

# Otsuka Pharmaceutical (UK) Ltd.

ABPI disclosure: UK

Methodology note applicable to transfers of value, for the reporting year: 2024 (published June 2025)

## 1. Introduction

The aim of this document is to provide definitions and explanations with regards to how transfer of values made to; healthcare professionals, other relevant decision makers or healthcare 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)

## 2. Definitions

### 2.1. Recipients – Healthcare Professional (HCP) and Other Relevant Decision Makers (ORDMs)

HCP: includes any member of the medical, dental, pharmacy or nursing profession and any other person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

ORDM: particularly includes someone with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not a health professional.

### Exclusions:

- 2.1.1. 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 Pharmaceutical (UK) Ltd.
- 2.1.2. Employees of Otsuka Pharmaceutical (UK) Ltd. who are still members of the said professions and able to prescribe are deemed excluded.
- 2.1.3. Employees of Otsuka Pharmaceutical (UK) Ltd. collaboration partners who are still members of the said professions and able to prescribe are deemed excluded.

## 2.2. Recipients – Healthcare Organisation (HCO)

Means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services

## 2.3. Kind of ToV

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, educational event.
HCP/ HCO Travel & Accommodation	Examples: flight, train, taxi, hotel. Meals are excluded, except where breakfast is included in the hotel room rate 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 Pharmaceutical (UK) Ltd. 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, mileage or out of pocket expense).
R&D related expenses	Expenses related to the planning and conduct of an Otsuka Pharmaceutical (UK) Ltd. sponsored study. Refer to section 4.4 for further explanation.
HCO Collaborative Working	Contribution to working with organisations to deliver initiatives which either enhance patient care, benefits patients or benefits National Health Service (NHS) and maintains patient care. Joint working is a limited form of collaborative working.

## 3. Disclosure's scope

### 3.1. Products concerned

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

- 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 Pharmaceutical (UK) Ltd.) provides governance, oversight, and compliance monitoring for interactions between Otsuka Group companies and European recipients. Throughout this methodological note, Otsuka Pharmaceutical (UK) Ltd. 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 Pharmaceutical (UK) Ltd. 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. Transfers of Value (ToV)

### 4.1. Direct ToV

Direct ToV will be disclosed in the ToV period which the payment is made irrespective of the contract date, contract duration or event date. ToV associated with multi-year agreements will be reported as each payment is made. Indirect ToV will be disclosed based on the payment date provided to Otsuka Pharmaceutical (UK) Ltd. by the intermediary. In the event that the payment date is not provided by the intermediary, then the event date is used.

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 based in the year the payment was made.

#### 4.2. Indirect ToV

Indirect ToV will be disclosed based on the payment date provided to Otsuka Pharmaceutical (UK) Ltd. 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 ToV in case of partial attendances or cancellation

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

- If Otsuka Pharmaceutical (UK) Ltd. sponsors a United Kingdom HCP/HCO to attend an event and the relevant HCP does not attend, a ToV will not be disclosed for that HCP.

#### 4.3. Cross-border activities

Otsuka group companies in scope for providing ToV data for ABPI 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 United Kingdom, concludes an agreement with an HCP or HCO, that are resident or practicing in United Kingdom.

Otsuka Pharmaceutical (UK) Ltd. will disclose all ToV's made to United Kingdom HCPs for engagements by any Otsuka Group Companies. In these cases, disclosure will be made in accordance with the ABPI Code of Practice.

#### 4.4. R&D

Research and Development (R&D) Otsuka Pharmaceutical (UK) Ltd. has adopted the definition as per the ABPI Code of Practice with the additional clarifications:

- Otsuka Pharmaceutical (UK) Ltd. 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 Pharmaceutical (UK) Ltd.'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.

#### 5. Specific considerations

##### 5.1. 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.

##### 5.2. Self-incorporated HCP

For situations where HCO's are owned by a solo HCP, disclosure will be made against the HCP rather than the HCO.

#### 6. Data protection management

##### 6.1. Consent collection

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.

##### 6.2. Management of recipient consent withdrawal

Any recipient wishing to withdraw consent to disclose ToV, must either initiate a request through the ABPI Disclosure UK platform, or contact the Otsuka EU Transparency & Disclosure team directly at [transparency@otsuka-europe.com](mailto:transparency@otsuka-europe.com)

Received disclosure consent withdrawals will be processed and the affected report(s) updated as soon as is reasonably practicable. Throughout the

processing, the recipient will be kept informed of the target timelines for completion of the request.

#### 6.3. Management of recipient's request

Otsuka Pharmaceutical (UK) Ltd. requires all healthcare professionals to provide their consent to us before publishing details of any ToV they receive from us on an individual named basis. The consents will:

- apply for all engagements of United Kingdom HCPs by any Otsuka Group Company; and
- be unlimited in time unless and until revoked in writing by the HCP.

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

### 7. Disclosure Form

#### 7.1. Date of publication

The Otsuka Pharmaceutical (UK) Ltd. 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.

#### 7.2. Disclosure platform

The Otsuka Pharmaceutical (UK) Ltd. disclosure report will be published on ABPI Disclosure UK platform. Hyperlinks to ABPI Disclosure UK platform will be published on the main website; <https://www.otsuka.co.uk/hcp-disclosure-information>

### 8. Disclosure language

The Otsuka Pharmaceutical (UK) Ltd. disclosure report will be published in English, according to the processes defined for the ABPI Disclosure UK platform.

### 9. Disclosure financial data

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

Otsuka Pharmaceutical (UK) Ltd. 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 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 Pharmaceutical (UK) Ltd. expects the differences to be relatively insignificant.

#### 9.2. VAT included or excluded

For the most part, Otsuka Pharmaceutical (UK) Ltd. 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.

## 10. Calculation rules

For calculations associated with currency conversions, see section 9.1.

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.

## 11. Additional information

### 11.1. Sources of Data

Data will be captured through a number of platforms:

- Internal Otsuka Database the bespoke Otsuka Pharmaceutical (UK) Ltd. 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 ToV's are captured via a manual spreadsheet template which is manually uploaded to the Transparency Reporting System.

### 11.2. Data Quality

Otsuka Pharmaceutical (UK) Ltd. 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 Pharmaceutical (UK) Ltd. to HCP/HCOs located in the United Kingdom for the period of 01 January 2024 to 31 December 2024.