



Methodological Note - 2020

Accompanying document for the public disclosure of
Transfers of Value to Healthcare Professionals and
HealthCare Organisations

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Methodological Note 2020

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1. General Introduction

Collaboration between industry and healthcare professionals' benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives. Industry and healthcare professionals collaborate in a range of activities from clinical research, sharing best clinical practice and exchanging information on how new medicines fit in to the patient pathway. Bringing greater transparency to this, already well-regulated, vital relationship is about building and strengthening the basis for collaboration in the future. Society has increasingly high expectations for transparency, none more so than in healthcare. Takeda, as a member of the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), wants to ensure we meet those expectations going forward.

This methodological note is intended for anyone who wants to better understand the working assumptions used to generate a Takeda Hellas disclosure report and how the disclosed activities are defined within Takeda. Please note that although Shire Pharmaceuticals are now part of Takeda, disclosure reports will continue to be generated and published separately until the company has become one legal entity.

2. Scope of the Disclosure

Takeda made several decisions around reportable Transfers of Value under EFPIA requirements (<http://transparency.efpia.eu/the-efpia-code-2>), article 66 (paragraph 7) of Law 4316/2014, of the Code of Ethics of SFEE (<https://www.sfee.gr/disclosure-code>), the Opinions No. 5/2016 and 2/2017 of the Personal Data Protection Authority, as well as the relevant Announcements of the National Organization for Medicines. We have summarized below our interpretation and working assumptions along with a definition of recipients and expenses that are in scope.

2.1. Recipient scope

2.1.1. Healthcare Professionals (HCP): Definition and scope

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 (HCO): Definition and scope

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. Company owned by an HCP

If the company (HCO) is owned by an HCP, the transfer of value is disclosed as a transfer to HCO.

2.1.4. Clearly identified recipient

Takeda implements an internal procedure to ensure that transfers of value are distributed to the correct HCP or HCO, and to ensure that the information disclosed is accurate and complete (e.g. name, address, principal place of business).

2.2. Medicinal scope

The report refers solely to prescription only medicine

2.3. Activities scope

Definitions of activities may differ between companies. Within Takeda, all our interactions with HCPs are guided by TAKEDA internal Policies and Standard Operating Procedures that have been developed in alignment with local country laws and regulations and local industry requirements. Please see below for Takeda Company definitions.

2.3.1. Donations and grants to HCO

All transfers of value regarding a donation or a grant between Takeda and an HCO are included in the scope of the disclosure. The transfers of value could be for instance:

- i. Donations (monetary and non-monetary)
- ii. Charitable contributions (if the organisation is classified as an HCO in the country)
- iii. Grants, as follows:
 - Medical educational grants (e.g. support of the education of HCPs): Monetary (e.g. IISRs, identified as unsolicited, independent research if the researcher or institution (academic, private or public) acts as a sponsor and Takeda provides support in the form of a drug study and / or funding), and non-monetary (i.e. in-kind; e.g. anatomical models)
 - Non-Medical educational grants (e.g. support for healthcare institutions in improving infrastructure)

2.3.2. Contribution to costs of event

All the transfers of value regarding a contribution to costs of an event between Takeda and an HCP (directly, or indirectly via a third party) or an HCO are included in the scope of the disclosure. These transfers of value could be for instance:

- i. A travel fee (*e.g. flight, train, taxi, mileage reimbursement, tolls*)
- ii. An accommodation fee
- iii. A registration fee (*Fees paid for an HCP or an HCO, to allow HCPs to attend medical/educational events not organized by Takeda.*)
- iv. A sponsorship agreement with an HCO or a third party appointed by an HCO to manage an event, for instance: *Sponsorships via Medical Societies; National Industry Organizations; Hospitals and Teaching Institutions; Scientific Organizations; Regional, National, International and Global Conferences; Local Hospitals; Medical Centres.*

Invoicing to Takeda Hellas SA (as a sponsor) of all services for scientific events and the collection of sponsorship contracts was carried out by the Conference Organizing Companies designated by the HCO (as scientific organizing entities).

Where an HCP, whose participation in a third-party meeting was subsidized, had to cancel his / her participation, this is not included in our report.

Examples of activities that could be included in the "Sponsorship Contracts" section of the Takeda Disclosure Report: Kiosk rental, advertising space (electronic, printed, etc.) satellite symposia in a scientific congress, scientific seminars from an HCO, promotion of our products (including non-promotional), one-day sponsorships (e.g. event support).

2.3.3. Fees for Services and Consultancy

All the transfers of value regarding a fee for services and consultancy between Takeda and an HCP or an HCO are included in the scope of the disclosure. These ToVs concerns, for instance, a meeting or event, where the HCP or the HCP working for an HCO, is a speaker, a trainer, an advisor, etc., could be:

- i. Fees (e.g. fee for services such as preparation time, rehearsal time, reasonable travel time and time required for the activity, etc.)
- ii. Related expenses to consultancy (e.g. travel cost, accommodation fees, etc.)

Note that any expenses incurred for an event which is later cancelled have been disclosed.

