

Otsuka Pharmaceutical S.A.

("Otsuka Spain")

Farmaindustria disclosure: Spain

Methodology note applicable to transfers of value, for the reporting year: 2022

1. Introduction

This Methodology Note covers the disclosure of data relating to healthcare professionals (HCPs) whose primary practice or principal professional address is in Spain or healthcare organisations (HCOs) incorporated or trading in Spain. For data relating to HCPs or HCOs based in other countries, please refer to the website of Otsuka Pharmaceutical Europe Ltd (www.otsuka-europe.com).

In order to comply with the requirements of the Farmaindustria Code of Practice for the Pharmaceutical Industry ("[Farmaindustria Code of Practice](#)"), Otsuka Spain agrees to document and publish details of any Transfer of Value (ToV) any Otsuka Group Company (as defined in section II.3.1 below) may provide directly or indirectly to any HCPs or HCOs.

The reporting period in each case will be the previous calendar year and we agree to publish the relevant report before the end of June of the following year ("**Reporting Period**").

The aim of these guidelines is to provide a clear and simple explanation of how Otsuka Spain intends to record and publish this information in accordance with the [Farmaindustria Code of Practice](#). In particular, Otsuka Spain would like to outline the underlying methodology applied and to explain specific issues as to how Otsuka Spain will apply this in publishing the relevant information. Otsuka Spain will only refrain from publishing the details of those ToVs where this is clearly not required under the [Farmaindustria Code of Practice](#).

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)

Otsuka Spain has adopted the definition as per the [Farmindustria Code of Practice](#).

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

Exclusions:

2.1.1. Employees of Otsuka Spain who are still members of the said professions and able to prescribe are deemed excluded.

2.1.2. Employees of Otsuka Spain collaboration partners who are still members of the said professions and able to prescribe are deemed excluded.

2.2. Recipients – Healthcare Organisation (HCO)

Otsuka Spain has adopted the definition as per the [Farmindustria Code of Practice](#).

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.

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

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 are 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)
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, , speaker training, medical writing and data analysis). In addition to fee for services in relation to consultancy services, Otsuka Spain will disclose under this category any ToV relating to retrospective non interventional studies sponsored by investigator (e.g. Investigator Sponsored Studies (ISS)).
HCP/HCO agreement related expenses	Travel and accommodation or any other expense as per the fee-for-services agreement (e.g. taxi, outof pocket expense).
R&D related expenses	Expenses related to the planning and conduct of a study whose promoter is Otsuka, and which includes healthcare professionals or healthcare organizations practicing their professional activity in Spain or whose principal professional address or place of incorporation is in Spain.. Refer to section 4.5 for further explanation.

3. Disclosure's scope

3.1. Products concerned

Otsuka Spain has adopted the definition as per the [Farmindustria Code of Practice](#), 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. 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. 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 Spain 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 Spain 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.

Example (1): for an event in December 2022, it is possible that part of the ToVs for that event are invoiced in 2022 and the remainder in 2023. Invoices processed in 2022 are disclosed for the period 1 January - 31 December 2022. The ToVs related to the event and payment in December 2022, have been part of the 2022 ToV disclosure in 2022 calendar year.

Example (2): for multi-year contracts, ToVs to the same HCP/ HCO under the same contract will be disclosed as per date of individual invoices. Refer to section 7 for more detail.

Example (3): Contracts of more than one year: The ToV associated with multi-year agreements will be published as each payment is made. If a multi-year agreement is established that covers a period of 3 years, payments made in year 1 will be included in the transparency report for that calendar year; payments made in years 2 and 3 will be included in the transparency reports of the following calendar years.

Payments to a transparency report will not be withheld or advanced before or after the actual ToV payment date. Payment to charities on behalf of HCPs:

In the event that Otsuka Spain make payment to an entity, at the request of an HCP in relation to a fee for service engagement, such payment shall not be disclosed in this report on the basis that no ToV have been made to an HCP/HCO.

