

Otsuka Pharmaceutical S.A.

Farmaindustria disclosure: SPAIN

Methodology note applicable to HCP/HCO transfers of value, for the reporting year: 2025 (published June 2026)

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 organizations have been calculated for the current reporting year.

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

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 medicine.

ORDM: particularly includes someone with a role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine.

Exclusions:

- 2.1.1. Non-practicing HCPs, including retired HCPs 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 S.A. (Spain)
- 2.1.2. Employees of Otsuka Pharmaceutical S.A. (Spain) who are still members of the said professions and able to prescribe are deemed excluded.
- 2.1.3. Employees of Otsuka Pharmaceutical S.A. (Spain) collaboration partners who are still members of the said professions and able to prescribe are deemed excluded.

2.2. Recipients – Healthcare Organization (HCO)

Means either a healthcare, medical or scientific association or organization 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 Spain or an organization through which one or more health professionals or other relevant decision makers provide 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 practicing HCPs, are excluded.

Example: an HCP working for a consultancy firm engaged by Otsuka Spain 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 (Transfer of Value)

Expense Category	Description
HCO Donations and Grants	Contribution to donations 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). This section also includes ToV related to HCO Collaborative Working, i.e. contribution to working with organizations 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.
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 S.A. will disclose under this category any transfer of value (ToV) relating to observational retrospective non interventional studies sponsored by investigators (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 expenses as per the fee-for-services agreement (e.g. taxi, mileage or out of expenses).
R&D related expenses	Expenses related to the planning and conduct of an Otsuka Pharmaceutical, S.A. (Spain) sponsored study. Refer to section 3.10 for further explanation.

3. Disclosure's scope

3.1. Products concerned

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

- 3.1.1. Medicinal Product will include products for which application for a marketing authorization 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 is 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 included, when applicable.
- 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 S.A.) provide governance, oversight, and compliance monitoring for interactions between Otsuka Group companies and European recipients. Throughout this methodological note, Otsuka Pharmaceutical S.A. represents the presence and interactions of Otsuka Group companies and affiliates within Europe.

Collaboration Partners – principle: each partner company (refers to an external company that collaborates with the organization under a professional or contractual relationship) 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.. 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 defense,
- Prosecution, and
- Settlement or judgment of a civil or criminal action and arbitration or other legal action.

3.4. ToV dates:

The report on Transfers of Value published on the Company's website, as well as on the official Farmaindustria website, includes all payments made to HCP and HCOs within the relevant transparency reporting cycle, including data from 1 January to 31 December of the year preceding the publication of the report.

3.5. Direct ToV

Direct ToV will be disclosed in the ToV period in 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.

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.

3.6. Indirect ToV

Indirect ToV will be disclosed based on the payment date provided to Otsuka Pharmaceutical S.A. (Spain) 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 data protection provision that third parties are informing the HCP about OPSA disclosure obligations relating to ToV and must demonstrate such to us ToV in case of partial attendances or cancellation

3.7. Non-monetary ToV (in kind)

In accordance with applicable internal company policies, this type of ToV is not permitted for HCPs or HCOs.

3.8. ToV Transfers of Value arising from situations such as partial attendance, cancellation and reimbursement

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

- If Otsuka Pharmaceutical S.A (Spain) sponsors a Spanish HCP/HCO to attend an event and the relevant HCP does not attend, a ToV will be disclosed for that HCP, except in the case that Otsuka could cancel it and get the reimbursement of the ToV.
- If Otsuka Pharmaceutical S.A. (Spain) sponsors a Spanish HCP/HCO to attend an event that has been cancelled or postponed because of pandemics

situation and/or another force majeure event, and the relevant HCP does not attend, this ToV will not be disclosed for that HCP.

3.9. Cross-border activities

Otsuka group companies in scope for providing ToV data for Farmaindustria reporting are all Otsuka group companies (incorporated in any jurisdiction) that:

- develop or commercialize 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 for an Otsuka Group Company incorporated in a country other than the country in which the healthcare professional or 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 Spain concludes an agreement with an HCP or HCO, that are resident or practicing in Spain.

Otsuka Pharmaceutical S.A. will disclose all ToV's made to Spanish HCPs for engagements by any Otsuka Group Companies. In these cases, disclosure will be made in accordance with the Farmaindustria Code of Practice.

3.10. R&D

Research and Development (R&D) Otsuka Pharmaceutical S.A. (Spain) has adopted the definition as per the Farmaindustria Code of Practice with the additional clarifications, these ToV are disclosed on aggregated basis:

- Transfers of Value made to HCOs and HCPs in connection with retrospective observational studies involving medicinal products, although classified as Research and Development (R&D), are disclosed on an individual basis under the category "Fees for Service".
- Otsuka Pharmaceutical S.A (Spain) will disclose under this category any ToV relating to studies sponsored by investigator (E.g. Investigator Sponsored Studies (ISS)).
- In the transparency report, ToV (direct or indirect) related to Research and Development (R&D) activities are disclosed in aggregate, reflecting a total annual amount corresponding to all payments made to HCPs and HCOs under this category.

3.11. Voluntarily disclosed ToV

Although the local Code of Practice does not apply, Otsuka Pharmaceutical S.A. voluntarily commits to the disclosure of all Transfers of Value related to medical device activities.

