



Methodological Notes – 2022

Accompanying document for the public disclosure
concerning transfers of value to healthcare
professionals and healthcare Organisations and Patient
Organisations

Takeda Hellas SA

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1. General introduction

Collaboration between the industry and patient Organisations and the Healthcare Professionals is beneficial to patients. These relationships have delivered numerous innovative medicines and changed the way many diseases affect our lives. Greater transparency in these important, already well-regulated relationships, should help to create a stable foundation for future collaboration. Society has ever-increasing expectations regarding transparency, especially in healthcare sector. As a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), we aim to ensure that we meet these expectations in the future.

This methodological note is intended for all those who wish to better understand the working assumptions within Takeda used for the creation of the disclosure report of transfers of value of Takeda Hellas and the manner under which the disclosed transfers of value to patient organizations are defined.

Each transfer of value made in 2022 with an identifiable recipient will be disclosed in June 2023, such as donations and grants, contributions to costs related to remote events, fee for services. The registration fee for an event, live and/or recorded, is a transfer of value and will be disclosed.

2. Scope of disclosure

We have summarized below our interpretation and working assumptions along with a definition of recipients and expenses that are in scope.

2.1. Recipients within the scope of disclosure

We introduced an internal process to guarantee that transfers of value are assigned to the correct HCP or HCO or PO, and to ensure that the disclosed information is correct and complete (e.g., name, address, unique official ID (if necessary), country where the principal practice is located).

2.1.1. Healthcare professionals (HCPs):

In the disclosure report, Takeda has taken into account the following definition of HCPs with whom we can have Transfers of Value as per the SFEE Code of Practice, for example the following types of healthcare professionals with whom we may have Transfers of Value (members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine). The addresses of the HCPs that are taken into account in the disclosure report are related to the HCPs' primary place of work.

2.1.2. Healthcare Organisations (HCOs):

In the disclosure report, Takeda has taken into account the following definition of HCOs with whom we may have Transfers of Value as per the SFEE Code of Practice (Associations, Hospital Organization, Hospital Department, Educational Care Center, Clinic, Dental Clinic, Clinic, Institution, School, University, Academic School, Organization, Group / Network of Pharmacies, Healthcare Institution). The addresses of the HCOs that are taken into account are the public addresses of the HCOs.

2.1.3 Patient Organisations (PO's):

Is a non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

2.1.4 Patient Organisation representative

Is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area

2.1.5 Companies owned by an HCP:

If a healthcare organization consists of only one healthcare professional or other relevant decision maker, then it would be subject to the requirements in the code regarding the disclosure on the individual healthcare professional name.

2.1.6. Third Party and PCO

Third parties are entities or individuals that represent our company in the marketplace or interact with other third parties on behalf of our company or relating to our company's product. Among others, these thirds parties can be distributors, travel agents, consultants, contract research organisations.

PCO is a company/individual specialized in the organisation and management of congresses, conferences, seminars, and similar events (all "Events")

2.2. Medical scope

The report covers only prescription medicines and not over-the-counter products.

2.3. Activities definition within the scope of disclosure

The definitions of activities can differ from one company to the next. All our interactions with healthcare professionals, healthcare organizations and patient organizations are governed by internal policies and standard operating procedures which have been created in accordance with the industry codes and guidelines, local country-specific laws and principles, and local industry requirements. Below you will find our corporate definitions which should help you with the readability of the disclosure report.

2.3.1. Donations and grants

We provide funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return. All transfers of value related to donations or grants to a HCO or a PO are included within the scope of the disclosure. Such transfers of value include:

- i. Donations (cash and benefits in kind)
- ii. Charitable donations (if the organization is classified in the country as an HCO or PO)
- iii. Grants as follows:
 - o Medical training (e.g. support in the training of HCPs):

- monetary nature (e.g., IISR, defined as unsolicited, independent research, irrespective of whether the investigator or the organization (academic, private, or state) acts as sponsor, where Takeda provides support in the form of the study medication and/or financing)
- non-monetary nature (e.g., benefits in kind such as anatomic models)
- Non-medical educational training (e.g. support for healthcare institutions to improve their infrastructure)

2.3.2. Contribution to events costs

We may provide support or cover the costs of the attendance of an individual HCP or PO representative to an Event. We consider any transfer of value made directly or indirectly through a third party to a HCO or PO as the scope of the disclosure. Such transfers of value include for example:

- i. Travel expenses (*flights, rail travel, taxi, rental car, tolls, mileage*)
- ii. Accommodation expenses
- iii. Registration fees (*fees paid to permit HCPs to attend medical congresses/training events organized by a third party and not organized by Takeda*)
- iv. A sponsorship agreement with a HCO, PO or a third party nominated by the HCO or PO for managing an event, such as scientific conferences, congresses, or exhibitions by third parties: *sponsorships by medical associations, national industry Organisations, hospitals, and educational establishments; scientific Organisations; regional, national, international, and global conferences; local hospitals, medical centres.*
- v. Examples of activities that may be listed in the disclosure report under "Sponsorship Agreements:" *booth rental, advertising spaces (digital, paper, etc.), satellite symposia at a scientific congress, scientific courses provided by an HCP, HCO, or PO opportunities to present our products (including non-promotional presentations), event sponsorships (e.g., organizational support)*

meals are excluded of our reports

This instruction applies also to PCOs as third parties organising events involving HCO's, HCP's or PO's

2.3.3. Cancellation of an event

If an HCP had to cancel the sponsored attendance of a third-party event, this will not be included in our report. This also applies to any cancellation fees.

