

**OTSUKA PHARMACEUTICAL S.A**

**(“OTSUKA SPAIN”)**

**EFPIA DISCLOSURE: SPAIN**

**METHODOLOGY NOTE APPLICABLE TO**

**TRANSFERS OF VALUE**  
**FOR THE 2021 REPORTING YEAR**

**PREAMBLE**

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](http://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 report should be directed to:**  
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## I. PRINCIPLES OF CONSENT MANAGEMENT

### 1. LEGAL BASIS TO PUBLISH INFORMATION

#### 1.1 LEGAL BASIS

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.

#### 1.2 OUR APPROACH

It is mandatory to publish all ToV received from us during 2021 period on an individual named basis, just some exceptional cases should be reported in aggregate, and these cases should be well documented and justified.

1.2.1. 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 2021, 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.

1.2.3. For HCOs and HCPs, ToV consents are not being requested.

### 2. DURATION OF PUBLICATION

The Otsuka Spain report will remain publicly available for a period of 3 years minimum.

## II. GENERAL QUESTIONS

### 1. DEFINITIONS:

#### 1.1 HEALTHCARE PROFESSIONAL (HCP)

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

Otsuka Spain report will be based and dependent on reference data stored in Otsuka internal database which is populated with data purchased from IMS (OneKey Database, IQVIA) as well as data sourced internally, or those provided by the HCP.

#### Exclusions:

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

## 1.2 HEALTHCARE ORGANISATION (HCO)

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

### Exclusion:

- a. 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 (and so is not currently working as an HCP) contracted as a service provider by Otsuka Spain to provide general advice on a disease area not related to a specific product.

- b. Relative to fee for services arrangements, if payment is made to a corporate entity, then the amount will be disclosed as a ToV to an HCP.

## 1.3 MEDICINAL PRODUCTS

Otsuka Spain has adopted the definition as per the [Farmaindustria Code of Practice](#), with the additional clarification:

- a. Medicinal Product will include products for which application for a marketing authorization to the EMA or any National Competent Authority in Europe is made.
- b. Transfers of Value relating to any activity in respect of 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.
- c. Combination product are included.

## 2. SOURCES OF DATA:

Data will be captured through a number of platforms:

- a. Internal Otsuka Database – the bespoke Otsuka platform for reference data and document management.
- b. ERP system (SAP B1) where direct payments to HCP/HCO’s are managed.
- c. Third Party systems – ad hoc payments made by intermediaries who cannot access Internal Database. These ToVs are captured via the manual spreadsheet template which has to be manually uploaded on SharePoint.
- d. Otsuka utilizes a third party to consolidate all source data and prepare report.

## 3. CROSS-BORDER ENGAGEMENTS

### 3.1 BACKGROUND

Otsuka 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 Europe Ltd. (“OPEL”) and any subsidiary of these three companies;
- engage (provide transfers of value to) HCPs whose primary practice or principal professional address is in Spain.

(hereafter referred to as “**Otsuka Group Companies**”)

### 3.2 EXAMPLES

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 HCP or HCO 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 resident or practicing in Spain.

### 3.3 OUR APPROACH

Otsuka Spain will disclose all ToVs made to Spanish HCPs/ HCOs for engagements by any Otsuka Group Companies. In these cases, disclosure will be made in accordance with the [Farmaindustria 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. PUBLICATION OF TOV GRANTED IN A FOREIGN CURRENCY: CURRENCY ASPECTS

Otsuka Spain reports all ToV in EURO. Any amounts where the ToV has been in a foreign currency will be converted using the rate of the last day of the month when the ToV has been conducted or 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.

## 5. TREATMENT OF VAT

On the most part, Otsuka Spain 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. REPORTING OF TRANSFERS OF VALUE (TOV)

- All ToV will be disclosed in 2021 period during which payments are made, irrespective of the contract date, contract duration or event date.

Example (1): for an event in December 2020, it is possible that part of the ToVs for that event are invoiced in 2020 and the remainder in 2021. Only invoices processed in 2021 are disclosed for the period 1 January - 31 December 2021. The ToVs related to the event and payment in December 2020, have been part of the 2020 ToV disclosure in 2021 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 payments.

- Provision of Product for study purpose:

- Value study drug for marketed products as per the COG price, except where quantities are of nominal value.
- Where product is not commercialised following authorisation, no value is attributed.
- 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 pandemic situation and/or other global situation, and the relevant HCP does not attend, this ToV will not be disclosed for that HCP.
- Payment to charities on behalf of HCPs:
  - In the event that Otsuka makes 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 ToVs have been made to an HCP/HCO.

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

- 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”.

## **7. INDIRECT PAYMENT OF TOV TO HEALTHCARE PROFESSIONALS**

In the event that we become aware that ToVs granted by us to a third party have been passed onto an HCP, or those persons have benefitted from such, we will generally publish the details of each of those ToVs under the name of the relevant HCP. Our contractual arrangements with third parties include a data protection provision that third parties require the consent of their own contracting partner for the publication of details relating to ToVs and must demonstrate such to us.

## 8. EXPENSE CATEGORIES USED BY OTSUKA SPAIN

EXPENSE CATEGORY	DESCRIPTION
HCO Grant & Donation	Donation and grant in money or kind (e.g. medical educational books and brochures, scholarship, R&D, humanitarian &/or healthcare &/or social assistance.) to HCO. <b>Refer to section 9 for further explanation.</b>
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	E.g. 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 service provided by an HCP or member of an HCO (e.g. speaker fee, consultant fee, , speaker training, medical writing and data analysis, or any other type of funding not covered in the previous categories.). <b>Refer to section 11 for further explanation,</b>
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).
R&D related expenses	Expenses related to the planning and conduct of an Otsuka sponsored study including healthcare professionals (HCPs) whose primary practice or principal professional address is in Spain. As an exception to the terms set out in the above paragraph, Transfers of Value made to Healthcare Organisations and to Healthcare Professionals related to observational studies with medicinal products that are retrospective nature, which are nonetheless considered as Research and Development, must be published on an individual basis by pharmaceutical companies under the category "provision of services". <b>Refer to section 10 for further explanation.</b>



## 9. GRANTS AND DONATIONS:

Definition: any ToV related to medical and educational goods and services which enhance patient care or benefit the healthcare system and maintain patient care.

**Donations either in cash or kind, that support healthcare research are included.**

## 10. RESEARCH AND DEVELOPMENT

Otsuka Spain has adopted the definition as per the [Farmaindustria Code of Practice](#) with the additional clarification:

- a. 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.
- b. Support by Otsuka Spain to medical publication in connection to R&D activities, whether direct or indirect, will be disclosed under this category.

## 11. COLLABORATION PARTNERS

The principle: each partner company will disclose ToVs made by that entity to HCPs/ HCOs, irrespective of reimbursement.

Otsuka Spain has disclosed all ToVs in respect of HCPs engaged or sponsored by Otsuka Spain to attend a collaboration event. Where Otsuka Spain has acted as the lead for a collaboration event, it has disclosed all ToVs for that event, except for HCPs engaged or sponsored by the collaboration partner.

## 12. DATA QUALITY

Otsuka Spain is confident that the data included in the disclosure report is a complete and accurate account of the ToVs made by or on behalf of Otsuka Spain to HCPs/HCOs located in Spain for the period of January 1,2021 to December 31, 2021.

In the event that ToVs disclosable for this Reporting Period are discovered subsequent to publication of the disclosure report, these ToVs shall be included in the next disclosure report for the Reporting Period of 1 January 2022 - 31 December 2022.