

OTSUKA PHARMACEUTICAL ITALY S.R.L.
("OTSUKA ITALY")

EFPIA DISCLOSURE: ITALY

METHODOLOGY NOTE APPLICABLE TO TRANSFERS OF VALUE
FOR THE 2019 REPORTING YEAR

Preamble

In order to comply with the requirements of the [EFPIA Disclosure Code](#), Otsuka Italy agrees to document and publish details of any Transfer of Value (ToVs) we may provide directly or indirectly to any healthcare professionals (HCPs) or healthcare organisations (HCOs). The reporting period in each case will be the previous calendar year and we agree to publish the relevant report by the end of June of the following year ("Reporting Period").

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

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

CONTENTS

I.	PRINCIPLES OF CONSENT MANAGEMENT	3
1.	CONSENT TO PUBLISH INFORMATION	3
1.1.	<i>LEGAL BACKGROUND</i>	3
1.2.	<i>OUR APPROACH</i>	3
2.	PARTIAL CONSENT	3
2.1.	<i>EXAMPLE</i>	3
2.2.	<i>OUR APPROACH</i>	3
3.	DURATION OF PUBLICATION	3
II.	GENERAL QUESTIONS	4
1.	DEFINITIONS	4
1.1.	<i>HEALTHCARE PROFESSIONAL (HCP)</i>	4
1.2.	<i>HEALTHCARE ORGANISATION (HCO)</i>	4
1.3.	<i>MEDICINAL PRODUCTS</i>	4
2.	SOURCES OF DATA	5
3.	CROSS-BORDER ENGAGEMENTS	5
3.1.	<i>BACKGROUND</i>	5
3.2.	<i>EXAMPLE</i>	5
3.3.	<i>OUR APPROACH</i>	5
4.	PUBLICATION OF TOVS GRANTED IN A FOREIGN CURRENCY: CURRENCY ASPECTS	5
5.	TREATMENT OF VAT	6
6.	REPORTING OF TRANSFERS OF VALUE (TOVS)	6
7.	INDIRECT PAYMENT OF TOVS TO HEALTHCARE PROFESSIONALS	7
8.	EXPENSE CATEGORIES USED BY OTSUKA ITALY	7
9.	GRANTS AND DONATIONS	8
10.	RESEARCH AND DEVELOPMENT (R&D)	8
11.	FEE FOR SERVICE TO HCOS	8
12.	COLLABORATION PARTNERS	8
13.	CIVIL OR CRIMINAL ACTION OR ADMINISTRATIVE PROCEEDING	8
14.	DATA QUALITY	9

I. PRINCIPLES OF CONSENT MANAGEMENT

1. CONSENT TO PUBLISH INFORMATION

1.1. LEGAL BACKGROUND

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.

1.2. OUR APPROACH

Otsuka Italy requires all healthcare professionals to provide their consent to us before publishing details of any ToVs 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 3.1 below); 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, ToVs 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.

2. PARTIAL CONSENT

2.1. EXAMPLE

This situation may arise, for instance, where the healthcare professional agrees to the publication of details of having received funding to attend a professional congress or seminar but does not agree to the publication of the travel and accommodation costs associated with the trip. Another potential example is where the person concerned agrees to the publication of the expenses paid in connection with attending such an event, but not to the publication of any associated consultancy fee.

2.2. OUR APPROACH

If consent to disclose is revoked for any individual engagement, all engagements (past and future) 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 Otsuka Italy's control to update the report.

3. DURATION OF PUBLICATION

Otsuka Italy's report will remain publicly available for a period of 3 years.

II. GENERAL QUESTIONS

1. DEFINITIONS

1.1. HEALTHCARE PROFESSIONAL (HCP)

Otsuka Italy has adopted the definition as per the [EFPIA Disclosure Code](#).

Otsuka Italy report will be based and dependant on reference data stored in Otsuka Italy internal database (OPTICS) populated with data purchased from IMS (OneKey Database) as well as data sourced internally.

Exclusions:

- a. Persons who are registered, but who do not practice as HCPs, including retired HCPs (excluding HCPs conducting research 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 Italy.

Example 1: an HCP working for a consultancy firm but also practicing from a clinic, ToVs shall be disclosable.

Example 2: a pharmacist working full time in a consultancy firm providing Otsuka Italy with regulatory advice, ToVs shall not be disclosable.

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

1.2. HEALTHCARE ORGANISATION (HCO)

Otsuka Italy has adopted the definition as per the [EFPIA Disclosure Code](#).

Exclusions:

- 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 practising HCPs, are excluded.
Example: an HCP working for a consultancy firm engaged by Otsuka Italy 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 and not a natural person, then the amount will be disclosed as a ToVs to an HCO.