Example: HCP requests that his fee for service be paid to a charitable organisation of his choice.

4.2. Indirect ToV

Indirect ToV will be disclosed based on the payment date provided to Otsuka Spain by the intermediary. In the event that the payment date is not provided by the intermediary, then the event date is used.

Transfers of value to health professionals paid through a third party will be published associated with the name of the health professional (always individually).

In the transparency report, all accommodation and/or travel expenses associated with the provision of services will be reflected in the column “HCP/ HCO Travel & Accommodation”. In this case, the minimum travel expenses (such as cab, gasoline or parking) will be reflected in the column corresponding to “HCP/HCO agreement related expenses”.

4.3. ToV in case of partial attendances or cancellation

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

- If Otsuka 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 sponsors a Spanish HCP/HCO to attend an event that has been cancelled or postponed because of pandemics situation and/or other global situation, and the relevant HCP does not attend, this ToV will not be disclosed for that HCP.

4.4. 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 commercialise Medicinal Products (as defined);
- are controlled (i.e. more than 50% ownership) by Otsuka Pharmaceutical Co., Ltd., (“OPC”); Otsuka America Inc. (“OAI”); Otsuka Spain (“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 Spain, concludes an agreement with an HCP or HCO, that are resident or practicing in Spain.

Otsuka Spain will disclose all ToVs made to Spanish HCPs for engagements by any Otsuka Group Companies, except those from the company AKEBIA. In these cases, disclosure will be made in accordance with the [Farmindustria Code of Practice](#).

Example: If Otsuka US engages a Spanish HCP, Otsuka Spain will disclose ToV made to the Spanish HCP on behalf of Otsuka US.

4.5. R&D

Research and Development (R&D) – Otsuka Spain has adopted the definition as per the [Farmindustria Code of Practice](#) with the additional clarifications:

- Otsuka Spain 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 Spain's support, direct or indirect, to medical publication in connection to R&D activities, will be disclosed under 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 cases in which a health professional is self-employed (person who works on their own), or in cases in which a health professional wants to bill through a commercial company: In accordance with local requirements that dictate the obligation to disclose the information in the name of the healthcare professional, regardless of the billing entity or the beneficiary, all billed ToV in both cases will be published in the name of the healthcare professional.

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. To publish the ToV the legal basis is the legitimate interest of the company accordingly with the Spanish Data Protection Agency Inform n° 143318/2016, which endorse that ToV data does not need the HCP disclosure consent.

It is mandatory to publish all ToV received from us during 2022 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 period of 2022, 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.

6.2. 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.

6.3. Legitimate interest

Farmaindustria Code of Practice: Code Of Practice of FI 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.

7. Disclosure Form

7.1. Date of publication

The Otsuka Spain report will be published every year, at the end of June, and in compliance with the provisions of Farmaindustria. The information will be publicly available for at least a period of 3 years.

7.2. Disclosure platform

Details of the transparency report that includes collaborations with Spanish doctors can be found on the company's 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>

7.3. Disclosure language

The Otsuka Spain disclosure report will be published in English and Spanish.

8. Disclosure financial data

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

Otsuka Spain 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 Spain expects the differences to be relatively insignificant.

8.2. VAT included or excluded

For the most part, Otsuka Spain will publish payments wherever possible as gross amounts, i.e. without including VAT. As multiple VAT regimes exist globally with different reimbursement approaches some payments may be reported as net amounts.

9. Calculation rules

For calculations associated with currency conversions, see section 8.1.

Where one ToV payment is covering multiple recipients and the ToV is not individually itemised, 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.

10. Additional information

10.1. Sources of Data

Data will be captured through a number of platforms:

- Internal Otsuka Database – the bespoke Otsuka Spain 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 has to be manually uploaded to SharePoint.
- Otsuka Spain utilizes services of a third party to consolidate all source data and prepare reports.
- Data obtained directly from the Health Professional

10.2. Data Quality

Otsuka 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 Spain to HCP/HCOs located in Spain for the current period from 01 January to 31 December.

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.