Methodological Notes – 2019

Supporting document on public transparency concerning transfers of value to healthcare professionals and healthcare organizations

Takeda Pharma AG and Takeda Pharmaceuticals International AG

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Notes on methodology 2019

1. General introduction

Collaboration between the industry and healthcare professionals is beneficial to patients. This relationship has delivered numerous innovative medicines and changed the way many diseases affect our lives. Many activities are undertaken jointly by industry and healthcare professionals. These include clinical research, sharing best clinical practices and exchanging information on how new medicines fit into the treatment pathway. Greater transparency in this important, already well-regulated relationship should help to create a stable foundation for future collaboration. Society has ever-increasing expectations regarding transparency, especially in healthcare. As a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), Takeda Pharma AG and Takeda Pharmaceuticals International AG aims to ensure that we meet these expectations in the future.

These methodological notes are intended for all those who wish to better understand the assumptions behind the creation of the disclosure report of Takeda Pharma AG and Takeda Pharmaceuticals International AG and wish to know how the disclosed activities are defined at Takeda Pharma AG and Takeda Pharmaceuticals International AG.

2. Scope of disclosure

Several internal interpretations were required to duly identify which transfers of value must be reported in accordance with the current year's EFPIA Code (http://transparency.efpia.eu/the-efpia-code-2), the Code of Conduct of the Pharmaceutical Industry in Switzerland concerning collaboration between healthcare professionals and patient organizations (Pharma Cooperation Code), and the Swiss industry association scienceindustries Switzerland (https://www.scienceindustries.ch).
Below, Takeda Pharma AG and Takeda Pharmaceuticals International AG have summarized the interpretations and assumptions consistently applied during data collection, what the recipients mean to us, and the activities and costs that lie within the scope of disclosure.

2.1. Recipients within the scope of disclosure

2.1.1. Healthcare professionals (HCPs): definition and scope

In the disclosure report, Takeda Pharma AG and Takeda Pharmaceuticals International AG have taken the definition of HCPs accordance to the Pharma Cooperation Code and scienceindustries Switzerland. It entails healthcare professionals to whom value may be transferred. The addresses of the HCPs published in the disclosure report, provided the HCPs have consented, are generally the principal practice addresses of the HCPs.

2.1.2. Healthcare organizations (HCOs): definition and scope

In the disclosure report, Takeda Pharma AG and Takeda Pharmaceuticals International AG have used the following definition of HCOs according to the Pharma Cooperation Code and scienceindustries Switzerland. It covers, for example, the following types of HCO to which value may be transferred (*associations, hospital associations, hospital departments, nursing schools, clinics, dental surgeries, hospital pharmacies, institutes, faculties, universities, academies, foundations, pharmacy groups, medical facilities, professional congress organizers*). The published addresses of the HCOs in question are their public addresses.

2.1.3. Companies owned by an HCP

If the company (HCO) is owned by an HCP, the value is disclosed as transferred to the HCP. If the company is owned by more than one HCP, the value is disclosed as transferred to the HCO.

2.1.4. Clearly identifiable recipient

Takeda Pharma AG and Takeda Pharmaceuticals International AG have introduced an internal process with which to guarantee that transfers of value are assigned to the correct HCP or HCO, 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).

2.2. Medical scope

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

2.3. Activities within the scope of disclosure

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

2.3.1. Donations and grants to HCOs

All transfers of value related to donations or grants from Takeda Pharma AG or Takeda Pharmaceuticals International AG to an HCO 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) Exceptions are globally operating organizations headquartered in Switzerland with a focus on non-profit activity in the healthcare sector (e.g., WHO, UNHCR, IKRK, GABI); these are special institutions where any disclosure of grants in disclosure reports does not make sense according to the PKK in view of the sense and purpose of the transparency initiative.
iii. Following grants:
    - Grants for medical training (e.g., support in the training of HCPs): they could be of a 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) or non-monetary nature (e.g., benefits in kind such as anatomic models)
    - Grants for non-medical training (e.g., helping medical facilities to improve their infrastructure)

2.3.2. Contribution to events costs

Any transfer of value in terms of contributions towards events costs from Takeda Pharma AG or TAKEDA Pharmaceuticals International AG to an HCP (directly or indirectly through a third party) or an HCO are covered by the scope of the disclosure. Such transfers of value include, for example:

i. Travel expenses *(flights, rail travel, taxi, rental car, tolls, mileage, parking, visas or other official documents required by an HCP for arranging travel, overseas health insurance, etc.)*
ii. Accommodation
iii. Registration fees *(fees paid for an HCP or an HCO to permit HCPs to attend medical congresses/training events not organized by Takeda)*
iv. A sponsorship agreement with an HCO or a third party nominated by the HCO for managing an event, such as scientific conferences, congresses or exhibitions by third parties: *sponsorships by medical associations, national industry organizations, hospitals and educational establishments; scientific organizations; regional, national, international and global conferences; local hospitals, medical centres*.

