



Methodological Note - 2015

Accompanying document for the public Transparency
of Transfer of Value to Healthcare Professionals and
HealthCare Organizations

Takeda Pharma Vertrieb GmbH & Co. KG

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1. General Introduction

The collaboration between industry and health professionals benefits patients. It is a relationship that has delivered numerous innovative medicines and has changed the way many diseases impact on our lives. Industry and health professionals collaborate in a wide range of activities, starting from clinical research and sharing best clinical practice up to the exchange of information on how new medicines fit into the patient pathway. Bringing greater transparency to this already strongly-regulated, vital relationship is about creating and strengthening the basis for collaboration in the future. Society has increasingly high expectations in terms of transparency, and this is even more important when it comes to the field of healthcare. Takeda, as a member of the European Federation of Pharmaceutical Industries Associations (“EFPIA”), wants to ensure that we meet these expectations going forward.

This methodological note is aimed at anyone who wants to better understand the working assumptions used for generating the disclosure report of Takeda Pharma and how the various activities disclosed are defined within Takeda.

2. Scope of Disclosure

In order to correctly define what is to be regarded as a reportable Transfer of Value (ToV) operation according to the applicable EFPIA guidelines (<http://transparency.efpia.eu/the-efpia-code-2>) and to the requirements of the industrial associations relevant for the company Takeda in the Federal Republic of Germany, i. e. the Code of Transparency of the Association of Voluntary Self-Control of the Pharmaceutical Industry (Verein Freiwillige Selbstkontrolle für die Arzneimittelindustrie – FSA) for the interaction with Healthcare Professionals and Healthcare Organizations (“FSA Transparency Code”) (www.fsa-pharma.de) and the German Association of Research-Based Pharmaceutical Companies (Verband forschender Arzneimittelunternehmen, VfA) (www.vfa.de), various internal interpretations were required.

We have summarized below our interpretations and working assumptions which we consistently applied while gathering data, what the term “covered recipients” means for us and what exactly are the recipients, activities and expenses that are covered within the scope according to our definitions.

2.1 Recipient Scope

2.1.1 Healthcare Professionals (HCP): Definition and Scope

In their disclosure report, the company Takeda has taken into consideration the definitions established in line with the FSA code with regard to those healthcare professionals with whom our company may conduct Transfer of Value transactions. In this context, the category of healthcare professionals includes any full-time physicians and pharmacists located in Europe, as well as any healthcare professionals from the medical, dental and pharmaceutical field or from any other kind of healthcare-related sectors, and any other kind of individuals who, within the framework of their professional activities, are entitled to prescribe or administer any medicinal products for human use or to trade in this kind of pharmaceutical products. This category also covers and comprises, for example, any employees of public institutions, health insurance companies and other kinds of cost units that are responsible for or in charge of prescribing, purchasing, supplying or administering any medicinal products or who are entitled to decide on the reimbursability of such products. The address of publication of the HCPs that are taken into account in the disclosure report will be the primary practice address of the respective HCP.

2.1.2 Healthcare Organizations (HCO): Definition and Scope

In their disclosure report, the company Takeda has taken into consideration the definitions established in line with the FSA code with regard to those healthcare organizations with whom our company may

conduct Transfer of Value transactions. Any kind of medical or scientific institutions or associations located in Europe and consisting of healthcare professionals are to be considered healthcare organizations, regardless of their respective legal structure; such organizations include the following: *associations, hospital federations, hospital departments, care education centers, clinics, dental clinics, dispensaries, institutions, faculties, universities, academic schools, foundations, pools or groupings of pharmacies, healthcare institutions*). The address of publication of the HCOs that are taken into account in the disclosure report will be the public address of the respective HCO.

2.1.3 Companies Owned by a Healthcare Professional

In case a Transfer of Value made in favor of a company (HCO) can be indirectly assigned to a HCP, that Transfer of Value is reported and disclosed by assigning or allocating this ToV to that individual HCP. If, however, the company is owned by more than one HCP, the Transfer of Value is reported and disclosed as a Transfer of Value made in favour an HCO.

