example: If Otsuka US engages a Norwegian HCP, Otsuka Pharma Scandinavia AB will disclose ToV made to the Norwegian HCP on behalf of Otsuka US.

5.5. R&D

Research and Development (R&D) – Otsuka Pharma Scandinavia AB has adopted the definition as per the EFPIA Code of Practice with the additional clarifications:

- Otsuka Pharma Scandinavia AB 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.
- Otsuka Pharma Scandinavia AB’s support, direct or indirect, to medical publication in connection to R&D activities, will be disclosed under this category.

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

6. Specific considerations

6.1. Country unique identifier

Where required according to the market code, a country unique identifier will be included for each recipient. If the country unique identifier is not available, an internal Otsuka unique identifier will be used.

Where there are no specific requirements for inclusion of a unique country identifier (but there is a location available on the report template) – or the inclusion is optional – then the most appropriate unique identifier will be used, primarily country unique identifier, or (secondarily) internal Otsuka unique identifier.

6.2. Self-incorporated HCP

A self-incorporated HCP is a one-person company, owned by an HCP. Disclosure will be made against the invoicing entity/payee – i.e.

- Where ToV are invoiced by the company, and/or the payee bank account is in the company name, the ToV will be treated as a direct payment to an HCO.
- Where ToV are invoiced by the HCP, and/or the payee bank account is in the HCP name, the ToV will be treated as an indirect payment to an HCP.

In both cases, consent management will be applicable as for the final recipient type (HCP or HCO). Where local requirements necessitate a different approach – such as mandating disclosure against the HCP, irrespective of the invoicing entity/payee – those local requirements will be followed.

7. Multi-year agreements

ToV associated with multi-year agreements will be reported as each payment is made

Example: if a multi-year agreement is established, covering a 3 year period, payments made in year-1 will be reported in the disclosure report for that calendar year; payments made in year-2 and year-3 will be reported in the disclosure reports for the subsequent calendar years. No payments will be held back, or brought forward, to a disclosure report before or after the actual ToV payment date.

8. Data protection management

8.1. Consent collection

It is mandatory to publish all ToV received from Otsuka Pharma Scandinavia AB during 2022 period on an individual named basis.

8.2. Management of recipient consent withdrawal

Otsuka Pharma Scandinavia AB uses legitimate interest. Refer to section 8.5 for further details.



8.3. Management of recipient's request

Any recipient wishing to discuss disclosed ToV, must contact the Otsuka EU Transparency & Disclosure team directly, at transparency@otsuka-europe.com

8.4. Partial consent

Refer to sections 8.1 and 8.2.

8.5. Legitimate interest

As described in the Association of the Pharmaceutical Industry in Norway (LMI) code (section 26.4), disclosures for HCPs and HCOs will be made on an individual named basis (refer to sections 8.1-8.4 for further detail).

9. Disclosure Form

9.1. Date of publication

The Otsuka Pharma Scandinavia AB disclosure report will be published within 6 months of the end of each calendar year, and will remain publicly available for a period of 3 years. The Otsuka Pharma Scandinavia AB disclosure report will have the report version date clearly stated on the report.

9.2. Disclosure platform

The Otsuka Pharma Scandinavia AB disclosure report will be published on the [Transparency Norway web page](#).

10. Disclosure language

The Otsuka Pharma Scandinavia AB disclosure report will be published in English and Norwegian.

11. Disclosure financial data

11.1. Currency (local or if not, specify the exchange rate)

Otsuka Pharma Scandinavia AB 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 Pharma Scandinavia AB expects the differences to be relatively insignificant.

11.2. VAT included or excluded

For the most part, Otsuka Pharma Scandinavia AB will publish payments wherever possible as gross amounts, i.e. including VAT. As multiple VAT regimes exist globally with different reimbursement approaches some payments may be reported as net amount excluding VAT.

12. Calculation rules

For calculations associated with currency conversions, see section 11.1.

Where one ToV payment is covering multiple recipients, that payment amount will be divided equally across all attending recipients, and those divided amounts included in the individual recipient totals.

Where possible, ToV amounts will be reported to 2 decimal places (0.00), with any division of amounts leading to greater than 2 decimal places accuracy, being rounded down.

Example: a ToV payment of £31 is attributed to 3 attending recipients. The division of the ToV amount equates to £10.3333... each. This will be reported as £10.33, per recipient.

13. Additional information

13.1. Sources of Data

Data will be captured through a number of platforms:

- Internal Otsuka Database – the bespoke Otsuka Group platform for reference data and document management.
- ERP system (SAP) where direct payments to HCP/HCO are managed.
- Third Party systems – ad hoc payments made by intermediaries who cannot access Internal database. These ToVs are captured via a manual spreadsheet template which has to be manually uploaded to SharePoint.
- Otsuka Pharma Scandinavia AB utilizes services of a third party to consolidate all source data and prepare reports.

13.2. Data Quality

Otsuka Pharma Scandinavia AB is confident that the data included in the disclosure report is to the best of our knowledge complete and accurate account of the ToVs made by or on behalf of Otsuka Pharma Scandinavia AB to HCP/HCOs located in Norway for the period of 01 January 2022 to 31 December 2022.