1.3. MEDICINAL PRODUCTS

Otsuka Italy has adopted the definition as per the [EFPIA Disclosure Code](#), with the additional clarification:

- a. Medicinal Product will include products for which application for a marketing authorisation to the EMA or any National Competent Authority in Europe is made.
- b. 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 ToVs.
- c. Medical Devices are not included.
 - d. Combination products are included.

2. SOURCES OF DATA

Data will be captured through a number of platforms:

- a. OPTICS – the bespoke Otsuka Italy platform for reference data, document management and capturing ToVs.
- b. ERP system (SAP) where direct payments to HCP/HCO's are managed.
- c. Third Party systems – ad hoc payments made by intermediaries who cannot access OPTICS. These ToVs are captured via the OPTICS Template spreadsheet which has to be manually uploaded.
- d. Otsuka Italy utilizes a third party to consolidate all source data and prepare reports.

3. CROSS-BORDER ENGAGEMENTS

3.1. BACKGROUND

Otsuka group companies in scope for providing ToVs 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; and
- engage (provide ToVs to) HCPs resident or practicing in any of the European Member State (hereafter referred to as “**Otsuka Group Companies**”)

3.2. EXAMPLE

A cross-border situation exists when the ToVs 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 Italy, concludes an agreement with an HCP or HCO resident or practicing in Italy.

3.3. OUR APPROACH

Otsuka Italy 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 [EFPIA Disclosure Code](#).

Example (1): if Otsuka US engages an Italian HCP, Otsuka Italy will disclose ToVs made to the Italian HCP on behalf of Otsuka US.

4. PUBLICATION OF TOVS GRANTED IN A FOREIGN CURRENCY: CURRENCY ASPECTS

Otsuka Italy reports all ToVs in the base currency of the local office in the reporting country. Any

amounts where the ToVs has been in a foreign currency will be converted using the rate of the last day of the month when the ToVs has been conducted. 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 ToVs and Otsuka Italy expects the differences to be relatively insignificant.

5. TREATMENT OF VAT

On the most part, Otsuka Italy will publish the ToVs paid as net amounts, i.e. excluding VAT. Where ToVs are entered into OPTICS manually after any indirect spends, the amount may include VAT.

6. REPORTING OF TRANSFERS OF VALUE (TOVS)

- Direct ToVs will be disclosed in the ToVs period during which payment are invoiced irrespective of the contract date, contract duration or event date.

Example (1): for an event in December 2019, it is possible that part of the ToVs for that event are invoiced in 2019 and the remainder in 2020. Only invoices processed in 2020 are disclosed for the period 1 January - 31 December 2020. The ToVs related to the event and payment in December 2019, have been part of the 2019 ToVs disclosure in 2020 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.

In the event that ToVs disclosable for this Reporting Period are discovered subsequent to cut-off date for disclosure data or publication of the disclosure report, these ToVs shall be included in the next disclosure report for the Reporting Period of 1 January 2020 - 31 December 2020.

- Indirect ToVs will be disclosed with the date provided to Otsuka Italy by the intermediary. In the event that the payment date is not provided by the intermediary, then the event date is used.
- 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 Italy sponsors a Italian HCP/HCO to attend an event and the relevant HCP does not attend, a ToVs will not be disclosed for that HCP.
- Payment to charities on behalf of HCPs:
 - In the event that Otsuka Italy 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 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.

7. INDIRECT PAYMENT OF TOVS TO HEALTHCARE PROFESSIONALS

In the event that we become aware that ToVs 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 ToVs 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 ToVs and must demonstrate such to us.

8. EXPENSE CATEGORIES USED BY Otsuka Italy

EXPENSE CATEGORY	DESCRIPTION
HCO Medical Educational Grant & Donation	Donation and grant in money or kind (e.g. medical educational books and brochures, scholarship) to HCO. Refer to section 9 for further explanation.
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 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). Refer to section 11 for further explanation.
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 Italy sponsored study. Refer to section 10 for further explanation.

9. GRANTS AND DONATIONS

Definition: any ToVs 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 are included.

10. RESEARCH AND DEVELOPMENT (R&D)

Otsuka Italy has adopted the definition as per the [EFPIA Disclosure Code](#) with the additional clarification:

- a. Otsuka Italy will disclose under this category any ToVs 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. Otsuka Italy'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.

11. FEE FOR SERVICE TO HCOs

In addition to fee for services in relation to consultancy services, Otsuka Italy will disclose under this category any ToVs 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 HCOs.

12. COLLABORATION PARTNERS

The 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 an Otsuka Italy's 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.

13. CIVIL OR CRIMINAL ACTION OR ADMINISTRATIVE PROCEEDING

In the case of an HCP who received a ToVs 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.

14. DATA QUALITY

Otsuka Italy 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 Italy to HCP/HCO's located in Italy for the period of January 1 to December 31 2019.