



Methodological Note – 2021

Accompanying document for the public Disclosure concerning transfers of value to Patient Organizations

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1. General introduction

Collaboration between the industry and patient organizations is beneficial to patients. This relationship has delivered numerous innovative medicines and changed the way many diseases affect our lives. 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 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 assumptions behind the creation of the patient organization disclosure report and how the disclosed activities are defined.

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. Interaction with Patient Organizations (POs)

2.1.1. Patient Organization (POs): definition and specific requirements

Patient Organization (PO) is a non-for-profit legal entity (including the umbrella organization 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 an EFPIA member country.

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

2.1.2. Time of disclosure

The reporting period refers to the annual disclosure cycle and covers a full prior calendar year. The common reporting period for publication of the transfer of values to the patient organization is set during the time interval from 20th to 30th June each following year at the latest. Where a national code provides a different time interval for its country, this must consistently apply to all disclosure obligations to recipients.

2.2. How the Transfer of Value (ToV) is provided

Direct: payments made directly to the patient organization

Indirect: payments made through an intermediary (third party) on behalf of Takeda.

In-Kind: is a non-monetary support provided to benefitting patient organization

In general, payments are reported at the level of the first identifiable recipient identified as a patient organization.

Payment to individual patients who do not represent or are not hired through a patient organization are not subject to disclosure

For example:

- Payments made to individual patients e.g. in a market research capacity
- A patient hired to create content

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 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 the EFPIA definitions which should help you with the readability of the disclosure report.

Types of the support or services provided:

- I. Financial support
- II. Significant indirect support: It is a support provided by a member company to a patient organization through a third party
- III. Non-financial support: It is when a member company provides a service to a patient organization without paying the PO. For example, when a member company lends a meeting room in its office to a patient organization. In that case, this service does not cost anything to the member company but there is a monetary value for this service that must be disclosed i.e. the cost of renting a similar meeting room in a hotel
- IV. Contracted services

2.3.1. Donations and grants to POs

All transfers of value related to donations or grants to a PO are included within the scope of the Disclosure. Such transfers of value include:

- i. Donations – financial support
- ii. Benefits in kind – non-financial support
- iii. Charitable donations (if the organization is classified in the country as a patient organization) financial and/or non-financial support

They do not constitute an inducement to recommend the prescription, purchase, supply or administration of specific medical products.

Donations and grants to individuals are not permitted.

2.3.2. Contribution to events costs and sponsorship

Any transfer of value in terms of contributions towards events costs directly or indirectly through a third party are covered by the scope of the disclosure and published as significant indirect support. 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 a PO representative for arranging travel, overseas health insurance, etc.*)
- ii. Accommodation fees
- iii. Registration fees (*fees paid to permit POs representative to attend medical congresses/training events organized by a third party and not organized by Takeda*)
- iv. A sponsorship agreement with patient organisation or a nominated third party for managing an event, such as scientific conferences, congresses, or exhibitions by third parties

2.3.3. Service and consultancy fees

Any transfer of value related to service and consultancy fees are included within the scope of the Disclosure and published as contracted services. Such transfers of value include, for example, a meeting or event where some PO representative 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*)

The arrangements that cover consultancy or other services have a written contract, the service is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services and will be disclosed in the name of the patient organization.

2.4. Cross-border transfer of value

Cross-border activities are considered when a PO is engaged or sponsored by any part of the company other than the country of the patient organization. We associate the transfer of value to the country where the principal address of the patient organization is located. Cross-border value transfers are included in our disclosure report.

3. Assumptions

3.1. Date of transfer of value

The transfers of value will be disclosed based on the payment dates.

If the payment date was between 1st January and 31st of December the same year, the payment will be included in our next disclosure report published in June.

Example: If an activity happens at the end of 2019 but the payment does not happen in 2019 but was made at the beginning of 2020, we will disclose this payment in our 2020 report.

Payments made at the end of 2021 for an activity completed in early 2022 will be regarded as value transfers in 2021 for disclosure in June 2022.

3.2. Currency

Takeda UK has used GBP for 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.

3.3. Taxes

In general for transfers of value, Takeda excludes tax and VAT for monetary payments and includes tax and VAT for In Kind transfers of value. Expenses such as for travel and accommodation are subject to sales tax. The documented and disclosed figures include sales tax.

4. 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 information.

If you have any comments or questions concerning the processing of your data by Takeda, this methodological note, the content of the Disclosure, or the privacy policy please send us a short note transparencyUKIE@takeda.com or use the contact named on the Takeda local website.

5. Company acquisition

Takeda acquired Shire Pharmaceuticals in January 2019 and Legal Entity Optimization was completed in the UK in early 2021. Transfer of value data will, therefore be disclosed for Takeda and Shire as one Takeda entity, commencing with the 2021 Disclosure.