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.

Examples of activities that may be listed in the disclosure report of Takeda Pharma AG and Takeda Pharmaceuticals International AG under "Sponsorship Agreements:" *booth rental, advertising spaces (digital, paper, etc.), satellite symposia at a scientific congress, scientific courses provided by an HCO, opportunities to present our products (including non-promotional presentations), event sponsorships (e.g., organizational support)*

2.3.3. Service and consultancy fees

Any transfer of value related to service and consultancy fees between Takeda Pharma AG or Takeda Pharmaceuticals International AG and an HCP or HCO 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:

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

Examples of fees that may be included in the disclosure report of Takeda Pharma AG and Takeda Pharmaceuticals International AG under "Service and consultancy fees (HCPs and HCOs):" *speaker fees for workshops, symposia and panel discussions; 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; market survey (except for double-blind studies); consulting (e.g., protocol advice, market access, reimbursement, leading-edge technology assessment)*

2.3.4. 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 of Takeda Pharma AG and Takeda Pharmaceuticals International AG under "R&D value transfers:" *clinical trials: regional and/or global, local non-interventional trials*.

Value transfers made indirectly through clinical research organizations (CROs) are likewise listed in the R&D section of the disclosure report.

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. Cross-border value transfer

Cross-border value transfers are included in our disclosure report. Cross-border activities are usually disclosed - provided the HCP has consented - in the country where the principal practice address of the HCP, as the recipient, is located.

For example, if a Swiss HCP is engaged as a consultant by a foreign legal entity of Takeda Pharma AG and Takeda Pharmaceuticals International AG, Takeda Pharma AG and Takeda Pharmaceuticals International AG will generally disclose - provided the HCP has consented - the associated value transfers in the Swiss disclosure report based on the HCP's principal practice address.

3. Consent to disclosure under data protection law and gross sum

In Switzerland, the HCP should give his individual consent to publication of the value transferred in accordance with data protection regulations. If consent is not given individually subject to the data protection law, Takeda Pharma AG and Takeda Pharmaceuticals International AG will publish the gross sum of the respective transfers of value to all HCPs who have not consented in accordance with the data protection law.

Takeda Pharma AG and Takeda Pharmaceuticals International AG have decided to obtain consent under the data protection law for individual HCP disclosure pertaining to each transfer of value individually; all related transfers of value will be disclosed separately. If the HCP/HCO does not consent for at least one transfer of value, all transfers of value relating to HCP or HCO in question will be disclosed as a gross sum.

For example, if an HCP is commissioned for five different activities during the year and consents to the publication of the first four but refuses consent for the last activity, then all associated transfers of value will be included in the total figures of the disclosure report.

The HCP or HCO may revoke consent to the publication of certain transfers of value at any time. If consent is revoked prior to the official disclosure, all transfers of value to the respective HCP or HCO will be included in the total figures of the report.

Takeda Pharma AG and Takeda Pharmaceuticals International AG will endeavor to comply with local data protection laws when obtaining the necessary individual consent under data protection law to disclosure

of transfers of value. Takeda Pharma AG and Takeda Pharmaceuticals International AG will retain evidence of the application/receipt/refusal of consent under the data protection regulations.

4. Assumptions

4.1. Date of value transfer

At Takeda Pharma AG and Takeda Pharmaceuticals International AG, every activity involving an HCO or an HCP is subject to a rigorous needs analysis and an internal approval procedure. The contract is concluded after approval. This includes the transfer of value and request for disclosure, which where relevant is subject to consent. 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, the transfer is included in our 2019 disclosure report.

If payment for an activity at the end of 2018 was made at the beginning of 2019, Takeda will consider this transfer in its 2019 disclosure report.

Payments made at the end of 2019 for an activity completed in early 2020 will be regarded as value transfers in 2020 for disclosure in June 2021.

4.2. Currency

Takeda Pharma AG and Takeda Pharmaceuticals International AG have decided that CHF 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 gross amounts.

4.3.1. Sales tax

Expenses such as for travel and accommodation are subject to sales tax. The documented and disclosed figures include sales tax.

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 Pharma AG and Takeda Pharmaceuticals International AG, please get in touch with Takeda Transparency at transparency-CH@takeda.com or the relevant contact named on the Takeda website: https://www.takeda.com/de-ch/unternehmerische-verantwortung/transparenz/arzte--und-gesundheitsorganisationen/