2.1.4 Clearly Identifiable Recipient

Takeda has put in place an internal process in order to ensure that Transfers of Value are allocated to the proper HCP or HCO, and to make sure that the disclosed information is accurate and complete (e.g. name, address, country of primary practice).

2.2 Medicinal Scope

This report includes and takes into consideration any kind of interactions with HCPs and HCOs, irrespective of whether the collaboration relates to any prescription drugs or to over-the-counter (non-prescription) products.

2.3 Scope regarding Transfer of Value activities

The definitions of the activities concerned may vary amongst companies. Within the Takeda group, all our interactions with healthcare professionals (HCPs) are regulated by internal policies and Standard Operating Procedures (SOPs) that have been developed in alignment with industry codes and guidelines and which are in line with local country laws and regulations as well as with local industry requirements. Please find below with our company definitions to make it easier for you to read and understand our disclosure report.

2.3.1 Grants and Donations to Healthcare Organizations (HCO)

Any kind of Transfers of Value regarding a donation or a grant between Takeda and a HCO are included in the scope of the disclosure. These Transfers of Value could be, for instance, the following:

- i. Donations (monetary);
- ii. Charitable contributions (if the organization is classified as HCO in the corresponding country);
- iii. Medical educational grants or contributions (e.g. for supporting the education of HCPs): Such grants could be monetary in nature, e.g. IISRs, defined as unsolicited, independent research where the investigator or the institution (academic, private or governmental) serves as the sponsor and Takeda provides support in the form of study drugs and /or by funding).

2.3.2 Contributions to Costs of Events

Any kind of Transfers of Value in connection with a contribution to costs of events between Takeda and a HCP (directly or indirectly via a third party) or a HCO are included in the scope of the disclosure. Such Transfers of Value (for example those granted in connection with the participation in any congresses, conferences, symposia etc. which have a medical and scientific emphasis and which serve as educational event for HCPs) could be, for instance, the following:

- i. Travel expenses (*expenses for flight tickets/railway tickets, use of private car, taxi use, use of rental cars, parking fees*);
- ii. Accommodation costs;
- iii. Registration fees (*fees paid for a HCP or a HCO in order to allow them or their employees to attend any medical/educational events that are not organized by Takeda*);
- iv. Sponsorship agreements with a HCO or a third party appointed by a HCO to manage and organize an event, for instance third party scientific conferences, congresses or exhibits: *sponsorships via medical societies; national industry organizations; hospitals and teaching institutions; scientific organizations; regional, national, international and global conferences; local hospitals; medical centres.*

In case a scientific event is organized by any event planning agency and the non-cash grant is made to this agency – with this respective event having a clearly recognizable reference to a HCO - then the disclosure will be made by mentioning the event planning agency involved, including a corresponding declaration incorporated in this Methodological Note as to the purpose of use of that Transfer of Value. This declaration can be found in the “List of further supplements to the Methodological Notes – Healthcare Organizations” linked on the webpage.

Whenever a HCP who is sponsored in order to attend a third party meeting had to cancel his/her participation, this information as well as any information on any cancellation fees incurred will not be included in our report.

Examples of activities that may be covered in the Takeda disclosure report under the category of “Sponsorship Agreement” may be the following: *rental of booth, rental of advertisement space (electronic, paper, etc.), participation in satellite symposia at a scientific congress, scientific courses provided by a HCO, opportunities to promote our products.*

2.3.3 Fees for Services and Consultancy

Any Transfers of Value transactions in connection with fees for services and consultancy between Takeda and a HCP or a HCO are included in the scope of the disclosure. These Transfers of Value concern, for instance, any meetings or events (promotional or non-promotional in nature) where the corresponding HCP or the HCP working for an HCO acts in the capacity of a speaker, trainer or advisor, and such Transfers of Value could be the following:

- i. Fees (fees for any services such as preparation time, rehearsal time, travel time and time required for the activity itself);
- ii. Any expenses related to consultancy services (e.g. travel and accommodation costs).

