



OTSUKA PHARMACEUTICAL (UK) LTD

ABPI DISCLOSURE:

UNITED KINGDOM

METHODOLOGY NOTE APPLICABLE TO TRANSFERS OF VALUE

FOR THE 2020 REPORTING YEAR

Preamble

In order to comply with the requirements of the ABPI Code of Practice, Otsuka Pharmaceutical (UK) agrees to document and publish details of any Transfer of Value (ToV) we may provide directly or indirectly to any healthcare professionals (HCPs) (including other relevant decision maker 'ORDM') or healthcare organisations (HCOs). The reporting period in each case will be the previous calendar year and we agree to submit the relevant report by March and publish the 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 Pharmaceutical (UK) intends to record and publish this information in accordance with the ABPI Code of Practice. In particular, Otsuka Pharmaceutical (UK) would like to outline the underlying methodology applied and to explain specific issues as to how Otsuka Pharmaceutical (UK) will apply this in publishing the relevant information. Otsuka Pharmaceutical (UK) will only refrain from publishing the details of those ToV where this is clearly not required under the ABPI Code of Practice.

Any questions relating to this Methodology Note and / or the report should be directed to:

disclosures@otsuka.co.uk

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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 Pharmaceutical (UK) 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 UK 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 an updated report and consent change will apply as well to any future engagements, as far as it is within Otsuka Pharmaceutical (UK)'s control to update the report.

3. DURATION OF PUBLICATION

Otsuka Pharmaceutical (UK)'s report will remain publicly available for a period of 3 years.

II. GENERAL QUESTIONS

1. DEFINITIONS

1.1. HEALTHCARE PROFESSIONAL (HCP)

Otsuka Pharmaceutical (UK) has adopted the definition as per the ABPI Code of Practice. In addition, Otsuka Pharmaceutical (UK) has to disclose ToV to 'other relevant decision maker' (ORDM) as defined in section 1.5 of the ABPI Code of Practice.

Otsuka Pharmaceutical (UK) report will be based and dependant on reference data stored in Otsuka Pharmaceutical (UK) systems and tools which are 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 Pharmaceutical (UK).

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

Example 2: a pharmacist working full time in a consultancy firm providing Otsuka Pharmaceutical (UK) with regulatory advice, ToV shall not be disclosable, unless section 1.5 of the ABPI Code of Practice applies.

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

1.2. HEALTHCARE ORGANISATION (HCO)

Otsuka Pharmaceutical (UK) has adopted the definition as per the ABPI Code of Practice.

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: a HCP working for a consultancy firm engaged by Otsuka Pharmaceutical (UK) 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 ToV to an HCO.

1.3. MEDICINAL PRODUCTS

Otsuka Pharmaceutical (UK) has adopted the definition as per the ABPI Code of Practice, 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 ToV.
- 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. Internal Otsuka Database – the bespoke Otsuka Pharmaceutical (UK) platform for reference data and document management.
- b. ERP system (SAP) where direct payments to HCP/HCO are managed.
- c. 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.
- d. Otsuka Pharmaceutical (UK) utilizes services of 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 ToV data for ABPI 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 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 UK, concludes an agreement with an HCP or HCO resident or practicing in UK.

3.3. OUR APPROACH

Otsuka Pharmaceutical (UK) will disclose all ToVs made to UK HCPs for engagements by any Otsuka Group Companies. In these cases, disclosure will be made in accordance with the ABPI Code of Practice.

Example (1): if Otsuka US engages a UK HCP, Otsuka Pharmaceutical (UK) will disclose ToV

made to the UK HCP on behalf of Otsuka US.

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

Otsuka Pharmaceutical (UK) 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 last day of the month when the ToV 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 ToV and Otsuka Pharmaceutical (UK) expects the differences to be relatively insignificant.

5. TREATMENT OF VAT

On the most part, Otsuka Pharmaceutical (UK) 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)

- Direct ToV will be disclosed in the ToV 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. Invoices processed in 2019 are disclosed for the period 1 January - 31 December 2019. The ToVs related to the event and payment in December 2019, have been part of the 2019 ToV 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 ToV disclosable for this Reporting Period are discovered subsequent to cut-off date for disclosure data or publication of the disclosure report, these ToV shall be included in the next disclosure report for the Reporting Period of 1 January 2021 - 31 December 2021.

- Indirect ToV will be disclosed with the date provided to Otsuka Pharmaceutical (UK) 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 Pharmaceutical (UK) sponsors a UK HCP/HCO to attend an event and the relevant HCP does not attend, a ToV will not be disclosed for that HCP.

- Payment to charities on behalf of HCPs:
 - In the event that Otsuka Pharmaceutical (UK) 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.

7. INDIRECT PAYMENT OF TOV TO HEALTHCARE PROFESSIONALS

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.

8. EXPENSE CATEGORIES USED BY Otsuka Pharmaceutical (UK)

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 Pharmaceutical (UK) sponsored study. Refer to section 10 for further explanation.
HCO Joint Working	Contribution to joint working with the National Health Service (NHS).

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 are included.

10. RESEARCH AND DEVELOPMENT (R&D)

Otsuka Pharmaceutical (UK) has adopted the definition as per the ABPI Code of Practice with the additional clarification:

- a. Otsuka Pharmaceutical (UK) 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. Otsuka Pharmaceutical (UK)'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 Pharmaceutical (UK) 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 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 Pharmaceutical (UK)'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 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.

14. DATA QUALITY

Otsuka Pharmaceutical (UK) 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 (UK) to HCP/HCOs located in the UK for the period of January 1 to December 31, 2020.