

OTSUKA PHARMACEUTICAL (UK) LTD

METHODOLOGY NOTE FOR THE 2016 REPORTING YEAR

Note: 2016 disclosure data has been collected and processed by Otsuka in alignment with the below methodological note.

With the incoming EU General Data Protection Regulation (“GDPR”), effective as of May 25th 2018, Otsuka has decided to publish reports in an aggregated manner in all applicable report sections, until consent, which is in full alignment with the requirements of GDPR has been collected. Otsuka is working on the collection of revised consents to allow the report to be republished individually, in line with the applicable consent granted.

Preamble

In order to comply with the requirements of the ABPI Code of Practice, Otsuka agrees to document and publish details of any Transfer of Value (ToV) 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 March of the following year (“Reporting Period”).

The aim of this Methodology Note is to provide a clear and simple explanation of how Otsuka intends to record and publish this information in accordance with the ABPI Code of Practice. In particular, Otsuka would like to outline the underlying methodology applied and to explain specific issues as to how Otsuka will apply this in publishing the relevant information. Otsuka 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

1.1.1 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

1.2.1 Otsuka 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.

1.2.2 The consents will:

- apply for all engagements of UK HCPs by any Otsuka Group Company (as defined in section II.3.1 below); and

- be unlimited in time unless and until revoked in writing by the HCP.

1.2.3 In the event that responses to consents have not been received from the HCPs, despite best efforts, ToVs will be reported in aggregate.

1.2.4 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 actual disclosure or after data has been processed for disclosure (generally thirty (30) days prior to a disclosure date), The revocation will only apply to future engagements. Consent for past periods cannot be retracted.

3. DURATION OF PUBLICATION

Otsuka's report is generally available for a period of 3 years.

II. GENERAL QUESTIONS

1. DEFINITIONS

1.1 HEALTHCARE PROFESSIONAL (HCP)

1.1.1 Otsuka has adopted the definition as per the ABPI Code of Practice. In addition, Otsuka has to disclose ToV to "other relevant decision makers" as defined in section 1.5 of the ABPI Code of Practice.

1.1.2 Otsuka report will be based and dependant on reference data stored in Otsuka 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.

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 with regulatory advice, TOV shall not be disclosable, unless section 1.5 of the ABPI Code of Practice applies.

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

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

1.2 HEALTHCARE ORGANISATION (HCO)

1.2.1 Otsuka has adopted the definition as per the ABPI 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 practising HCPs, are excluded.

Example: a HCP working for a consultancy firm engaged by Otsuka 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, generally the amount will be disclosed as a Transfers of Value to an HCO.

1.3 MEDICINAL PRODUCTS

1.3.1 Otsuka 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. Transfers of Value 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

2.1 Data will be captured through a number of platforms:

a. OPTICS – the bespoke Otsuka platform for reference data, document management and capturing ToV.

b. ERP system (Navision or SAP) where direct payments to HCP/HCO's (such as sponsorships) are managed.

c. Third Party systems –ad hoc payments made by intermediaries who cannot access OPTICS. These Transfers of Value are captured via the OPTICS Template spreadsheet which has to be manually uploaded.

3. CROSS-BORDER ENGAGEMENTS

3.1 BACKGROUND

3.1.1 Otsuka 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

- engage (provide transfers of value 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 granted 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 we, as an Italian-based subsidiary of the Otsuka Group Companies conclude a consultancy agreement with a doctor based in the UK.

3.3 OUR APPROACH

3.3.1 Otsuka 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.

3.3.2 Any ToV which Otsuka grants to healthcare professionals or organisations based in another European member state in our capacity as a UK subsidiary of the Otsuka Group Companies shall be published by our affiliated company based in that country.

Example: if Otsuka engages an Italian HCP, Otsuka Italy will disclose ToV made to the Italian HCP on behalf of Otsuka,

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

4.1 Otsuka report 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 average rate for the year. In many 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 expects the differences to be relatively insignificant.

4.2 EXAMPLE

A Swedish HCP has to be paid SEK 810 by Otsuka Germany; the invoice will state 900SEK and the GBP-SEK rate in Otsuka accounting platform is 9:1. The payment will be recorded in the Otsuka accounting system as GBP 90 and the clearing bank will deposit a payment of 810 SEK to the HCP account. The accounting discrepancy is written off as FX rounding.

5. TREATMENT OF VAT

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

6. REPORTING OF TRANSFERS OF VALUE (ToV)

6.1 OUR APPROACH

6.1.1 Direct ToV will be disclosed in 2017 for the 2016 ToV period during which the payments have been entered into the financial system, irrespective of the contract date, contract duration or event date.

Example (1): for an event in December 2015, it is possible that part of the ToVs for that event are invoiced in 2015 and the remainder in 2016. Only invoices processed in 2016 are disclosed for the period 1 January - 31 December 2016. The ToVs related to the event and payment in December 2015, have been part of the 2015 ToV disclosure in 2016 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. 6.1.2 Indirect ToV will be disclosed with the date provided to

Otsuka by the intermediary. In the event that the date is not provided by the intermediary, then the event date is used.

6.1.3 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.

6.1.4 participant attendance at sponsored events and “no-shows”:

- If Otsuka sponsors an HCP/HCO to attend an event and the relevant HCP does not attend, a transfer of value will not be disclosed for that HCP.

6.1.5 Payment to charities on behalf of HCPs:

- In the event that Otsuka 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 Transfers of Value 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

7.1 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

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

Expenses agreed with an HCO (e.g. booth hire, advertisement space, space for satellite symposia, contribution towards the cost of meetings- such as venue hire and speaker/chairperson fees).

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, train fare).

R&D related expenses

Expenses related to the planning and conduct of an Otsuka sponsored study. Refer to section 10 for further explanation.

HCO Joint working

Contribution to joint working with the National Health Service (NHS). Otsuka has no ToV related to HCO joint working.

9. GRANTS AND DONATIONS

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

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

10. RESEARCH AND DEVELOPMENT (R&D)

10.1 Otsuka has adopted the definition as per the ABPI Code of Practice, with the additional clarification:

a. Otsuka 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's support, direct or indirect, to medical publication in connection to R&D activities, will be disclosed under this category.

10.2 It should be noted that this will increase the total annual amount disclosed against this category.

11. FEE FOR SERVICE TO HCOs:

11.1 In addition to fee for services in relation to consultancy services, Otsuka will disclose under this category any ToV relating to retrospective non interventional studies sponsored by investigator (E.g. Investigator Sponsored Studies (ISS)).

11.2 It should be noted that this will increase the total annual amount disclosed against this category for certain HCOs.

12. COLLABORATION PARTNERS

12.1 The principle: each partner company will disclose Transfers of Value made by that entity to HCPs/HCOs, irrespective of reimbursement. However, each country has defined the process applicable to jointly sponsored events.

12.2 Any TOVs made by an Otsuka partner in respect of a product not licenced or commercialised in Europe will not be disclosed.

12.3 Exclusive Distributors of Otsuka Medicinal Products are responsible for disclosing Transfers of Value in accordance with their own compliance requirements

13. CIVIL OR CRIMINAL ACTION OR ADMINISTRATIVE PROCEEDING:

13.1 In the case of an HCP who received a Transfer of Value solely for services with respect to a civil or criminal action or an administrative proceeding, such Transfers of Value 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 is confident that the data included in the disclosure report is to the best of our knowledge complete and accurate account of the transfers of values made by or on behalf of Otsuka to HCP/HCO's located in the UK for the period of January 1, 2016 to December 31, 2016.

In the event that ToV 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 2017 - 31 December 2017.