2.3.4. Service and consultancy fees

Any transfer of value related to service and consultancy fees between our company and an HCP, HCO or PO are included within the scope of the disclosure. Such transfers of value include for example, a meeting or event (promotional or non-promotional) where the HCP, or the HCP working for an HCO, appears as a speaker, trainer, or consultant. These include, among others:

- vi. Consultancy Fees (*fees for services such as preparation time, rehearsal time, travel time, and time expended on the activity*)
- vii. Related costs (*e.g., travel expenses, accommodation*)

Examples of fees that may be included in the disclosure report under "Service and consultancy fees (HCPs, HCOs, POs):" *speaker fees for workshops and symposia; ad hoc consultancy/advisory agreements; training facility for speaker training programs or for training Takeda employees or external parties; training facility for advisory board meetings; market research participants (except double-blind studies); medical writing;*

data analysis; development of training materials; consulting (e.g., protocol advice, market access, reimbursement, leading-edge technology assessment)

2.3.5. Research and development

Transfers of value related to research and development (R&D) activities are covered by the scope of the disclosure. This includes transfers of value to HCPs or HCOs for planning or conducting:

- i. non-clinical studies for submission of data to regulatory authorities (as defined in the OECD Principles of Good Laboratory Practice).
- ii. clinical trials (as defined in European Directive 2001/20/EC).
 - a. Clinical trials in humans with an unauthorized medicinal product
 - b. Clinical trials in humans where an unauthorized medicinal product is used in an unauthorized indication or is otherwise prescribed beyond the scope of the marketing authorization, or where patients are previously assigned to different treatments, or where the protocol proposes diagnostic or monitoring procedures that would not have been performed if the patient had not taken part in the trial.
 - c. Other clinical trials in humans that would necessitate marketing authorization from the regulatory authorities if they were to be conducted in accordance with EU Directive 2001/20/EC.
- iii. a prospective non-interventional study in which the patient is treated with an approved medicinal product in accordance with the marketing authorization and standard practice, and the other requirements as set out in section 15.01 of the EFPIA HCP Code.
- iv. Other activities:
 - d. Activities related to the planning of the inclusion criteria, the design or the timing of non-clinical studies, clinical studies and/or prospective non-interventional studies within the framework of the drug development plan.
 - e. Activities related to the planning of certain non-clinical studies, clinical studies, or prospective non-interventional studies.
 - f. Activities related to conducting certain non-clinical studies, clinical studies, or prospective non-interventional studies.

Examples of activities that may be included in the disclosure report under "R&D value transfers:"

- a. *clinical trials: regional and/or global,*
- b. *local non-interventional trials.*
- c. value transfers made indirectly through clinical research Organisations (CROs)

Transfers of value with respect to R&D are reported as a gross sum, except for value transfers associated with retrospective non-interventional studies which must comply with the provisions of Article 15 of the EFPIA HCP Code and are listed under the name of the respective recipient.

2.4. Activities out of scope

Transfers of value that:

- i. samples of medicinal products to HCPs
- ii. objects intended for HCPs, information and training materials of moderate value which are intended exclusively for the medical or pharmaceutical activity, or used for advanced,

- or further medical, or pharmaceutical training and which in both cases are also of benefit to patients.
- iii. payment for meals (including beverages) on a reasonable and modest scale, subject to a maximum of 70€ per HCP per meal

2.5. Cross-border value transfer

The EFPIA definition of cross-border payments as being a transfer of value to a HCO, HCPs or Patient Organisation that is registered outside the country where the Takeda affiliate, who has provided the funding is based, unless local law specifies otherwise.

For example, if a HCP is engaged as a consultant by a foreign legal entity of Takeda this will generally be disclosed – consent for disclosure is needed, where applicable - the payment on the country report where the HCP's principal practice address is registered.

3. Disclosure and Consent to disclose

The obligation of the pharmaceutical companies to post on their websites the names of the HCP / HCO and their respective legal entities (medical associations), to whom they provide any kind of transfers of value, as well as the amount of these transfers, which is entered under article 66 par. 7 of Law 4316/2014 and is interpreted with the opinions No. 5/2016 and 2/2017 of the Personal Data Protection Authority, serves the public interest in transparency in the field of Health according to article 21 par. 3 of the Constitution.