4. Specific considerations

4.1. 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.

4.2. Self-incorporated HCP

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

4.3. Contracts with a duration exceeding one year

In cases where an agreement with an HCP or HCO extends beyond one year, ToV is disclosed in the reporting period corresponding to the relevant reporting date (i.e. the payment date), regardless of the duration of the agreement.

4.4. Country-specific considerations

- Transfers of Value made to HCOs and HCPs in connection with retrospective observational studies involving medicinal products, although classified as Research and Development (R&D), are disclosed on an individual basis under the category "Fees for Service".
- ToV to Patient Organisations (PO) are disclosed in a separate report. A specific Methodological Note relating to PO ToV is published on the same website as the relevant disclosure.

4.5. Data Quality

Otsuka Pharmaceutical S.A. (Spain) 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 S.A. to HCP/HCOs located in the Spain including all data paid during the January 1st and until December 31st for the current disclosure cycle.

In the case of receiving ToV that must be included in the current report after the deadline for the review of the data to be published, or once the report has already been published, whenever possible the published report will be updated including the additional ToV. When it is not possible to update the report, these ToV will be included in the next transparency report corresponding to the next Publication Period.

Prior to the final publication of the report, and to guarantee that all the data to be made transparent are correct, a letter detailing all the ToV is sent to all the health professionals with whom collaboration has been carried out during the current publication period.

5. Data protection management

5.1. 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. To publish the ToV the legal basis is the legitimate interest of the company accordingly with the Spanish Data Protection Agency Inform nº 143318/2016, which endorse that ToV data does not need the HCP disclosure consent.

It is mandatory to publish all ToV received during the disclosure reporting period on an individual named basis, just some exceptional cases should be reported in aggregate, and these cases should be well documented and justified.

According to the enquiry carried out by the National Pharmaceutical Industry Association (Farmaindustria), submitted to the Spanish Agency for Data Protection (AEPD), during the currently period, it was not necessary to obtain the consent of the health professionals to disclose the ToV received by Otsuka, with the names and surnames of each health professional. For HCOs and HCPs, ToV consents are not being requested.

Furthermore, pharmaceutical companies shall inform Healthcare Professionals, pursuant to Organic Law 3/2018 of 5 December on the Protection of Personal Data and the Guarantee of Digital Rights, that their personal data will be published in accordance with the provisions set out in this Code.

Any individual wishing to exercise, at any time, their rights of access, information, rectification, erasure, objection, restriction of processing, or data portability in relation to the published data may do so by contacting: OPSA's Data Protection Officer (DPO) via the following email address: gdpr@otsuka.es.

5.2. Partial consent

In accordance with applicable local regulatory requirements and considering that consent is not required in Spain for the disclosure of ToV, the concept of partial consent is not applicable. ToV are disclosed on an individual basis, except in exceptional, duly justified circumstances where disclosure on an aggregated basis is required.

5.3. Legitimate interest

Farmaindustria Code of Practice: In the case of Healthcare Professionals, in accordance with Directive 95/46/EC article 7f), on the protection of individuals with regard to the processing of personal data and on the free movement of such data, there is a legitimate interest for the companies subject to the Code, recognized by the report issued by the SDPA, of 22 April 2016 (Code Annex I), so that the Healthcare Professional's consent is not necessary for the disclosure, on an individual basis, the Transfers of Value made to Healthcare Professionals.

In any case, pharmaceutical companies will inform Healthcare Professionals, under Organic Law 3/2018, of 5 December, for Personal Data Protection and Guarantee of Digital Rights, that their data will be disclosed in accordance with the Code.

6. Disclosure Form

6.1. Date of publication

The Otsuka Pharmaceutical S.A (Spain) 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.

6.2. Disclosure platform

Details of the transparency report that includes collaborations with Spanish HCP/HCO can be found on the Otsuka Pharmaceutical S.A. website, the following link [Otsuka Pharmaceutical S.A. HCP/HCO Disclosure](#), as well as at the following link on the Farmaindustria website:

<https://www.codigofarmaindustria.org/servlet/sarfi/colaboracionesps.html>

6.3. Disclosure language

The Otsuka Pharmaceutical S.A. disclosure report will be published in English and Spanish.

7. Disclosure financial data

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

Otsuka Pharmaceutical S.A. (Spain) all ToV in the base currency of the local office in the reporting country. Any amount 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 S.A. expects the differences to be relatively insignificant.

7.2. VAT included or excluded

For the most part, Otsuka Pharmaceutical S.A. will publish payments wherever possible without including VAT. As multiple VAT regimes exist globally with different

reimbursement approaches some payments may be reported as net amount including VAT.

7.3. Calculation rules

For calculations associated with currency conversions, see section 9.1.

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 of accuracy, being rounded down.

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

8. Additional information

8.1. Sources of Data

Data will be captured through a number of platforms:

- Internal Otsuka Database the bespoke Otsuka Pharmaceutical S.A. 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.

8.2. Management of recipient's request

Anyone who disagrees with any data that has been published, who has any questions about the information published, or who wants to see the details or wants more information about any data published should contact transparencyopsa@otsuka.es.