Examples of fees that could be covered under "*Fee for Services & Consultancy (HCPs and HCOs)*" in the Takeda disclosure report: *speaker fees for speaker programmes and roundtables; ad hoc consulting/advising arrangements; faculty for speaker training programmes or training of Takeda employees or external parties; faculty for advisory board meetings; medical writing; data analysis; development of educational materials; consultancy (e.g. advice relating to; clinical protocol, market access, reimbursement, health technology assessment, etc.)*

2.3.4. Research & Development

Transfers of value related to a Research and Development (R&D) activity are included in the scope of the disclosure. These transfers of value include transfers of value to HCPs or HCOs related to the planning or conduct of:

- i. Non-clinical studies intended for submission to regulatory authorities (as defined in OECD Principles on Good Laboratory Practice)
- ii. Clinical trials (as defined in the European Directive 2001/20/EC)
 - a. Any clinical trial in humans using an unapproved medicinal product.
 - b. Any clinical trial in humans using an approved medicinal product where it will be used for an unapproved indication or otherwise it will be prescribed outside the terms of its marketing authorisation, or where patients are prospectively assigned to different treatments, or where the protocol requires diagnostic or monitoring procedures which would not have been performed if the patient was not in the trial;
 - c. Any other clinical trial in humans for which clinical trial approval from the regulatory authorities would be needed if the trial were to be conducted in the EU in line with EC Directive 2001/20.
- iii. A prospective observational study where the patient is prescribed and treated with an approved medicinal product in accordance with the marketing authorisation and current practice and with the other requirements set out in section 15.01 of the EFPIA HCP Code.
- iv. Other type of activity:

- d. Activities associated with planning the inclusion, design or timing of non-clinical studies, clinical trials and/or prospective observational studies within the context of a development plan for a medicine
- e. Activities associated with planning of particular non-clinical studies, clinical trials or prospective observational studies.
- f. Activities associated with conduct of particular non-clinical studies, clinical trials or prospective observational studies.

Examples of activities that could be covered under “*R&D transfers of value*” in the Takeda disclosure report: *Clinical trials: regional and/or global, local non-interventional studies.*

The transfers of value realized indirectly via a Clinical Research Organisation (CRO) are also included in the R&D section of the disclosure report.

Transfers of value related to R&D are reported as an aggregate total figure, with the exception of transfers of value related to retrospective non-interventional studies, which shall comply with the provisions of Article 15 of the EFPIA HCP Code, which are disclosed under the name of the individual recipient.

2.4. Transfers of value in Cross border interactions

Transfers of value for cross border activities are a part of our disclosure report. The cross-border activities are disclosed in the country of the HCP recipient’s primary practice address.

For example, if a Greek HCP consultant enters into a contract with a foreign legal entity of Takeda, Takeda will disclose the relevant transfer(s) of value in the Greek disclosure report, according to the primary practice address of the HCP.

3. Data Privacy

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 01/01/2020 - 31/12/2020 to Healthcare Institutions (HCO), 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 a centralized way, in compliance 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 HCP 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.

4. Working Assumptions

4.1. Date of Transfers of Value

Within Takeda, any activity with HCO and HCP is subject to a strict need assessment and internal approval process. Upon approval, Takeda enters into a contract, which covers the Provision and request for information and / or consent for Disclosure, where required. The execution of the services is monitored, so that the payments are made in accordance with the contractual terms and conditions.

In our country, we consider the date of payment as recognition of the transfer of value.

By payment day, we mean the date on which payment is released within our internal system, subject to the provision of the service and compliance with EFPIA guidelines and Takeda internal approval mechanisms.

As a final limit we apply the following:

If the payment date took place between **1 January and 31 December 2020**, the transfer of value falls within the scope of our **2020** disclosure report. Also, if any payment, for an activity made in 2019 due to Takeda's internal systems, or / and for other reasons, finalized in 2020, this transfer of value will be included in our disclosure report for 2020.

For any payment, which takes place at the beginning of **2021** for an activity that took place at the end of **2020**, we will take into account this transfer of value for our publication of **2021 in June 2022**.

4.2. Currency

Takeda Hellas has used EURO for the disclosure report, as - at the time of disclosure - is the official currency of the country. In the case of a ToVs being made in another currency, the amount has been converted using Takeda Company Treasury exchange rates that are updated monthly.

An example of a ToVs being made in a foreign currency might be where the HCP incurred travel costs in another country where he/she has delivered the service which Takeda reimbursed.

4.3. Taxes

Remuneration paid is subject to taxation. Our disclosure report mentions "net" amounts.

4.3.1 Value-Added Tax (VAT)

Expenses, such as travel or accommodation expenses are subject to VAT. The data published 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 ToVs Report

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

5. Dispute Resolution Management

Takeda has implemented an internal process for Dispute Resolution Management for the tracking and resolution of general questions and disagreements with the data that has been reported, and/or requests to add or remove HCP/HCO privacy consent to disclose data.

In case you have any comments or questions regarding the processing of your data by Takeda, this Methodological Note, the content of the disclosure, or the Takeda Privacy Policy, please contact Takeda Hellas SA. :

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