Examples of fees that could be covered under the category of “Fees for Services & Consultancy (HCPs and HCOs)” in the Takeda disclosure report may be the following: *speaker fees for speaker programs and roundtables; ad-hoc consulting/advising arrangements; faculty for speaker training programs or training of Takeda employees or external parties; faculty for advisory board meetings; study participant for market*

research (only if no double-blinded research); medical writing; data analysis; development of educational material; market survey (only if not double-blinded survey); consultancy services (e.g. protocol-related advice, market access, indemnity payments).

2.3.4 Research & Development

Any 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 any Transfers of Value made to HCPs or HCOs in connection with the planning or conduct of:

- iii. Any non-clinical trials intended to be submitted to regulatory authorities (as defined in the OECD principles on Good Laboratory Practice);
- iv. Any clinical trials (as defined in the European Directive 2001/20/EC), namely
 - a. Any clinical trials in humans using an unapproved medicinal product;
 - b. Any clinical trials 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 authorization, or where patients are prospectively assigned to different treatments, or where the protocol requires any diagnostic or monitoring procedures which would not have been performed if the patient had not been included in the respective clinical trial;
 - c. Any other type of clinical trials in humans for which a clinical trial approval from the regulatory authorities would be needed if the trial were to be conducted in the EU in line with the EU Directive 2001/20/EC;
- v. Any prospective observational studies where the patient has received a prescription for an approved medicinal product and is treated with that medicinal product in accordance with the marketing authorization and the current practice as well as in accordance with the other requirements set out in section 15.01 of the EFPIA HCP Code;
- vi. Any other kinds of activities such as:
 - a. Any activities associated with the planning of patient recruitment and inclusion, of the design or timing of non-clinical studies, clinical trials and/or prospective observational studies within the context of a development plan for a particular medicinal product;
 - b. Any activities associated with the planning of non-clinical studies, clinical trials or prospective observational studies;
 - c. Any activities associated with the conduct of particular non-clinical studies, clinical trials or prospective observational studies.

Examples of activities that could be covered under the category “R&D Transfers of Value” in the Takeda disclosure report include the following: *clinical trials: regional and/or global, local non-interventional studies.*

The Transfers of Value made indirectly via a Clinical Research Organization (CRO) are also included in the R&D section of the disclosure report. Any payments made to CROs for CRO-specific services are not part of the disclosure report and will not be disclosed unless:

- i. the respective CRO is composed of HCPs or is associated with any medical institution (such as university hospitals or state-owned institutions). In this case, that CRO is considered an

- organization with any Transfer of Value operations being disclosed by us on an individualized basis in accordance with the general rules;
- ii. the respective CRO makes indirect Transfers of Value to HCPs (so-called “pass-through costs”). In this case, we will disclose such non-cash grants in an individualized way, specifying the corresponding HCP.

Any Transfers of Value related to R&D activities are reported as an aggregate total figure, with the exception of transfer of values related to retrospective, non-interventional studies, which shall comply with the provisions of Article 15 of the EFPIA HCP Code, which are disclosed by naming the individual recipient.

2.4 Transfer of Value in Cross-Border Interactions

Any Transfers of Value made in connection with cross-border interactions and activities are part of our disclosure report. The cross-border activities concerned are disclosed in the country of the HCP recipient’s primary practice address.

So if, for instance, a German HCP acting in the capacity of a consultant is contracted by a foreign Takeda legal entity, Takeda will disclose the associated Transfer(s) of Value in the disclosure report for Germany, in line with the respective HCP’s primary practice address.

3. Private Consent to Disclosure and Aggregate Amount

The HCP-related individual disclosure of the Transfers of Value provided to an HCP is covered and governed by local privacy regulations.

In Germany, the respective HCP should provide his/her privacy consent to allow the publication of the received Transfer of Value at an individual level. If such individual privacy consent is not provided, Takeda will publish the relevant Transfer of Value as an aggregate value including all HCPs who did not provide their privacy consent.

