

Otsuka Pharma Scandinavia AB (OPSAB)

EFPIA disclosure: Norway

Methodology note applicable to transfers of value, for the
reporting year: 2025

Introduction

The aim of this document is to provide definitions and explanations with regards to how transfer of values made to; healthcare professionals or healthcare organisations have been calculated for the current reporting year in accordance with the requirements of the Association of the Pharmaceutical Industry in Norway (LMI) code and EFPIA Code of Practice.

Any questions relating to this Methodology Note and / or the disclosure report should be directed to: transparency@otsuka-europe.com

1. Definitions

1.1. Recipients

Healthcare Professional (HCP): includes Healthcare Professionals means doctors, dentists, authorized nurses, pharmacists, opticians and dental hygienists as well students in the related subjects. Other Health Professionals mean Healthcare Professionals according to the Health Professionals Act § 3, who are not covered by the definition of HCP above but work in healthcare. The definition of HCP is to be broadly interpreted.

Healthcare Organisation (HCO): are defined as any legal entity, (i) which provides health assistance or patient treatment, such as a health enterprise, doctor's practice etc. (ii) which is a research or institution within medical, biological or other health-related disciplines such as a university or another institution of learning, (iii) through which health professionals provide health services.

Exclusions:

- 1.1.1. Non-practicing HCPs, including retired HCPs (excluding HCPs conducting research, education 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.

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

Data relating to deceased HCPs

- 1.1.4. If Otsuka Pharma Scandinavia AB is contacted by the family of a deceased HCP requesting all their data be put into aggregate, then OPSAB will honor that request on a case-by-case basis.

1.2. Kind of ToVs

Expense Category	Description
HCO Donations and Grants	Contribution to donations (physical items, services or benefits-in-kind) and grants (provision of funds), which are given for the purpose of supporting healthcare, scientific research or education.
HCO Sponsorship	A contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created, etc. by a healthcare organisation or other independent organisation
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).
HCP/HCO agreement related expenses	Travel and accommodation or any other expense as per the fee-for-services agreement (e.g. taxi, mileage or out of pocket expense).
R&D related expenses	Expenses related to the planning and conduct of an Otsuka sponsored study. Refer to section 2.10 for further explanation.

2. Disclosure's Scope

2.1. Products concerned

Any branded or unbranded medicine intended for use in humans which requires a marketing authorisation. Please also note that:

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

- 2.1.2. 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.
- 2.1.3. Medical Devices are not included.
- 2.1.4. Combination products are included.

2.2. Company concerned

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.

2.3. Excluded ToVs

ToV relating to meals provided to HCPs in connection to OSPAB organised meetings/events are excluded from disclosure. 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.

2.4. ToVs date

The transfers of value cover the period of 01 January 2025 to 31 December 2025.

2.5. Direct ToVs

Direct ToV's are payments made direct to ToV recipients as defined in 1.2. The payments are disclosed in the ToV period which the payment is made irrespective of the contract date, contract duration or event date.

Example: for an event which took place at the end of the year, it is possible that part of the ToV's for that event are invoiced in two different years. Invoices will be disclosed in the year the payment was made.

2.6. Indirect ToVs

Indirect ToV's are payments made to third-party vendors as defined in 1.2, and are disclosed where there is a known ToV recipient. The payment 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.

If OPSAB has confirmation that ToV to an HCO is transferred to an individual HCP the ToV will be published on the name of the HCP.

2.7. Non-Monetary ToVs

Otsuka Pharma Scandinavia AB does not carry out Non-monetary ToVs for HCPs or HCOs.

2.8. 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.

2.9. 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.

2.10. Voluntary Disclosure

Otsuka Pharma Scandinavia AB does not carry out voluntary disclosures. All activities that are conducted are within the scope of the LMI Code.

3. Specific considerations

3.1. 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.

3.2. Self-incorporated HCP

A self-incorporated HCP is a one-person company, owned by HCP, e.g. enkeltpersonforetak (eng: sole proprietorships).

Disclosure will be made against

- Transfers of value to enkeltpersonforetak will be published as TOV to the HCP that owns the enkeltpersonforetak, unless Otsuka finds it technically difficult to carry to correctly disclose the TOV.
- Transfers of Value that go to companies (e.g. AS or ANS) owned by one or more persons are published under the name of the HCO.

3.3. Multi-year agreements

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

3.4. Country Specificities

LMI Norway has published a statement that all companies must rely on legitimate interest for the publication of TOV to HCPs. Otsuka Pharma Scandinavia AB. follows this guidance. It is mandatory to disclose consultancy payments on an individual named basis.

As the Norwegian LMI code does not allow sponsorship of individual HCP Registration Fees and related Travel and Accommodation costs related to third party meetings, these columns are not used and blank in the report.

4. Data protection management legal basis

4.1. Legitimate interest as a basis for disclosure.

The guidance from the Pharmaceutical Industry in Norway (LMI) code is to disclose based on legitimate interest. Otsuka Pharma Scandinavia AB follows this guidance and disclosures for HCPs will be made on an individual named basis.

For enkeltpersonforetak, the legal basis is to publish the TOV to the HCP this is based on legitimate interest in line with LMI guidance.

5. Form of Disclosure

5.1. 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.

5.2. Disclosure platform

The Otsuka Pharma Scandinavia AB disclosure report will be published on the Transparency Norway web page: <https://www.otsuka.se/no-hcp-disclosure-information>.

5.3. Disclosure language

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

6. Disclosure financial data

6.1. Currency

Otsuka Pharma Scandinavia AB reports all ToV in NOK. Any amounts where the ToV has been in a foreign currency will be converted using the rate of the payment date. In some cases, the exchange 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.

6.2. 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.

6.3. Calculation rules

For calculations associated with currency conversions, see section 6.1.

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.

7. Additional information

7.1. 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) and Otsuka's salary system– where direct payments to HCP's/HCO's 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 is manually uploaded to the Transparency Reporting System.

7.2. 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 2025 to 31 December 2025.