Given the above, the transfers of value of TAKEDA HELLAS SA are made public by name for the period from 01/01/2022 - 31/12/2022 to Healthcare Institutions (HCO) and Patient Organizations (PO), as well as to Health Professionals (HCP), who have given (regardless of any restrictions and exceptions provided in No. 5 / 2016 opinion of the Personal Data Protection Authority), and have not revoked their relevant consent, or for whom the relevant consent is not required. In any other case, the disclosure of the transfers of value to the HCP for the respective period of time is done in an aggregate way, in compliance also with Article 3.02 of the Disclosure Code of EFPIA.

This obligation strengthens the professional prestige of doctors and ensures their credibility in public opinion.

This obligation also ensures the individual right of information of patients for free choice of doctor and hospital in accordance with the provisions of article 5 par. 5 of the Constitution.

The consent of the HCP, which does not fall under any restrictions and exceptions provided in opinion No. 5/2016 of the Personal Data Protection Authority, is not required in order for a company to make public the benefits in question.

DISCLAIMER NOTICE

It is pointed out that the N.O.M. publishes at its own risk the data of HCPs based on the reports submitted by the pharmaceutical companies, while the pharmaceutical companies publish on their websites the data of HCPs based on their respective methodological note. Therefore, Takeda does not bear and in any case disclaims any responsibility for the disclosure of HCP data on the relevant publication platform of the NOM website, for which the NOM is solely responsible.

The disclosure of transfer of value to Patient Organisation will not require the individual consent.

4. Assumptions

4.1. Date of value transfer

After the service is provided and the contract is concluded, the payment is made, as specifically stated in the above chapter 3, and depending of the consent this amount will be disclosed in the individual or in the aggregate section of the report.

The provision of the commissioned service is monitored so that payments can be made in accordance with the terms of the contract. In our country, we use the date on which the payment is made as acknowledgement of the transfer of value.

By date of payment, we mean the date on which the payment is released in our internal system. This is subject to the provision of the service and compliance with the EFPIA Code and the internal approval mechanisms of Takeda Pharma AG and Takeda Pharmaceuticals International AG.

We thereby apply the following rule:

If the payment date was between January 1 and December 31, 2022, the transfer is included in our 2022 disclosure report. Also, if any payment, for an activity made in 2021 due to Takeda's internal systems, or / and for other reasons, finalized in 2022, this transfer of value will be included in our disclosure report for 2022.

Or for Entities using event date:

In our country, we will use, based upon local industry code guidance, the date of service provision as basis for the recognition of the respective Transfer of Value.

By the “date of service” we mean the date when the service was effectively rendered and delivered, which means, for example, that when a HCP participated in a Congress, then the date when the Congress effectively took place will be the date used for collecting all associated Transfers of Value (e.g. travel cost), and the relevant information and data will be disclosed accordingly, even if some reimbursements will actually take place at a later stage.

Regarding the cut-off rule we have established that the following shall apply:

If the date of service provision has taken place between January 1st and December 31st of the year 2022, the respective Transfer of Value transaction will be in scope for our 2022 disclosure report.

4.2. Currency

We have decided that EURO shall be the currency used in the disclosure report as this is the official local currency at the time of disclosure. If value is transferred in a currency other than the official local currency, the amount will be converted using the monthly updated exchange rates of the Takeda Company Treasury.

Value is transferred in a foreign currency, for example, if travel expenses are incurred by an HCP abroad, where the services have been rendered, and we reimburse these expenses.

4.3. Taxes

Any amounts paid are subject to tax. The sums stated in our report are amounts before taxes.

4.3.1. Value-Added Tax (VAT)

Expenses such as for travel and accommodation are subject to VAT. The documented and disclosed figures do not include VAT.

Expenses, such as renting a kiosk, advertising space (electronic, printed, etc.), satellite symposia at a scientific conference, are subject to VAT. The data published do not include VAT.

4.4. Third Party ToV Report

Takeda Hellas SA used the services of a Third-Party Sales Organization (ELPEN Pharmaceutical) for certain promotional activities in Greece. Takeda's obligations under the EFPIA Disclosure Code would be met by that Sales Organization, as contractually agreed.

5. Conflict management

Takeda has introduced an internal conflict management process with which to handle, for example, any general questions and inconsistencies relating to the published data and/or requests for addition or removal of the consent under data protection law of an HCP/HCO with a view to disclosure of data.

If you have any comments or questions concerning the processing of your data by Takeda, these methodological notes, the content of the disclosure, or the privacy policy of Takeda Hellas SA please get in touch with the Takeda Transparency team at Cco.smbx.gr-TransparencyGreece@takeda.com or the relevant contact named on the Takeda Hellas SA website: Note: Lydia Kappelletti - Postal Address: Ag. Konstantinou 59-61, 151 24 Maroussi, Athens, Greece, e-mail: lydia.kappelletti@takeda.com, Fax Number: +30 210-6387801