With regard the individual HCP-related disclosure, Takeda has decided to collect privacy consent for each Transfer of Value on the basis of which the respective HCP then agrees to the corresponding Transfers of Value being disclosed at an individual level. If, however, the HCP refuses to give his/her consent for at least one Transfer of Value, then all Transfers of Value operations related and made to this HCP will be disclosed as a total amount as well as on an aggregate basis and in an anonymized form referring to all persons of that particular group.

If, for instance, a HCP is contracted for five individual activities throughout the year and gives his consent to disclosure for the first four of them and refuses to provide his consent for the last one, then all the related Transfers of Value will be disclosed in the aggregate section of the report on an aggregate basis and in an anonymized form.

A HCP may, at any moment, make use of his/her right to withdraw and revoke his/its consent for a given Transfer of Value. If such revocation is made before the official disclosure, then all Transfers of Value for this particular HCP will be disclosed in the aggregate section of the report on an aggregate basis and in an anonymized form.

While respecting the local privacy legislation, Takeda has made the best efforts to obtain the privacy consents necessary to the disclosure of Transfer of Value transactions at the individual level and retains documented evidence regarding any request/receipt/denial of privacy consent.

4. Working Assumptions

4.1 Date of Transfer of Value

Within Takeda, each interaction with a HCO and a HCP is subject to a rigorous need assessment and to an internal approval process. Upon grant of approval, Takeda then proceeds to the contracting process which covers the Transfer of Value and the request for consent to disclosure, whenever relevant. The performance of service requested is tracked so that payments can be made according to the terms and conditions stipulated by contract.

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

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

With regard to the cut-off rule we have established, the following shall apply:

If the date of service provision has taken place between January 1st and December 31st of the year 2015, the respective Transfer of Value transaction will be in scope for our 2015 disclosure report.

In addition, disclosure of Transfers of Value for a particular activity or service may also be done over a period of more than one year, taking into account those points in time or dates when the corresponding payments are effectively being made.

4.2 Currency

Takeda Pharma Vertrieb GmbH & Co. KG has adopted the currency EUR (euro) for the disclosure report, as this is - at the point of the disclosure- the official national currency. In the case a Transfer of Value is made in a currency other than the official one, the amount will be converted using the current exchange rates that are applicable at the time of service provision.

An example of a Transfer of Value made in a foreign currency would be when travel costs have incurred by a HCP in a foreign country where he/she delivers his/her service and we are reimbursing his/her transportation expenses.

4.3 Taxes

Any fees being paid are subject to taxes. The amounts captured in our report are net amounts which do not include VAT. However, these amounts are subject to income tax to be paid by the person in receipt of the benefit.

4.4 Value-Added Tax (VAT)

Any expenses such as travel or accommodation costs are subject to VAT. The data captured and disclosed do not include VAT.

5. Other General Provisions

This Methodological Note is in line with the basic principles of FSA, which can be found at www.pharma-transparenz.de.

5.1 Duration of Disclosure

As a general rule, the disclosure report on Transfers of Value for the year 2015 will be accessible on our homepage for a period of three years. If a HCP revokes his/her consent to disclosure before the expiry of this period, we will adjust our report accordingly.

5.2 Clearing Institution / Dispute Resolution Management

Takeda has implemented a clearing institution in case of the occurrence of, for instance, any general questions and disagreements as far as any of the reported data and/or any requests for adding or removing a privacy consent given by a HCP/HCO to disclose data are concerned; this clearing institution will be available for handling and clarifying any questions and inconsistencies that may arise.

If you have any comments or questions about Takeda's mode of processing of specific data and information, about this Methodological Note, about the content of the disclosure or about Takeda's internal Privacy Policy, please feel free to contact the corresponding persons regarding the FSA Transparency Code Takeda Transparency function using the e-mail address "transparenz@takeda.com" or the contact indicated on the Takeda website (<http://www.takeda.de/transparenz>).