



Otsuka Pharmaceutical Italy S.R.L.

Farindustria disclosure: Italy

Methodology Note applicable to transfers of value

1. Introduction

In order to comply with the requirements of the Farindustria Code, Otsuka Pharmaceutical Italy S.R.L. agrees to document and publish details of any Transfer of Value (ToV) we may provide directly or indirectly to any Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) and Patient Organisations (POs). 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 Pharmaceutical Italy S.R.L. intends to record and publish this information in accordance with the Farindustria Code. Otsuka Pharmaceutical Italy S.R.L. will only refrain from publishing the details of those ToV where this is clearly not required under the Farindustria Code.

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

2. Definitions

2.1. Recipients – Healthcare Professional (HCP)

Otsuka Pharmaceutical Italy S.R.L. has adopted the definition as per the Farmindustria Code: *Every person who exercises their activity in the medical, dental, public pharmacy, private or hospital pharmacy sectors, nurses, General and Health Directors of Local Health Authorities/Hospitals (ASL/AO), technical and administrative staff of public and private health facilities, and any other subject who, within their professional activity, may prescribe, dispense, purchase, or administer a medicinal product and who carries out their main activity in Europe. However, intermediate drug distributors are excluded.*

Otsuka Pharmaceutical Italy S.R.L. report will be based and dependent on reference data stored in Otsuka Pharmaceutical Italy S.R.L. systems and tools, which are populated with data purchased from IMS (OneKey Database) and data sourced during recipient interactions.

2.2. Recipients – Healthcare Organisation (HCO)

Otsuka Pharmaceutical Italy S.R.L. has adopted the definition as per the Farmindustria Code: Every legal entity that is an Association or Organization in the medical, scientific, health, or research sectors (regardless of its legal form), as well as Hospitals, Clinics, Foundations, Universities, Training and Specialization Schools (except patient Associations) that have their legal headquarters or primary place of business in Europe, or through which a doctor provides their services.

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.

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 is 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)
Sponsorship	All expenses agreed with an HCO which might comprehend booth hire, advertisement space, space for satellite symposia, and contribution towards the cost of meetings...etc) or expenses aimed to support other HCO or Patient Organization activities/projects.

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 Italy S.R.L. 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).
PO fee for service and related expenses	Compensation provided for any kind of services done by a PO (eg speaker fee), hospitalities (Travel and accommodation) related expenses included in the fee for service contract
PO Donation / Grant	Financial funds provided to support PO initiatives/projects
R&D related expenses	Expenses related to the planning and conduct of an Otsuka Pharmaceutical Italy S.R.L. sponsored study. Refer to section 5.5 for further explanation.

3. Disclosure's scope

3.1. Products concerned

Otsuka Pharmaceutical Italy S.R.L. has adopted the definition as per the Farmindustria Code, 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. ToVs 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 – provides governance, oversight, and compliance monitoring for interactions between Otsuka Group companies and European recipients. Throughout this methodological note, Otsuka Pharmaceutical Italy S.R.L. 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 Pharmaceutical Italy S.R.L. 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.

Any kind of ToVs related to Over-the-Counter (OTC) medical products, as well as those relating to promotional material, food and beverage and sample of medicines are excluded from the disclosure.

4. ToV date

Direct ToV will be disclosed in the ToV period which the payment is made, irrespective of the contract date, contract duration or event date.

Indirect ToV will be disclosed based on the payment date provided to Otsuka Pharmaceutical Italy S.R.L. 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 which the payment is made, irrespective of the contract date, contract duration or event date.

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.

5.2. Indirect ToV

Indirect ToV will be disclosed based on the payment date provided to Otsuka Pharmaceutical Italy S.R.L. 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 attendance or cancellation

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

- If Otsuka Pharmaceutical Italy S.R.L. sponsors an Italian 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 Italy S.R.L. (“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, organisation or patient organization 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 Italy, concludes an agreement with an HCP or HCO, that are resident or practicing in Italy.

Otsuka Pharmaceutical Italy S.R.L. will disclose all ToVs made to Italian HCPs for engagements by any Otsuka Group Companies. In these cases, disclosure will be made in accordance with the Farmindustria Code.

Example: If Otsuka US engages an Italian HCP, Otsuka Pharmaceutical Italy S.R.L. will disclose ToV made to the Italian HCP on behalf of Otsuka US.

5.5. R&D

Research and Development (R&D) – Otsuka Pharmaceutical Italy S.R.L. has adopted the definition as per the Farmindustria Code with the additional clarifications:

- Otsuka Pharmaceutical Italy S.R.L. 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 Italy S.R.L.’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

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.

8.2. Management of recipient consent withdrawal

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

Received disclosure consent withdrawals will be processed – and the affected report(s) updated. Throughout the processing, the recipient will be kept informed of the target timelines for completion of the request.

If consent to disclose is revoked for any individual engagement, all engagements 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 the control of Otsuka Pharmaceutical Italy S.R.L. to update the report.

8.3. Management of recipient's request

Otsuka Pharmaceutical Italy S.R.L. 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 Italian HCPs by any Otsuka Group Company (as defined in section 5.4); 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.

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.

Otsuka Pharmaceutical (UK) Ltd. does not use partial consent as a basis of disclosure.

8.4. Legitimate interest

Currently, Otsuka Group are not using Legitimate Interest as a basis for disclosure. Disclosure consent remains the basis for named disclosure of ToV to HCPs (refer to sections 8.1-8.4 for further detail).

9. Disclosure Form

9.1. Date of publication

The Otsuka Pharmaceutical Italy S.R.L. 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 Pharmaceutical Italy S.R.L. disclosure report will have the report version date clearly stated on the report.

9.2. Disclosure platform

The Otsuka Pharmaceutical Italy S.R.L. disclosure report will be published on the [Otsuka Pharmaceutical Italy S.R.L. HCP Disclosure](#) website.

10. Disclosure language

The Otsuka Pharmaceutical Italy S.R.L. disclosure report will be published in English and Italian.

11. Disclosure financial data

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

Otsuka Pharmaceutical Italy S.R.L. 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 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 Pharmaceutical Italy S.R.L. expects the differences to be relatively insignificant.

11.2. VAT included or excluded

For the most part, Otsuka Pharmaceutical Italy S.R.L. will publish payments wherever possible as nett amounts, i.e. excluding VAT. As multiple VAT regimes exist globally with different reimbursement approaches some payments may be reported as gross amounts including VAT.

12. Calculation rules

For calculations associated with currency conversions, see section 11.1.

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

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 Pharmaceutical Italy S.R.L. 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 is manually uploaded to the Transparency Reporting System.

13.2. Data Quality

Otsuka Pharmaceutical Italy S.R.L. 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 Italy S.R.L. to HCPs, HCOs and POs located in Italy.