

# Otsuka Pharma Scandinavia AB

CGR (EFPIA) disclosure: Netherlands

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, healthcare organisations or Patient Organisations have been calculated for the current reporting year.

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

## 1. Definitions

### 1.1. Recipients

Healthcare Professional (HCP): includes individuals who practices medicine, dentistry, pharmacy or nursing or may prescribe, purchase, supply, recommend, hire, use or administer medicinal products or medical devices. Nurses are considered HCPs for premiums & benefits and are included in Transfer of value reporting.

Healthcare Organisation (HCO): includes any association or organization active in healthcare, medical or scientific field, regardless of its legal or organizational form, as well as any legal entity through which one or more Health Care Professionals provide services.

### Patient Organisation (PO)

Otsuka Pharma Scandinavia AB has adopted the definition as per the CGR Code of Conduct.

### 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 are contacted by the family of a deceased HCP requesting all their data be put into aggregate, then OPUK 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.
HCP/ HCO Registration Fee	Fee paid to allow an HCP or member of an HCO to attend a congress, course or educational event.
HCP/ HCO Travel & Accommodation	Support provided to the HCP or HCO to attend a congress, course, or educational event where there is no contracted service provided by them. Examples: flight, train, taxi, hotel and meals (meals are included if the total value of the ToVs is larger than 500 EUR during the reporting year) are excluded, except where breakfast is included in the hotel room rate amount.
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). Meals related to a consultancy agreement or hospitality when attending a meeting are disclosed when the meeting is organized by Otsuka and involved travel and accommodation. Disclosure is for accumulated values exceeding 500 EUR on a yearly basis.
R&D related expenses	Expenses related to the planning and conduct of an Otsuka sponsored study. Refer to section 2.10 for further explanation.
PO agreements and expenses	Fee for service and related travel expenses paid to a Patient Organisation.
PO Donation, Grant & Sponsorship	Financial or non-financial funds provided to support healthcare, scientific research or education

## 2. Disclosure's Scope

### 2.1. Products concerned

Any branded or unbranded medicine intended for use in humans which requires 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 is 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/POs, 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

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. If the payment date is not provided by the intermediary, then the event date is used.

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.

For consultancies with HCOs and where the HCP consultant is known, disclosure will be made on the name of the HCP in line with CGR requirements.

### 2.7. Non-Monetary ToVs

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

### 2.8. ToV in case of partial attendance or cancellation and refund

Participant attendance at sponsored events and "no-shows":

- If Otsuka Pharma Scandinavia AB sponsors an HCP to participate/attend an OPSAB organised or third-party organised event and the relevant HCP does not attend or the event is cancelled, a ToV will not be disclosed for that HCP. The HCP will be reimbursed provided there is proof of purchase, and a refund is not possible.

### 2.9. 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 Pharmaceuticals 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 Netherlands concludes an agreement with an HCP or HCO, that are resident or practicing in Netherlands.

Otsuka Pharma Scandinavia AB will disclose all ToV's made to Dutch HCPs for engagements by any Otsuka Group Companies. In these cases, disclosure will be made in accordance with the CGR Code.

#### 2.10. R&D

Research and Development (R&D) Otsuka Pharma Scandinavia AB has adopted the definition as per the CGR Code 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 individuals, 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.

#### 2.11. Voluntary Disclosure

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

### 3. Specific considerations

#### 3.1. Country unique identifier

Where required according to the CGR code, the BIG/Chamber of Commerce/registration numbers will be included for each recipient. If the BIG identifier is not available, an internal Otsuka unique identifier will be used.

#### 3.2. Self-incorporated HCP

For situations where there is a sole proprietorship (Eenmanszaak) ( owned by a solo HCP, the disclosure will be made against the HCP. ..

#### 3.3. Multi-year agreements

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

### 3.4. Country Specificities

Transfer of Value will be disclosed against the recipient when the total amount exceeds the accumulated value of € 500 per calendar year.

### 3.5. Quality Checks

Pre disclosure quality checks are undertaken prior to data submission, these include Master Data Management ID, expense type, reportability of the ToV etc. The quality checks are performed throughout the data collection and disclosure process.

## 4. Data protection management legal basis

### 4.1. Consent collection

Otsuka Pharma Scandinavia AB does not use consent as a basis for disclosure in the Netherlands.

#### 4.1.1. Partial consent

Otsuka Pharma Scandinavia AB does not use partial consent as a basis of disclosure in the Netherlands.

#### 4.1.2. Withdrawal of consent

Consent withdrawal does not apply in the Netherlands as it is not the basis for disclosure.

### 4.2. Legitimate interests

As described in the CGR Code of Conduct, disclosures for HCPs will be made on an individual named basis. CGR considers transfer of value above 500 EUR per year to be of legitimate interest to publish on individual level. This applies also in situations where HCPs are paid for consultancies via their employer (HCO). As a result of the CGR requirements OPSAB relies on legitimate interest for disclosure purposes.

## 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 CGR page for disclosure: <https://www.transparantieregister.nl> and the Transparency Netherlands web page: <https://www.otsuka.se/nl-hcp-disclosure-information>. Note: R&D ToV's are published on the Otsuka website.

### 5.3. Disclosure language

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

## 6. Disclosure financial data

### 6.1. Currency

Otsuka Pharma Scandinavia AB reports all ToV in EUR in the Netherlands. 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 EUR 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 covers 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) where payments to HCOs and POs are managed or in some cases the OPSAB Salary system Provider where direct payments to individual HCPs is managed.
- Third Party systems – ad hoc payments made by intermediaries who cannot access Internal database. These ToV's 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/POs located in Netherlands for the current reporting period of 01 January 2025 to 31 December 2025.